enacted would have delayed implementation of the hospital outpatient PPS.

To derive weights based on median hospital costs for services in the hospital outpatient APC groups, we converted billed charges to costs and aggregated them to the procedure or visit level. To accomplish this, we first identified the cost-to-charge ratio that was specific to each hospital's cost centers (''cost center specific cost-to-charge ratios'' or CCRs). We then developed a crosswalk to match the hospital's CCRs to revenue centers used on the hospital's 1996 outpatient bills. The CCRs included operating and capital costs but excluded costs associated with direct graduate medical education and allied health education.

To determine the hospital CCRs, the most recent available cost report from each hospital was identified. For the proposed rule, we used cost reports from cost reporting periods beginning on or after October 1, 1994 and before October 1, 1995 (referred to as PPS–12) or earlier. For this final rule, more recent cost reports were available for hospitals. We used cost reports from cost reporting periods beginning on or after October 1, 1996 and before October 1, 1997 (PPS–14) for approximately 94 percent of the hospitals in our database.

If the most recent available cost report for a hospital was one that had been submitted but not settled, we calculated a factor to adjust for the differences that generally exist between settled and ''as submitted'' cost reports. The adjustment factor was determined by dividing the outpatient department cost-to-charge ratio from the hospital's most recent settled cost report by the outpatient department cost-to-charge ratio from the hospital's ''as submitted'' cost report for the same period. The resulting ratio was used to adjust each of the CCRs in the hospital's most recent ''as submitted'' cost report. We repeated this process for every hospital for which the most recent available cost report was a cost report that had not been settled.

The Office of Inspector General (OIG) for DHHS is concerned that the cost reports we are using may reflect some unallowable costs. Therefore, the OIG, in conjunction with HCFA, is proposing to examine the extent to which the cost reports used reflect costs that were inappropriately allowed. If this examination reveals excessive inappropriate costs, we will address this issue in a future proposed rule, or perhaps seek legislation to adjust future payment rates downward.

We next eliminated from the hospital CCR database 258 hospitals that we have identified as having reported charges on their cost reports that were not actual charges (for example, they make uniform charges for all services). These excluded hospitals were Kaiser, New York Health and Hospital Corporation, and all-inclusive rate hospitals. After removing these hospitals, we calculated the geometric mean of the total operating CCRs of hospitals remaining in our CCR database. We identified 58 hospitals whose total operating CCR exceeded the geometric mean by more than 3 standard deviations. These hospitals were also removed from our CCR database.

After assembling and editing our new CCR database, we matched revenue centers from approximately 80 million claims to CCRs of approximately 5,700 hospitals. We excluded from the crosswalk approximately 15 million claims in which the bill type denoted services that would not be covered under the PPS (for example, bill type 72X for dialysis services for patients with ESRD). We also excluded almost 3 million claims from the hospitals that we had removed or trimmed from the hospital CCR database. The table below shows the five cost reporting periods used and the percentage of the cost reports within each PPS period for which we were able to match 1996 claims.

Reporting period	Percentage of cost reports matched
PPS–15 (cost reporting period beginning on or after 10/1/97 and before 10/1/98)	0.1
PPS–14 (cost reporting period beginning on or after 10/1/96 and before 10/1/97)	94.2
PPS–13 (cost reporting period beginning on or after 10/1/95 and before 10/1/96)	3.7
PPS–12 (cost reporting period beginning on or after 10/1/94 and before 10/1/95)	1.7
PPS–11 (cost reporting period beginning on or after 10/1/93 and before 10/1/94)	0.3
Total	100.0

Next, we took the estimated 80 million claims that we had matched with a cost report and separated them into two distinct groups: Single-procedure claims and multiple-procedure claims. Single-procedure claims were those that included only one HCPCS code (other than laboratory and incidentals such as packaged drugs and venipuncture) that could be grouped to an APC. Multiple-procedure claims included more than one HCPCS code that could be mapped to an APC. There were approximately 45.4 million single-procedure claims and 34.6 million multiple-procedure claims.

To calculate median costs for services within an APC, we used only the single-procedure bills. (Of the roughly 45.4 million single-procedure claims, about 24 million were excluded from the conversion process largely because the only HCPCS codes reported on the claims were for laboratory procedures or other outpatient services not paid under the outpatient PPS.) This approach was taken because the information on claims does not enable us to specifically allocate charges or costs for packaged items and services such as anesthesia, recovery room, drugs, or supplies to a particular procedure when more than one significant procedure or medical visit was billed on a claim. Use of the single-procedure bills minimizes the risk of improperly assigning costs to the wrong procedure or visit. Although we used only single-procedure/visit bills to determine APC relative payment weights, we used multiple-procedure bills in the conversion factor and service mix calculations, regressions, and impact analyses.

For each single-procedure claim, we calculated a cost for every billed line item charge by multiplying each revenue center charge by the appropriate hospital-specific CCR. If the appropriate cost center did not exist for a given hospital, we crosswalked the revenue center to a secondary cost center when possible, or to the hospital's overall cost-to-charge ratio for outpatient department services. We excluded from this calculation all charges associated with HCPCS codes previously defined as not paid under this PPS (for example, laboratory, ambulance, and therapy services).

To calculate the per-procedure or per-visit costs, we used the charges shown in the revenue centers that contained items integral to performing the procedure or visit. These included those items that we previously discussed as being subject to our proposed packaging provision. For instance, in calculating the surgical procedure cost, we included charges for the operating room, treatment rooms, recovery, observation, medical and surgical supplies, pharmacy, anesthesia, casts and splints, and donor tissue, bone, and organ. For medical visit cost estimates, we included charges for items such as medical and surgical supplies, drugs, and observation. A complete listing of the revenue centers that we used is shown below in Table 1, Packaged Services by Revenue Center.

TABLE 1.—PACKAGED SERVICES BY REVENUE CENTER

ASC AND OTHER SURGERY

250 PHARMACY
251 GENERIC
252 NONGENERIC
257 NONPRESCRIPTION DRUGS
258 IV SOLUTIONS
259 OTHER PHARMACY
260 IV THERAPY, GENERAL CLASS
262 IV THERAPY/PHARMACY SERVICES
263 IV THERAPY/DRUG/SUPPLY/DELIVERY
264 IV THERAPY/SUPPLIES
269 OTHER IV THERAPY
270 M&S SUPPLIES
271 NONSTERILE SUPPLIES
272 STERILE SUPPLIES
276 INTRAOCULAR LENS
279 OTHER M&S SUPPLIES
370 ANESTHESIA
379 OTHER ANESTHESIA
390 BLOOD STORAGE AND PROCESSING
399 OTHER BLOOD STORAGE AND PROCESSING
630 DRUGS REQUIRING SPECIFIC IDENTIFICATION, GENERAL CLASS
631 SINGLE SOURCE DRUG
632 MULTIPLE SOURCE DRUG
633 RESTRICTIVE PRESCRIPTION
700 CAST ROOM
709 OTHER CAST ROOM
710 RECOVERY ROOM
719 OTHER RECOVERY ROOM
720 LABOR ROOM
721 LABOR
723 CIRCUMCISION
762 OBSERVATION ROOM
810 ORGAN ACQUISITION
819 OTHER ORGAN ACQUISITION
890 OTHER DONOR BANK
891 BONE
892 ORGAN
893 SKIN
899 OTHER DONOR BANK

MEDICAL VISIT

250 PHARMACY
251 GENERIC
252 NONGENERIC
257 NONPRESCRIPTION DRUGS
258 IV SOLUTIONS
259 OTHER PHARMACY
270 M&S SUPPLIES
271 NONSTERILE SUPPLIES
272 STERILE SUPPLIES
279 OTHER M&S SUPPLIES
630 DRUGS REQUIRING SPECIFIC IDENTIFICATION, GENERAL CLASS
631 SINGLE SOURCE DRUG
632 MULTIPLE SOURCE DRUG
633 RESTRICTIVE PRESCRIPTION
700 CAST ROOM
709 OTHER CAST ROOM
762 OBSERVATION ROOM

OTHER DIAGNOSTIC (BLENDED SERVICES)

254 PHARMACY INCIDENT TO OTHER DIAGNOSTIC
372 ANESTHESIA INCIDENT TO OTHER DIAGNOSTIC
622 SUPPLIES INCIDENT TO OTHER DIAGNOSTIC

TABLE 1.—PACKAGED SERVICES BY REVENUE CENTER—Continued

710 RECOVERY ROOM
719 OTHER RECOVERY ROOM
762 OBSERVATION ROOM

RADIOLOGY SUBJECT TO THE FEE SCHEDULE AND OTHER RADIOLOGY

255 PHARMACY INCIDENT TO RADIOLOGY
371 ANESTHESIA INCIDENT TO RADIOLOGY
621 SUPPLIES INCIDENT TO RADIOLOGY
710 RECOVERY ROOM
719 OTHER RECOVERY ROOM
762 OBSERVATION ROOM

ALL OTHER APC GROUPS

250 PHARMACY
251 GENERIC
252 NONGENERIC
257 NONPRESCRIPTION DRUGS
258 IV SOLUTIONS
259 OTHER PHARMACY
260 IV THERAPY, GENERAL CLASS
262 IV THERAPY PHARMACY SERVICES
263 IV THERAPY DRUG/SUPPLY/DELIVERY
264 IV THERAPY SUPPLIES
269 OTHER IV THERAPY
270 M&S SUPPLIES
271 NONSTERILE SUPPLIES
272 STERILE SUPPLIES
279 OTHER M&S SUPPLIES
630 DRUGS REQUIRING SPECIFIC IDENTIFICATION, GENERAL CLASS
631 SINGLE SOURCE DRUG
632 MULTIPLE SOURCE DRUG
633 RESTRICTIVE PRESCRIPTION
762 OBSERVATION ROOM

We then applied to these cost estimates an adjustment to calibrate the costs to calendar year 1996 for those services in hospitals whose CCRs were calculated using FY 1997 or later cost reports. On average, hospital charges were rising faster than costs in FY 1997. We therefore made this adjustment for the calculation of the weights, as well as for the hospital costs used in the conversion factor and impact model, to ensure that we did not underestimate costs and payments. We based this hospital specific CCR adjustment on the observed change in each hospital's overall CCR (total operating + total capital) from the proposed rule cost report database to the new final rule database. If applicable, we then calculated a monthly rate of change and applied it based on the number of months past 1996 encompassed in a hospital's cost reporting period; if a hospital's period coincided completely within calendar year 1996, no adjustment was made.

After calibrating the costs to calendar year 1996, we standardized costs for geographic wage variation by dividing the labor-related portion of the operating and capital costs for each billed item by the FY 2000 hospital inpatient prospective payment system wage index published in the **Federal Register** on July 30, 1999 (64 FR 41585). As in the proposed rule and correction notice, we used 60 percent to represent our estimate of that portion of costs attributable, on average, to labor. A more detailed discussion of wage index adjustments is found below in section III.G of this document.

The standardized labor-related cost and the nonlabor-related cost component were summed for each billed item to derive the total standardized cost for each procedure or medical visit. Extremely unusual costs that appeared to be errors in the data were trimmed from standardized procedure and visit costs. This trimming methodology is analogous to that used in calculating the DRG weights for the inpatient PPS: eliminate any bills with costs outside of 3 standard deviations from the geometric mean. We used the geometric mean and the associated standard deviation because the distribution of costs more closely resembles a lognormal distribution than a normal distribution: There are no negative costs, and the average cost is greater than the median cost. Use of the geometric mean minimizes the impact of the most unusual bills in the determination of the mean. The geometric mean is calculated by taking the mean of the natural logarithm cost. Because the distribution of the natural logarithms of a set of numbers is more compact than the distribution of the numbers themselves, bills with extreme costs do not appear as extreme as they would if non-logged costs were examined. This ensures that only the most aberrant data will be removed from the calculation.

After trimming the procedure and visit level costs, we mapped each procedure or visit cost to its assigned APC and calculated the median cost for each APC weighted by procedure volume. Using the median APC costs, we calculated the relative payment weights for each APC. We scaled all the relative payment weights to APC 601, a mid-level clinic visit, because it is one of the most frequently performed services. This approach is consistent with that used in developing relative value units for the Medicare physician fee schedule. By assigning APC 601 a relative payment weight of 1.0, hospitals can easily compare the relative relationship of one APC to another. Next, we divided the median cost for each APC by the median cost for a mid-level clinic visit, APC 601, to derive the relative payment weight for each APC.

The median cost for APC 601 is $47.00. In the proposed rule, we also used a mid-level clinic visit, APC 91336, which had a median cost of $54.00, as the scaler of APC weights. On average, due to the reduced value of the scaler used for this notice, the final weights will be higher than those published in the proposed rule.

Comment: Some commenters believe that the ratesetting methodology does not reflect complex cases because we eliminate statistical ''outlier'' claims from the calculation of the median costs and the weights.

Response: As noted above, we trimmed claims with estimated costs that were outside of three standard deviations from the geometric mean. Because we removed claims above or below the mean, we corrected for data errors that would have skewed the estimates of median costs and group weights upward or downward. We believe this trim is a valid method of removing extremely unusual costs that are most likely associated with data submission errors and do not represent actual costs. In addition, it is consistent with the method we use to set inpatient hospital diagnosis-related group (DRG) weights.

Comment: Numerous commenters disagreed with our use of single-procedure claims only in the calculation of the relative payment weights. One commenter was concerned that we could be masking differences in resource use attributable to patient characteristics by using only single-procedure claims to calculate relative weights.

Response: We used single-procedure claims to calculate the relative weight for each APC because we could not accurately allocate costs to a particular procedure when the costs were part of a bill for multiple procedures. Bills with a single major procedure provided are, in most cases, the best estimate of relative procedure costs. It is important to note that for all other calculations, including calculation of the conversion factor, we used both single-procedure and multiple-procedure bills.

We do not believe that using single-procedure bills biases the relative cost of any particular procedure. Although patients with more complex healthcare needs might have several procedures performed, hospital charges for an individual procedure would not be greater. Our most significant concern was that distribution of single bill procedures within an APC would not reflect the correct distribution of those procedure on all bills. However, careful statistical analyses demonstrated that the distribution of procedures within an APC group did not differ when single bill procedure frequencies were compared with all bills. It is also important to note that when items or services were to be packaged with a major procedure, we added their costs to that procedure prior to making the single bill determination. Therefore, the costs of contrast media, for example, are included in the relative weights. In some cases, we agreed with the commenters that this approach needed to be modified. For example, for chemotherapy, we are not grouping drugs, but rather paying for each one separately. Moreover, as a result of the transitional pass-through provisions of the BBRA 1999, radiopharmaceuticals will be paid separately from the nuclear medicine APCs.

Comment: Several commenters expressed concern that the 1996 claims data are insufficient or inadequate to develop the PPS model. For example, some commenters asserted that the 1996 data are not recent enough to reflect the current mix of outpatient services. Some commenters also argued that undercoding in the data would lead to underestimates of median costs. Other commenters recommended that we address alleged inadequacies in the data by gathering cost data on new procedures and by basing payment on these data until we can determine whether to place a new procedure in an existing APC or create a new APC.

Response: While we acknowledge limitations of setting payment rates with historical claims data, section 1833(t)(2)(C) of the Act requires us to use 1996 claims in developing the PPS. We discuss how we will price new procedures that are not reflected in our database in section III.C.8 of this preamble.

Comment: Commenters were concerned about the cost-to-charge ratios used to estimate median APC costs and pre-BBA payments. For example, one medical organization recommended that we account for the capital-intensive nature of radiology services by adjusting the cost-to-charge ratios applicable to these services for the step-down methodology that allocates capital expenses by square footage. The belief is that these allocation methods underestimate radiological equipment costs and certain cost-to-charge ratios, leading to underestimates of the median costs for relevant APC groups.

Response: Although capital-related costs may be allocated to routine and ancillary service cost centers using the step-down methodology based on square footage, as an alternative, the ''dollar value'' method may be used by hospitals. This method is made available to hospitals in Worksheet B–1 of the hospital cost report (HCFA 2552–96). The dollar value method more accurately distributes the capital costs associated with equipment to the revenue-producing cost center to which the equipment is assigned. We are not able to adjust the cost-to-charge ratios of those hospitals that allocate equipment based on square footage because we have no way of knowing which specific equipment costs should be allocated to revenue-producing cost centers in each hospital.

2. Conversion Factor

Section 1833(t)(3)(C)(i) of the Act requires that we establish a conversion factor for 1999 to determine the Medicare payment amounts for each covered group of services. For the proposed rule as corrected, we derived the conversion factor from a base amount of payments described in section 1833(t)(3)(A) of the Act, as enacted in the BBA 1997. Such base amount was calculated for the services included in the outpatient PPS as an estimate of the sum of (1) total payments that would be payable from the Trust Fund under the current (non-PPS) payment system in 1999, plus (2) the beneficiary coinsurance that would have been paid under the new (PPS) system in 1999. For the final rule, however, we derived the conversion factor from a base amount that includes beneficiary coinsurance that would have been made under the current (non-PPS) system rather than the proposed (PPS) system. Section 201(l) of the BBRA 1999 states: ''With respect to determining the amount of copayments described in paragraph (3)(A)(ii) of section 1833(t) of the Social Security Act, as added by section 4523(a) of the BBA, Congress finds that such amount should be determined without regard to such section, in a budget neutral manner with respect to aggregate payments to hospitals, and that the Secretary of Health and Human Services has the authority to determine such amount without regard to such section.''

Section 1833(t)(2)(C) of the Act requires us to project utilization for hospital outpatient services. We were unable to make precise projections of increases in the volume and intensity of services because we were not able to quantify some of the factors that affect utilization. For instance, we would anticipate that Medicare beneficiaries who choose to migrate to managed care plans may be healthier than those who choose to stay in fee-for-service plans. Thus, we could assume a decrease in the volume of services coupled with an increase in the intensity of services

furnished for Medicare beneficiaries in the fee-for-service program. Another factor that we believe will affect future utilization is the incentive to code billed services more accurately. Currently, hospitals are paid for the majority of the outpatient services they furnish on a cost basis, and inaccurate or improper coding does not necessarily affect the amount of payment. In contrast, under the PPS, hospitals are required to use HCPCS codes in order to receive payment. We expect that the frequency of some services may increase as a result of the coding requirements. We believe each of these assumptions will affect the reporting of volume and intensity of services, although we are not able to quantify them individually to project 1999 utilization. Therefore, we used what we believe to be a more reliable and valid approach to computing the conversion factor under the methodology described below.

Comment: A large national trade association commented that the exclusion of claims for unclassified services (for example, those claims for which we cannot identify the service to be paid) from the PPS model could bias the conversion factor downward if the excluded claims have a disproportionate number of services with high payment to cost ratios, such as clinic and emergency room visits.

Response: In order to set the conversion factor as accurately as possible, we used only claims for which the costs and volume of services could be identified on the bill. As noted by the commenter, this decision resulted in the exclusion of claims with unclassifiable services. Upon examination of these claims, we have determined that services with high payment to cost ratios (those that would gain under the PPS system) were not disproportionately represented. Therefore, we believe the exclusion of unclassifiable services does not bias the conversion factor.

Setting the Rates

In order to convert the relative weights determined for each APC (see section III.E.1) into payment rates, we calculated a conversion factor that would result in total estimated payments to hospitals under the PPS in 1999 equal to the total estimated payments that would have been payable from the Trust Fund in 1999 if PPS had not been enacted plus estimated beneficiary coinsurance for the same services during the same period. The prospective payment rate for each APC is calculated by multiplying the APC's relative weight by the conversion factor. For the calculation of the conversion factor, we have excluded all data from the 58 Maryland providers that qualify under section 1814(b)(3) of the Act for payment under the State's payment system. We computed the conversion factor by first adding together the aggregate Medicare hospital outpatient payments made under the cost-based payment system (referred to in this section as pre-PPS payments) for calendar year 1996, plus the estimated beneficiary coinsurance amounts made under pre-PPS law for the same services. We then divided that amount by a wage-adjusted sum of the relative weights for all APCs under the hospital outpatient PPS. The methodology we used to determine current law Medicare hospital outpatient payments and beneficiary coinsurance is discussed below in section III.E.2.a. A discussion of the sum of the relative weights follows in section III.E.2.b.

a. Calculating Aggregate Calendar Year 1996 Medicare and Beneficiary Payments for Hospital Outpatient Services (Pre-PPS)

To calculate Medicare hospital outpatient payment amounts before implementation of the PPS, we first identified calendar year 1996 single and multiple procedure bills for all the services that we will recognize under the outpatient PPS. As we identified services that will be paid under the outpatient PPS, we eliminated invalid or noncovered HCPCS codes.

Hospital payments include both operating and capital costs for the HCPCS coded services for which payment is to be made under the outpatient PPS. We summed these two types of costs by HCPCS code at the provider level. Consolidating the data in this manner allowed us to simulate provider payment on an aggregate basis. Then (as required by section 1861(v)(1)(S)(ii) of the Act as amended by section 201(k) of the BBRA 1999), we applied the capital cost reductions of 10 percent and operating cost reductions of 5.8 percent.

We determined for each HCPCS code the applicable payment methodology under the current system. Payment before implementation of PPS for procedures in the baseline was calculated using one of the following equations, as appropriate:

- For radiology procedures paid for under the radiology fee schedule, we determined payment in the aggregate for each provider as the lower of the cost, charge, or blended amount. We use the following equation to determine the radiology blended amount: (0.42 × lower of cost or charge minus beneficiary coinsurance) + (0.58 × ((0.62 × global physician fee schedule amount) − beneficiary coinsurance)).
- For surgical procedures for which Medicare pays an ASC facility fee, we determined payment in the aggregate for each provider as the lower of the cost, charge, or blended amount. We used the following equation to determine the ASC blended amount: (0.42 × lower of cost or charge minus beneficiary coinsurance) + (0.58 × (ASC payment rate − beneficiary coinsurance)).
- For diagnostic procedures paid for under the diagnostic fee schedule, we determined payment in the aggregate for each provider as the lower of the cost, charge, or blended amount. We used the following equation to determine the blended amount for diagnostic procedures: (0.50 × lower of cost or charge minus beneficiary coinsurance) + (0.50 × ((0.42 × global physician fee schedule amount) − beneficiary coinsurance)).

For all other covered services not subject to one of the blended payment method categories, we determined payment as the lower of costs or charges less beneficiary coinsurance. Because the formula-driven overpayment (FDO) was corrected beginning October 1, 1997, the blended equations eliminate FDO.

We then determined the Medicare payment amount for each provider by summing the aggregate amounts computed for each of the four types of payment methodologies discussed above. In addition, we determined the amount of the beneficiary coinsurance for each provider using the beneficiary coinsurance amounts that would have been paid before implementation of PPS. The total amount (Medicare and beneficiary payments) reflects the amount hospitals would be paid under the PPS and is the numerator in the equation for calculating the unadjusted conversion factor.

b. Sum of the Relative Weights

Next we summed the discounted relative weights for services that are within the scope of the outpatient PPS. (See discussion of discounting for surgical procedures in section III.C.7.) Specifically, we multiplied (using single and multiple procedure claims in a hospital) the discounted volume of procedures or visits in each APC group by the relative weights for each APC group; we wage-adjusted 60 percent of this total by each hospital's wage index, and we then summed the wage-adjusted and nonadjusted weights across all hospitals. (The wage indices used are included in Addenda H, I, and J.) The resulting sum equals the denominator in the calculation of the conversion factor.

We calculated the conversion factor by dividing the sum of the discounted relative weights into the total payment explained in section III.E.2.a, above, including both Medicare payment and beneficiary coinsurance. We then adjusted the conversion factor so that the outlier and pass-through payments are implemented in a budget neutral manner, as described in sections III.H.1 and III.D. The adjusted calendar year 1996 conversion factor is $43.023. To inflate the 1996 conversion factor to 1999, our Office of the Actuary estimated an update factor of 1.106. Therefore, the adjusted 1999 conversion factor is $47.583.

For calendar year 2000, we updated the conversion factor as specified in section 1833(t)(3)(C)(iii) of the Act. The update is the market basket percentage increase applied to hospital discharges occurring during the fiscal year ending in calendar year 2000 minus 1 percentage point. For 2000, the updated conversion factor is $48.487.

Comment: A number of commenters suggested that we remove the behavioral offset that we proposed to apply to the conversion factor. As proposed, the intent of the offset was to adjust for hospital coding changes that take place in response to reductions in beneficiary coinsurance.

Response: We have decided not to include a behavioral offset to the conversion factor in this final rule. Hospital coding changes are expected to occur under the outpatient PPS; however, we believe changes that occur during the first PPS years will result from hospitals billing more accurately under the new system. A behavioral offset implemented in the initial PPS years may distort the incentives to bill accurately. We may reconsider implementation of a behavioral offset in future years as we gather data and gain experience under the new system.

Comment: A large national trade association expressed concern that application of the 5.8 percent and 10.0 percent reduction to costs for all hospital outpatient services included in the PPS model underestimates the conversion factor. They recommended that we exclude the Part B services provided to inpatients who exhaust their Part A benefits from the reductions.

Response: Our analysis shows that fewer than 5,000 of the more than 80 million claims used to set the conversion factor were associated with these types of services. Total costs associated with these claims were less than $1.4 million, which is too small to have a measurable effect on the conversion factor.

Comment: Many commenters strongly argued that we misinterpreted the provisions of section 1833(t)(3) of the Act in calculating beneficiary coinsurance for purposes of setting the base amount of the conversion factor. The commenters noted that this methodology contributed significantly to the estimated 5.7 percent reduction in Medicare outpatient payments to hospitals reflected in the proposed rule. Most commenters further argued that the Congress did not intend for this loss to occur and that we had the authority to interpret the methodology described in the statute so that no net change in payments would result from the conversion factor.

Response: Section 1833(t)(3)(A) of the Act, as added by the BBA 1997, states that, for purposes of calculating the base amount used to determine the conversion factor, the Secretary shall calculate ''the total amount of copayments estimated to be paid *under this subsection.* * * *'' (Emphasis added.) For the proposed rule, we estimated the coinsurance that would be paid under PPS. In section 201(l) of the BBRA 1999, the Congress addressed the calculation of the base amount, stating, ''With respect to determining the amount of copayments described in paragraph (3)(A)(ii) of section 1833(t) of the Social Security Act, as added by section 4523(a) of the BBA, Congress finds that such amount should be determined without regard to such section, in a budget neutral manner with respect to aggregate payments to hospitals, and the Secretary of Health and Human Services has the authority to determine such amount without regard to such section.'' Therefore, for this final rule, we estimated the coinsurance that would have been paid if PPS had not been enacted.

F. Calculation of Coinsurance Payments and Medicare Program Payments Under the PPS

1. Background

In section III.E, above, we explained how we determined APC group weights, calculated an outpatient PPS conversion factor, and determined national prospective payment rates, standardized for area wage variations, for the APC groups. We will now explain how we calculated beneficiary coinsurance amounts for each APC group.

The outpatient PPS established by section 1833(t) of the Act includes a mechanism designed to eventually achieve a beneficiary coinsurance level equal to 20 percent of the prospectively determined payment rate established for the service. As discussed in the proposed rule, for each APC we calculate an amount referred to in section 1833(t)(3)(B) of the Act as the ''unadjusted copayment amount.'' The unadjusted coinsurance amount is calculated by taking 20 percent of the national median charges billed in 1996 for the services that are in the APC, trended forward to 1999; however, the coinsurance amount cannot be less than 20 percent of the APC payment rate. The unadjusted coinsurance amount for an APC remains frozen, while the payment rate for the APC is increased by adjustments based on the Medicare market basket. As the APC rate increases and the coinsurance amount remains frozen, the unadjusted coinsurance amount will eventually become 20 percent of the payment rate for all APC groups. Once the unadjusted coinsurance amount is 20 percent of the payment amount, both the APC payment rate and the unadjusted coinsurance amount will be updated by the annual market basket adjustment.

In the proposed rule, we proposed to not adopt new APCs for new procedures or services for at least 2 years, but instead assign them to existing groups while accumulating data on their costs. In the final rule we do provide for APCs for new procedures that do not fit well into another APC. When an APC is added that consists of HCPCS codes for which we do not have 1996 charge data upon which to calculate the unadjusted coinsurance amount, coinsurance will be calculated as 20 percent of the APC payment amount.

There is an exception to the coinsurance provisions for screening colonoscopies and screening sigmoidoscopies. Section 4104 of the BBA 1997 provided coverage for colorectal screening. This section, in part, added new sections 1834(d)(2) and (3) to the Act, which provide that for covered screening sigmoidoscopies and colonoscopies performed in hospital outpatient departments and ambulatory surgical centers (ASCs), payment is to be based on the *lesser* of the hospital or the ASC payment rates and coinsurance for both screening colonoscopies and screening sigmoidoscopies is to be 25 percent of the rate used for payment.

Section 4104 of the BBA 1997 also allows, at the Secretary's discretion, coverage of screening barium enemas as a colorectal cancer screening tool. We are including screening barium enemas as a covered service under the hospital outpatient PPS. The payment rate for screening barium enemas is the same as for diagnostic barium enemas. Coinsurance for a screening barium enema is based on 20 percent of the APC payment rate.

Sections 201(a) and (b) of the BBRA 1999 amend section 1833(t) of the Act to provide for additional payments to hospitals for outlier cases and for certain medical devices, drugs, and biologicals. These additional payments to hospitals will not affect coinsurance amounts. Redesignated section 1833(t)(8)(D) of the Act, as amended by section 201(i) of the BBRA 1999, provides that the coinsurance amount is to be computed as if outlier adjustments, adjustments for certain medical devices, drugs, and biologicals, as well as any other adjustments we may establish under section 1833(t)(2)(E) of the Act, had not occurred. Section 202 of the BBRA 1999 adds a new section 1833(t)(7) to the Act to provide transitional corridor payments to certain hospitals through calendar year 2003 and indefinitely for certain cancer centers.

Section 1833(t)(7)(H) of the Act provides that the transitional corridor payment provisions will have no effect on determining copayment amounts.

Section 204(a) of the BBRA 1999 amended redesignated section 1833(t)(8)(C) of the Act to provide that the coinsurance amount for a hospital outpatient procedure cannot exceed the amount of the inpatient hospital deductible for that year. The inpatient hospital deductible for calendar year 2000 is $776.00. We will apply the limitation to the wage adjusted coinsurance amount (not the unadjusted coinsurance amount) after any Part B deductible amounts are taken into account. Therefore, although the published unadjusted coinsurance amount for any APC may be higher or lower than $776.00 in 2000, the actual coinsurance amount for an APC, determined after any deductible amounts and adjustments for variations in geographic areas are taken into account, will be limited to the Medicare inpatient hospital deductible. Any reductions in copayments that occur in applying the limitation will be paid to hospitals as additional program payments. (See section III.F.3.a, below, for discussion of calculating the Medicare payment amount.)

MedPAC Comment: In its March 1999 report to the Congress, MedPAC expressed concern that the statute's approach to addressing the reduction in coinsurance could mean that it will be decades before coinsurance is 20 percent of all APC payment rates. MedPAC recommended that the Secretary seek and the Congress legislate a more rapid phase-in and that the cost be financed by increases in program spending, rather than through additional reductions in payments to hospitals. MedPAC agrees that the approach to calculating the coinsurance delineated in section 1833(t) of the Act is methodologically sound, but they recommend a shorter period to complete the coinsurance reduction.

Response: The coinsurance reductions enacted by the BBA 1997 already provide significantly higher levels of financial protection for beneficiaries than have existed in the past. While an acceleration of this protection might be desirable, the costs of such a policy must be balanced against other needs for increased Medicare spending and protection of the trust funds. The President's budget for FY 2001 does not contain such a proposal.

Comment: Three commenters discussed the delay in implementing the outpatient PPS until after January 1, 2000. A hospital association stated that it strongly believes that the outpatient PPS should not be implemented until all systems are ready, and suggested that implementation occur at the start of a calendar year so that Medigap insurers did not receive an unearned windfall by reason of a midyear decrease in beneficiary coinsurance amounts. Stating that the delay in implementation was of serious concern to it, an insurance group strongly urged us to implement the outpatient PPS as soon as possible. Finally, a beneficiary advocacy group stated that it is deeply concerned about the delay in implementation. While stating that it understood the magnitude of the Y2K problem, this group urged us to find a way to proceed with the phase-down of beneficiary coinsurance or, failing that, to offer our assurance that the phase-down will not be delayed beyond January 1, 2000.

Response: As noted elsewhere in this final rule, we intend to implement the outpatient PPS effective for services furnished on or after July 1, 2000. As noted in the proposed rule, we concluded that attempting to make the massive computer changes required to implement PPS at the same time we were trying to ensure that Medicare's computers were Y2K compliant would have jeopardized the compliance effort, which was HCFA's highest priority. Now that HCFA's efforts to make its computer systems, and those of its contractors, Y2K compliant are complete, we believe that July 1, 2000 is the earliest date on which we can feasibly implement the PPS. Pursuant to HCFA's contracts with the contractors responsible for maintaining its computer systems, HCFA makes programming changes such as those required to implement the outpatient PPS at the beginning of fiscal quarters. Thus, pursuant to this practice, after January 1, 2000, there are only three dates in 2000 on which the programming changes necessary to implement outpatient PPS can be put into effect—April 1, 2000, July 1, 2000 and October 1, 2000.

The first step in changing HCFA's computer systems to allow for implementation of the outpatient PPS is to expand the claim record of several HCFA and contractor systems to accept and retain specific information related to how a service is being paid or why it is denied. The claim record expansion is an indispensable prerequisite to implementation of outpatient PPS. Once expansion of the claim form is completed, we can then make the remaining programming changes necessary to implement the outpatient PPS. As we noted in the proposed rule, 63 FR 47605, these are massive changes that will require extensive testing. We anticipate that these software coding changes cannot be completed before the end of the second quarter of 2000. Therefore, the earliest possible date on which they can be installed and made operational is July 1, 2000.

We do not believe that it is technically feasible to complete installation of both the claims-form line item expansion and the coding changes needed to implement PPS any sooner than July 1, 2000. Each of these two stages of preparing HCFA's computer system for PPS constitutes major systems changes in and of itself. To attempt to make both changes simultaneously would be to run the risk that the system would not function properly at all, potentially requiring implementation to be delayed beyond July 1, 2000. We believe that the two-stage approach discussed above is the only feasible way to make the systems changes necessary to implement PPS and to be certain that they will work. The soonest date on which PPS can be implemented after the millennium is therefore July 1, 2000.

Despite one commenter's request that we implement the outpatient PPS at the start of a calendar year, we do not believe it would be appropriate to delay implementation beyond July 1, 2000. We see no reason to delay implementation beyond the time necessary for HCFA to have completed its Y2K efforts and make all the systems changes necessary for PPS. As with all of the other aspects of PPS, we believe that the beneficiary coinsurance reform contained in the outpatient PPS should be put into effect as soon as possible, so that beneficiaries can be subject to the lower coinsurance amounts under the new payment methodology at the

earliest date. We believe that this consideration outweighs any concern that Medigap insurers might receive a windfall because they set premiums for a given year assuming coinsurance amounts would be at one level only to see those amounts decrease in the middle of the year. In addition, we note that, if insurers received a large enough windfall for the reasons described by the commenter, the insurers might be required to refund premiums to beneficiaries or offer them a credit on premiums pursuant to section 1882(r) of the Act.

While none of the commenters specifically requested that we do so, we have considered the possibility of applying the outpatient PPS payment methodology retroactively to services furnished on or after January 1, 1999. We have decided not to make these retroactive payments for the reasons described below.

The first reason is the practical problem that the information needed to implement PPS retroactively does not exist in a usable form. Under current payment methodologies for many outpatient services, hospitals submit bills for furnished services based on their charges for the services. For these services, HCFA does not require hospitals to submit bills containing the HCPCS code for the furnished service and other data (such as the dates of service of multiple services submitted on the same bill) necessary to process bills under the new prospective payment methodology. Without the HCPCS code for a given service, we would be unable to determine retroactively into which APC group the service should be placed for payment under PPS. In turn, that would mean that we could not determine the appropriate payment amount for the service. Thus, given the information currently available to us, we could not now simply reprocess bills for outpatient services that had been furnished between January 1, 1999 and July 1, 2000 and recompute payment and coinsurance amounts for these services. As a result, the data needed to implement PPS retroactively do not exist in a form that would allow for such implementation.

Nor would it have been feasible to attempt to capture the information necessary for retroactive application during 1999. As noted above, we concluded that it would not have been prudent to make the computer programming changes necessary to implement PPS until our Y2K efforts were complete. Those same changes would have been necessary to allow us to capture the more detailed claims data needed to perform a retroactive application of PPS back to January 1, 1999 once the system was implemented prospectively. Because we delayed those changes out of concern that they would interfere with our Y2K efforts, no automated process existed for the period January 1, 1999 through July 1, 2000 by which we could have captured the more detailed claims data necessary to effect an eventual retroactive implementation of PPS. Publication of a final rule before January 1, 1999 would not have altered this situation. Even if we had published such a rule, it could not have become effective until we could make the computer changes necessary to implement PPS—the functional equivalent of what we have done through publication of the proposed rule and this final rule—and until we could make those changes, we could not compile by computer the data needed to later reprocess claims under PPS.

In theory, we might have been able to implement PPS retroactively despite the lack of an automated method of compiling the data necessary to do so. But it simply would not have been practicable to maintain and later process by hand such data for the period between January 1, 1999 and July 1, 2000, given the millions of claims for outpatient services submitted during that period. (Based on the latest data available, we process approximately 160 million claims for outpatient services over an 18-month period.) Neither HCFA nor its contractors have the staff needed to accomplish such a task.

We might also have conceivably required hospitals to maintain the data required for a later retroactive implementation of PPS, but this approach has practical difficulties. First, during the interim period between January 1, 1999 and implementation of PPS, hospitals themselves were exerting significant efforts to ensure the Y2K compliance of their own automated Medicare billing systems, and it is doubtful that those systems could have accommodated the necessary programming changes any more than Medicare's systems could have. Even if hospitals could have maintained the information (or if HCFA could have maintained it by hand or could obtain it from any source now), the burden associated with attempting to implement the new prospective payment methodology both retroactively and prospectively at the same time would have been prohibitive. As noted in the proposed rule and in this final rule, effecting the transition between the old payment methodologies and the new prospective payment methodology constitutes a massive programmatic undertaking. Any effort to reprocess the huge number of bills for outpatient services that would be involved in any attempt to retroactively implement PPS would compete for the same resources needed to implement PPS prospectively, and would compromise our ability to ensure the smoothest prospective implementation.

This is especially so if paper records of claims from the interim period would have to be manually input into Medicare's automated payment systems in order to make retroactive payments for services furnished on or after January 1, 1999. Undertaking an effort, once PPS is implemented, to review hospital records of every outpatient service furnished between January 1, 1999 and July 1, 2000; translate those records into the data needed to process a Medicare claim for the service under PPS; and issue a retroactive payment reflecting the PPS rate for the service would cause a huge backlog of current bills to be processed (and of other carrier tasks), and thus would not be practicable. Therefore, there was no feasible way to have captured the information necessary to make PPS apply retroactively.

In addition to the practical problems described above, the statute does not require retroactive application of PPS. The statutory requirement to implement the PPS for services furnished on or after January 1, 1999 is ambiguous. While section 1833(t)(1)(A)'s reference to outpatient services ''furnished during a year beginning with 1999'' might be read as imposing such a requirement, it is also true that section 1833(t)(1)(B)(i) does not expressly set a time limit for HCFA to designate which services are ''covered'' outpatient services for purposes of payment under PPS. Nor does it set a deadline for HCFA to issue regulations implementing the outpatient PPS. As a result, the statute can also be read to require implementation of PPS for services furnished in a year beginning in 1999 *if* HCFA has designated in its implementing regulations those services as covered services for purposes of PPS. The better reading is that the system applies prospectively only.

We recognize that, under section 1833(a)(2)(B), Congress arguably made the old payment methodologies for outpatient services inapplicable to services furnished on or after January 1, 1999. Again, though, Congress imposed no corresponding limit on the time within which HCFA must designate the services that would be ''covered'' services for purposes of PPS. While it is therefore possible to read the statute in such a way that an outpatient service

furnished after January 1, 1999 but not yet designated as a covered outpatient service by HCFA for purposes of PPS would have no payment methodology applicable to it, we do not believe that Congress intended such a result. We believe that where HCFA, because of significant Y2K concerns, has not yet designated a given outpatient service as a covered service for purposes of PPS, the most appropriate reading of section 1833(t)(1)(A) is that it authorizes the Secretary to continue to pay for the service under the existing methodology until PPS can be implemented. If the Congress had known about the Y2K problem at the time it enacted the PPS statute, this is the only rational approach it could have adopted.

We believe that a clear expression of Congressional intent not to require retroactive application of PPS can be found in the legislative history of amendments to section 1833(t) of the Act, enacted as sections 201, 202, and 204 of the BBRA 1999. In each instance, the legislation provides that the ''amendments made by this section shall be effective as if included in the enactment of the BBA,'' that is, the original enactment of PPS in section 1833(t) (sections 201(m), 202(b), and 204(c) of the BBRA 1999). This language was taken from the House version of the bill (H.R. Rep. No. 436 (Part I), 106th Cong., 1st Sess. 14, 16 (1999)). The House Report stated that the outpatient payment reforms contained in the BBRA 1999 (and hence in the BBA 1997) were intended to take effect ''upon implementation of the hospital prospective payment system'' by HCFA, *id.* at 52, 55, 56, not on January 1, 1999. The House Conference Committee Report reiterated the understanding that the payment and coinsurance provisions of the BBA and BBRA do not take effect until after implementation by HCFA. H. Conf. Rep. No. 479, 106th Cong., 1st Sess. 866 (1999) (''[c]urrently, beneficiaries pay 20% of charges for outpatient services,'' but ''[u]nder the outpatient PPS, beneficiary coinsurance will be limited to frozen dollar amounts based on 20% of national median charges for services in 1996, updated to the year of implementation of the PPS''); *id.* at 867 (''[t]he conferees fully expect that the beneficiary coinsurance phase-down will commence, as scheduled, on July 1, 2000''); 870 (''[h]ospital outpatient PPS is to be implemented simultaneously and in full for all services and hospitals (estimated for July 2000)'').

Both the House Report and the Conference Report expressly acknowledge, without disapproval, HCFA's decision to delay implementation of the outpatient PPS until after January 1, 2000. H.R. Rep. No. 436 (Part I) at 51 (stating that Secretary ''delayed implementation of the new system until after the start of CY 2000 in order to ensure that 'year 2000' data processing problems are fully resolved before the new system is implemented'' and that ''HCFA currently estimates that the outpatient department prospective payment system will be implemented in July 2000''); 145 Cong. Rec. at H12529 (daily ed. Nov. 17, 1999) (H. Conf. Rep. No. 479) (acknowledging ''[t]here has already been a one-year delay in implementation of the BBA 97 provision'' and stating that conferees ''fully expect'' that the outpatient prospective payment system ''will commence, as scheduled, on July 1, 2000''). These statements indicate Congressional intent that payments and coinsurance for covered hospital outpatient services would be governed prospectively by PPS only after HCFA promulgated and made effective final implementing regulations.

Finally, there is a serious question as to whether retroactive implementation of PPS might constitute prohibited retroactive rulemaking. In *Bowen* v. *Georgetown University Hospital*, 488 U.S. 204, 208 (1988), the Supreme Court stated that a statutory grant of legislative rulemaking authority does not encompass the power to promulgate retroactive rules unless that power is conveyed by Congress in express terms, even where some substantial justification for retroactive rulemaking might exist. The Court then declined to find this express authorization for retroactive rulemaking in the Medicare statute's general grant of rulemaking authority.

We do not find this express authorization in section 1833(t) or any other statutory provision concerning the outpatient PPS. Section 1833(t)(1) requires that payment for outpatient services that are furnished during any calendar year beginning after January 1, 1999 and that are designated by HCFA as ''covered'' outpatient services shall be made under a prospective payment system. While Congress may have presumed, when it enacted section 1833(t) as part of the BBA, that HCFA would be able to designate covered outpatient services and implement the outpatient PPS by January 1, 1999, Congress did not foresee at that time that Y2K concerns would prevent the agency from doing so. As a result, the statute is silent as to what was to occur if HCFA was unable to designate covered outpatient services and implement PPS by January 1, 1999. We do not believe that this silence constitutes the express authorization of retroactive rulemaking required by the Supreme Court's *Georgetown* decision.

Comment: Several commenters contended that the proposed rules for beneficiary coinsurance are overly complex and that the phase-in period is too long. One commenter asked HCFA to consider a less involved method and a more aggressive time period for implementation. Another commenter suggested using a 5-year phase-in period. One commenter requested that we recommend a legislative change to the Congress to reduce beneficiary coinsurance to 20 percent by January 1, 2003. Still another commenter expressed concern that calculations of coinsurance amounts for each hospital will be particularly burdensome to Medicare fiscal intermediaries and, as a result of the increased workload, errors may occur. The commenter also recommended a more rapid reduction of coinsurance to 20 percent of the payment amount.

Response: We agree that the rules governing how coinsurance is to be calculated under the PPS are complex, and the phase-in to 20 percent coinsurance is a lengthy one. However, the methods for calculating coinsurance are dictated by the statute. The legislative changes were made in order to put some control on rapidly increasing beneficiary coinsurance payments, to begin to decrease the proportion of beneficiary liability for hospital outpatient services, and to continue to reduce beneficiary liability over time. As we have stated, the impetus to accelerate the reduction of beneficiary coinsurance has to be viewed within the context of other needs for increased Medicare expenditures and long-term protection of the trust funds. The delay in implementing the hospital outpatient PPS past the statutory effective date was unavoidable due to systems constraints imposed by Y2K compliance requirements.

Comment: One commenter noted that the proposed rule set beneficiary coinsurance at 20 percent of *median* charges, but the commenter believes that coinsurance amounts should be recalculated to equal 20 percent of the *average* charge for the applicable APC group. The commenter indicates that such a change would provide some financial relief to hospitals.

Response: Section 1833(t)(3)(B)(i) of the Act requires that unadjusted coinsurance amounts be calculated as 20 percent of the national *median* of the charges for services within the APC group.

Comment: One commenter stated that because coinsurance is based on the median charges of the APC, some beneficiaries would pay a higher coinsurance than they would under the current system. The commenter believes that beneficiaries who require less intensive services in an APC group will essentially subsidize other beneficiaries who receive more intensive services within the group. The commenter asserted that fairness would dictate beneficiaries be charged coinsurance amounts that more appropriately reflect the services received, not an amount based on a median of multiple services they did not receive.

Response: Section 1833(t)(3)(B)(ii) of the Act provides that the unadjusted coinsurance amounts are based on the national median of the charges for the ''services within'' an APC. Because an APC group consists of services that are both clinically similar and similar with respect to the resources required to perform the service, we would expect that charges for the services should also be fairly homogeneous. We believe that services within a group are homogeneous enough to warrant a single payment amount and a single coinsurance amount.

In the following sections, we describe how we determined the beneficiary coinsurance amount and the Medicare program payment amount for services paid for under the hospital outpatient PPS.

2. Determining the Unadjusted Coinsurance Amount and Program Payment Percentage

To calculate Medicare program payment amounts and beneficiary coinsurance amounts, we first determined for each APC group two base amounts, in accordance with statutory provisions:

- An unadjusted copayment amount, described in section 1833(t)(3)(B) of the Act; and
- The predeductible payment percentage, which we call the program payment percentage, described in section 1833(t)(3)(E) of the Act.

a. Calculating the Unadjusted Coinsurance Amount for Each APC Group

In the proposed rule, we described the specific steps used to calculate the unadjusted coinsurance amounts for each APC group as follows:

(i) We determined the national median of the charges billed in 1996 for the services that constitute an APC group after standardizing charges for geographic variations attributable to labor costs. (To determine the labor adjustment, we divided the portion of each charge that we estimated was attributable to labor costs (60 percent) by the hospital's inpatient wage index value and added the result to the nonlabor portion of the charge (40 percent)).

(ii) We updated charge values to projected 1999 levels by multiplying the 1996 median charge for the APC group by 13.0 percent (increased to 14.7 percent in this final rule), which the HCFA Office of the Actuary estimates to be the rate of growth of charges between 1996 and 1999.

(iii) To obtain the unadjusted coinsurance amount for the APC group, we multiplied the estimated 1999 national median charge for the APC group by 20 percent. The unadjusted coinsurance amount is frozen at the 1999 level until such time as the program payment percentage (as determined below) equals or exceeds 80 percent (section 1833(t)(3)(B)(ii) of the Act).

b. Calculating the Program Payment Percentage (Predeductible Payment Percentage)

In the proposed rule and in this final rule, we use the term ''program payment percentage'' to replace the term ''pre-deductible payment percentage,'' which is referred to in section 1833(t)(3)(E) of the Act. The program payment percentage is calculated annually for each APC group, until the value of the program payment percentage equals 80 percent. To determine the program payment percentage for each APC group, we—

(i) Subtract the APC group's unadjusted coinsurance amount from the payment rate set for the APC group; and

(ii) Divide the difference (APC payment rate minus unadjusted coinsurance amount) by the APC payment rate, and multiply by 100.

The program payment percentage will be recalculated each year because APC payment rates will change when APC rates are increased by annual market basket updates and whenever we revise an APC.

Comment: One commenter expressed concern about how the coinsurance amounts are determined. The commenter stated that the calculation is flawed and penalizes beneficiaries in those States where charges for services tend to be lower than in other States. The commenter alleged that if the hospitals in those States where charges for services tend to be lower accept a reduced coinsurance in order to hold beneficiaries harmless, the hospitals will be penalized. The commenter also asserted that Medigap policies and Medicaid programs will also be affected. The commenter further stated that coinsurance should be based on regional, not national, charges. The commenter contended that the provision does not achieve the intended outcome of equalizing payment across the nation.

Response: Sections 1833(t)(3) and (t)(8) of the Act prescribe how coinsurance amounts are to be calculated under the PPS. Our method of calculating unadjusted coinsurance amounts for each APC group based on 20 percent of national median charges follows the requirements of section 1833(t)(3)(B) of the Act.

Comment: A number of commenters believe that the payment system as proposed would create gross anomalies in coinsurance for particular chemotherapy drugs. For example, the proposed $36.61 coinsurance for fluorouracil is 10 times the hospital's cost to purchase that drug. The commenters asserted that this excessive coinsurance represents an abuse of patients and would undermine beneficiary confidence in the new system. They recommended that coinsurance be limited to 20 percent of the payment amount for each drug.

Several other commenters noted that classifying drugs with widely varying costs in the same APC will have a significant negative effect on beneficiary coinsurance, and in some cases beneficiaries could be required to pay a greater percentage of coinsurance for less effective therapies. For example, one commenter alleged that the coinsurance for the drug 5–FU, which the commenter believes has a current coinsurance of approximately $1, would increase to $40 under the proposed system.

Response: The coinsurance anomalies for chemotherapy drugs that appeared in the proposed rule are not an issue under this final rule. Unlike the proposed chemotherapy drug APCs, which grouped all chemotherapy drugs under four APCs, in this final rule, each chemotherapy drug is assigned to a separate APC. As discussed in section III.D.5 of this preamble, the unadjusted coinsurance amounts for these APCs is calculated as 20 percent of the APC payment rate.

Comment: One commenter noted that the proposed national unadjusted coinsurance amounts for cardiovascular stress testing and perfusion imaging result in beneficiaries bearing 85 percent of the total payment for stress testing and 60 percent for perfusion imaging, which many beneficiaries will be unable to afford. Another commenter

requested that we either exclude cataract procedures and angioplasty from the hospital outpatient PPS or create an outlier policy that affords special treatment for these procedures in order to protect beneficiaries from excessive coinsurance amounts.

Response: Coinsurance amounts, by law, are based on 20 percent of the median of the charges actually billed in 1996 (updated to 1999) for the services within an APC. The fact that coinsurance is a larger proportion of the total payment for some APCs than for others reflects the differences in hospital charging practices for different services. For example, in examining departmental cost-to-charge ratios reflected on hospital cost reports, we have found that most hospitals have higher mark-ups in charges for radiology and diagnostic services than they do for clinic visits.

3. Calculating the Medicare Payment Amount and Beneficiary Coinsurance Amount

a. Calculating the Medicare Payment Amount

The national APC payment rate that we calculate for each APC group is the basis for determining the total payment (subject to wage-index adjustment) the hospital will receive from the beneficiary and the Medicare program. (A hospital that elects to reduce coinsurance, as described below in section III.F.4, may receive a total payment that is less than the APC payment rate.) The Medicare payment amount takes into account the wage index adjustment and the beneficiary deductible and coinsurance amounts. In addition, the amount calculated for an APC group applies to all the services that are classified within that APC group. The Medicare payment amount for a specific service classified within an APC group under the outpatient PPS is calculated as follows:

(i) Apply the appropriate wage index adjustment to the national payment rate that is set annually for each APC group.

(ii) Subtract from the adjusted APC payment rate the amount of any applicable deductible as provided under § 410.160.

(iii) Multiply the adjusted APC payment rate, from which the applicable deductible has been subtracted, by the program payment percentage determined for the APC group or 80 percent, whichever is lower. This amount is the *preliminary Medicare payment amount.*

(iv) If the wage-index adjusted coinsurance amount for the APC is reduced because it exceeds the inpatient deductible amount for the calendar year, add the amount of this reduction to the amount determined in (iii) above. The resulting amount is the *final Medicare payment amount.*

b. Calculating the Coinsurance Amount

A coinsurance amount is calculated annually for each APC group. The coinsurance amount calculated for an APC group applies to all the services that are classified within the APC group. The beneficiary coinsurance amount for an APC is calculated as follows:

Subtract the APC group's Medicare payment amount from the adjusted APC group payment rate less deductible; for example, coinsurance amount = (adjusted APC group payment rate less deductible)—APC group *preliminary Medicare payment amount.* If the resulting amount does not exceed the annual hospital inpatient deductible amount for the calendar year, the resulting amount is the beneficiary coinsurance amount. If the resulting amount exceeds the annual inpatient hospital deductible amount, the beneficiary coinsurance amount is limited to the inpatient hospital deductible. For example, assume that the wage-adjusted payment rate for an APC is $300; the program payment percentage for the APC group is 70 percent; the wage-adjusted coinsurance amount for the APC group is $90; and the beneficiary has not yet satisfied any portion of his or her $100 annual Part B deductible.

(A) Adjusted APC payment rate: $300.

(B) Subtract the applicable deductible:

$300–$100 = $200

(C) Multiply the remainder by the program payment percentage to determine the preliminary Medicare payment amount:

$0.7 \times \$200 = \$140$

(D) Subtract the Medicare payment amount from the adjusted APC payment rate less deductible to determine the coinsurance amount, which cannot exceed the inpatient hospital deductible for the calendar year:

$\$200 - \$140 = \$60$

(E) Calculate the final Medicare payment amount by adding the preliminary Medicare payment amount determined in step (C) to the amount that the coinsurance was reduced as a result of the inpatient hospital deductible limitation.

$\$140 + \$0 = \$140$

In this case, the beneficiary pays a deductible of $100 and a $60 coinsurance, and the program pays $140, for a total payment to the hospital of $300. Applying the program payment percentage ensures that the program and the beneficiary pay the same proportion of payment that they would have paid if no deductible were taken.

If the annual Part B deductible has already been satisfied, the calculation is:

(A) Adjusted APC payment rate: $300.

(B) Subtract the applicable deductible:

$\$300 - 0 = \$300$

(C) Multiply the remainder by the program payment percentage to determine the preliminary Medicare payment amount:

$0.7 \times \$300 = \$210$

(D) Subtract the Medicare payment amount from the adjusted APC payment rate less deductible to determine the coinsurance amount. The coinsurance amount cannot exceed the amount of the inpatient hospital deductible for the calendar year:

$\$300 - \$210 = \$90$

(E) Calculate the final Medicare payment amount by adding the preliminary Medicare payment amount determined in step (C) to the amount that the coinsurance was reduced as a result of the inpatient hospital deductible limitation.

$\$210 + \$0 = \$210$

In this case, the beneficiary makes a $90 coinsurance payment, and the program pays $210, for a total payment to the hospital of $300.

The following example illustrates a case in which the inpatient hospital deductible limit on coinsurance amounts applies. Assume that the wage-adjusted payment rate for an APC is $2,000; the wage-adjusted coinsurance amount for the APC is $900; the program payment percentage is 55 percent; the inpatient hospital deductible amount for the calendar year is $776 and the beneficiary has not yet satisfied any portion of his or her $100 Part B deductible.

(A) Adjusted APC payment rate: $2,000.

(B) Subtract the applicable deductible:

$\$2000 - \$100 = \$1,900$

(C) Multiply the remainder by the program payment percentage to determine the preliminary Medicare payment amount:

$0.55 \times \$1,900 = \$1,045$

(D) Subtract the preliminary Medicare payment amount from the adjusted APC payment rate less deductible to determine the coinsurance amount. The coinsurance amount cannot exceed the inpatient hospital deductible amount of $776:

$\$1,900 - \$1,045 = \$855$, but coinsurance limited to $776

(E) Calculate the final Medicare payment amount by adding the

preliminary Medicare payment amount determined in step (C) to the amount that the coinsurance was reduced as a result of the inpatient hospital deductible limitation ($855 − $776 = $79).

$1,045 + $79 = $1,124

In this case, the beneficiary pays a deductible of $100 and coinsurance that is limited to $776. The program pays $1,124 (which includes the amount of the reduction in beneficiary coinsurance due to the inpatient hospital deductible limitation) for a total payment to the hospital of $2,000.

4. Hospital Election To Offer Reduced Coinsurance

For most APCs, the transition to the standard Medicare coinsurance rate (20 percent of the APC payment rate) will be gradual. For those APC groups for which coinsurance is currently a relatively high proportion of the total payment, the process will be correspondingly lengthy. The law offers hospitals, but not CMHCs, the option of electing to reduce coinsurance amounts and permits hospitals to disseminate information on their reduced rates. In this section, we discuss the procedure by which hospitals can elect to offer a reduced coinsurance amount, and the effect of the election on calculation of the program payment and beneficiary coinsurance.

Section 1833(t)(5)(B) of the Act, as added by section 4523 of the BBA 1997, requires the Secretary to establish a procedure under which a hospital, before the beginning of a year, may elect to reduce the coinsurance amount otherwise established for some or all hospital outpatient services to an amount that is not less than 20 percent of the hospital outpatient prospective payment amount. The statute further provides that the election of a reduced coinsurance amount will apply without change for the entire year, and that the hospital may disseminate information on its reduced copayments. Section 1833(t)(5)(C) of the Act, as added by the BBA 1997, provides that deductibles cannot be waived. Finally, section 1861(v)(1)(T) of the Act (as added by section 4451 of the BBA 1997) provides that no reduction in coinsurance elected by the hospital under section 1833(t)(5)(B) of the Act may be treated as a bad debt. We note that section 1833(t)(5) of the Act has been redesignated as section 1833(t)(8) of the Act by sections 201(a) and 202(a) of the BBRA 1999.

Elections to reduce coinsurance will not be taken into account in calculating transitional corridor payments to hospitals (discussed in section III.H.2 of this preamble). That is, a hospital's transitional corridor payment will be determined as if the hospital received unreduced coinsurance amounts from beneficiaries.

In the proposed rule, we stated that we would require that hospitals make the election to reduce coinsurance on a calendar year basis. The proposed rule required that the hospital must notify its fiscal intermediary of its election to reduce coinsurance no later than 90 days prior to the date the PPS is implemented or 90 days prior to the start of any subsequent calendar year and that the hospital's notification must be in writing. It must specifically identify the APC groups to which the hospital's election will apply and the coinsurance amount (within the limits identified below) that the hospital has elected for each group. The election of reduced coinsurance must remain in effect and unchanged during the year for which the election is made. Because the law states that hospitals may disseminate information on any reduced coinsurance amounts, we provided in the proposed rule that hospitals would be allowed to publicly advertise this information.

The proposed regulations provided that a hospital may elect to reduce the coinsurance amount for any or all APC groups. A hospital may *not* elect to reduce the coinsurance amount for some, but not all, services within the same APC group.

As proposed, a hospital may not elect a coinsurance amount for an APC group that is less than 20 percent of the adjusted APC payment rate for that hospital. In determining whether to make such an election, hospitals should note that the national coinsurance amount under this system, based on 20 percent of national median charges for each APC, may yield coinsurance amounts that are significantly higher or lower than the coinsurance that the hospital previously has collected. This is because the median of the national charges for an APC group, from which the coinsurance amount is ultimately derived, may be higher or lower than the hospital's historic charges. Therefore, in determining whether to elect lower coinsurance and the level at which to make the election, we advise that hospitals carefully study the wage-adjusted coinsurance amounts for each APC group in relation to the coinsurance amount that the hospital has previously collected.

As discussed in section III.F.1, under sections 1834(d)(2)(C)(ii) and 1834(d)(3)(C)(ii) of the Act the coinsurance for screening sigmoidoscopies furnished by hospitals and screening colonoscopies furnished by hospital outpatient departments and ASCs is 25 percent of the applicable payment rate. The payment rate for these colorectal cancer screening tests is the lower of the hospital outpatient rate or the ASC payment rate. The payment rate for screening barium enemas is the same as that for diagnostic barium enemas. However, the coinsurance amount for screening barium enemas is 20 percent of the APC payment rate. Hospitals may *not* elect to reduce coinsurance for screening sigmoidoscopies, screening colonoscopies, or screening barium enemas.

Calculation of coinsurance amounts on the basis of a hospital's election of reduced coinsurance is similar to the formula described in section III.F.3. For example, assume that the adjusted APC payment rate is $300; the program payment percentage for the APC group is 60 percent; the hospital has elected a $60 *reduced* coinsurance amount for the APC group; and the beneficiary has not satisfied the annual Part B deductible.

(A) Adjusted APC payment rate: $300.

(B) Subtract the applicable deductible:

$300 − $100 = $200

(C) Multiply the remainder by the program payment percentage to determine the Medicare payment amount:

0.6 × $200 = $120

(D) Beneficiary's coinsurance is the difference between the APC payment rate reduced by any deductible amount and the Medicare payment amount, but not to exceed the lesser of the reduced coinsurance amount or the inpatient hospital deductible amount:

$200 − $120 = $80 (limited to $60 because of the hospital-elected reduced coinsurance amount)

(E) Calculate the final Medicare payment amount by adding the preliminary Medicare payment amount determined in step (C) to the amount that the coinsurance was reduced as a result of the inpatient hospital deductible limitation.

$120 + $0 = $120

In this case, Medicare makes its regular payment of $120, and the beneficiary pays a $100 deductible and a reduced coinsurance amount of $60. The hospital receives a total payment of $280 instead of the $300 that it would have received if it had not made its election to reduce coinsurance.

Comment: One commenter stated that it is currently illegal to accept lower coinsurance amounts from beneficiaries and asked for an explanation as to how

we could propose to encourage hospitals to lower coinsurance.

Response: Although Medicare, in general, has prohibitions against reducing beneficiary coinsurance, redesignated section 1833(t)(8)(B) of the Act specifically provides the legal authority for hospitals to make elections to reduce coinsurance amounts for purposes of the outpatient PPS. However, those coinsurance amounts cannot be reduced below 20 percent of the adjusted APC payment rate for the hospital.

Comment: One commenter asked whether, in view of our proposal to allow hospitals to elect lower coinsurance, Medigap insurance plans will be permitted to offer a waiver of a participating hospital's coinsurance. That is, can a Medigap plan act as a preferred provider organization (PPO) with a financial incentive to select those hospitals that elect to reduce coinsurance?

Response: There are two kinds of Medigap policies—regular Medigap and Medicare SELECT. While regular Medigap policies must pay full supplemental benefits on all claims that are submitted by all Medicare providers and are approved by Medicare carriers and intermediaries, Medicare SELECT plans, which are a managed care form of Medigap, may restrict payment of supplemental benefits to network providers. Thus, by design, Medicare SELECT plans are permitted to negotiate selectively with hospitals. Ordinarily, Medicare SELECT plans contract with certain hospitals to waive the hospital deductible for inpatient services.

Since the Congress has expressly permitted hospitals to reduce outpatient coinsurance to no less than 20 percent of the PPS payment amount, a Medicare SELECT plan is free to contract selectively with these hospitals. We note that a hospital's election to reduce coinsurance under redesignated section 1833(t)(8)(B) of the Act requires that the reduction be across-the-board for some or all APC groups. Thus, an agreement between a Medicare SELECT plan and a hospital to reduce coinsurance would result in coinsurance reductions for all beneficiaries who receive those APC group services at the hospital, whether or not they are enrolled in the Medicare SELECT plan.

Comment: One commenter requested that we seek a legislative change to offer hospitals more flexibility under the coinsurance reduction provision by permitting them to review and revise coinsurance amounts every 3 months.

Response: We believe that there would be a significant impact on contractors if hospitals were allowed to revise their reduced coinsurance more often than annually. More frequent coinsurance changes may also be confusing to beneficiaries. Because we do not have a good estimate of how many hospitals will make the elections and we do not yet know whether those hospitals that do make elections will elect to reduce coinsurance for just a few or for a significant number of APCs, we do not support allowing hospitals to make or change elections more often than annually. However, we may reconsider our position after we gain more experience under the PPS and can better assess what the impact of more frequent elections would be on hospitals, beneficiaries, and HCFA and its contractors.

Comment: One commenter noted that if we intend to publish a final rule no more than 90 days before implementation of the PPS, hospitals would not have sufficient time to make coinsurance election decisions. The commenter recommended that hospitals be permitted to make the election 60 days before implementation of the system.

Response: This final rule will not be published more than 90 days before the date of implementation of the PPS. Therefore, the final regulations require that hospitals inform their fiscal intermediaries (FIs) of their elections to reduce coinsurance not later than June 1, 2000. Beginning with elections for calendar year 2001, elections are required to be made by December 1 preceding the calendar year. At this time, we do not know how many hospitals will choose to reduce coinsurance or for how many APCs these hospitals will elect reductions. While we want to provide hospitals sufficient time to make their elections, we also must provide fiscal intermediaries with enough time to incorporate the elections into their systems.

Comment: Several commenters disagreed with our proposal to allow hospitals to advertise reduced coinsurance amounts. They noted that, although the BBA 1997 provision with respect to hospitals' election to reduce coinsurance amounts provides that hospitals may ''disseminate information'' on their reductions, we have interpreted that to mean that hospitals may ''advertise'' their reductions. Two commenters stated that disseminating information is not synonymous with granting one category of hospitals the unique opportunity to advertise to attract customers. They believe that this interpretation is antithetical to the spirit underlying provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) that prohibit beneficiary inducements and may conflict with State anti-kickback laws. Some commenters were also concerned that under our proposal to allow hospitals to advertise, hospitals may issue a general advertisement of reduced coinsurance when the reduction may apply only to certain services. Other commenters were concerned that hospital advertising may lead Medicare beneficiaries to believe that hospital outpatient care is more economical than other ambulatory settings, even when that is not the case, or beneficiaries may become confused and believe that all ambulatory providers have the ability to reduce coinsurance. These commenters asked us to reconsider our proposal to allow hospitals to advertise rather than to disseminate information. In addition, they asked us to establish additional requirements for hospitals' dissemination of information concerning coinsurance reductions so that beneficiaries are made aware that reduced coinsurance applies only to certain specified services, that it applies only to coinsurance billed by hospitals for those services, and that the law does not permit reduced coinsurance for other Part B services such as physician services.

Several other commenters stated that for the election to reduce coinsurance to be effective, hospitals must have the right to advertise and, therefore, the commenters supported our proposal to permit hospitals to advertise coinsurance reductions.

Response: We believe that hospitals must be able to advertise their coinsurance reductions in order to achieve what we believe to be the intent of the BBA provision, that is, to provide hospitals with some ability to compete with other ambulatory settings (where coinsurance is already 20 percent of the applicable Medicare payment rate) and to reduce beneficiary coinsurance liability.

Hospitals would have less incentive to reduce coinsurance if they could not advertise. In addition, beneficiaries need to be fully informed so that they can make informed decisions. We believe that advertising as a way of disseminating information has merit.

We were persuaded by some commenters' concerns that beneficiaries may not understand that reduced coinsurance applies to specific hospital outpatient services furnished by specific hospitals that choose to elect reductions and that similar reductions cannot be made by other providers of ambulatory services. We, therefore, are amending the regulations to require that all

advertisements or other information furnished to beneficiaries must specify that the coinsurance reductions advertised apply only to the specified services of that hospital and that these coinsurance reductions are available only where a hospital elects to reduce coinsurance for hospital outpatient services and reductions are not allowed in other ambulatory settings or physician offices.

Comment: One commenter, noting the complexity of the PPS coinsurance requirements, requested that we provide a phase-in period in the final rule to allow hospitals sufficient time to implement the changes necessary to meet the requirements.

Response: The method required to be used in calculating coinsurance under the PPS results in an overall decrease in the total coinsurance amounts beneficiaries pay for hospital outpatient services. Total coinsurance is somewhat reduced in the first year of implementation and will be reduced even more in future years, until coinsurance for all PPS services equal 20 percent of the applicable APC payment rate. It is only by fully implementing the coinsurance provisions under section 1833(t)(3)(B) of the Act that beneficiaries will realize these reductions. We, therefore, do not support a phase-in period.

Comment: One commenter recommended that we include, as part of the public record, year by year estimates of the total economic burden placed on beneficiaries by the prolonged coinsurance phase-in period, assuming hospitals charge the maximum and minimum coinsurance amounts. The commenter believes these estimates would be useful as a basis for future discussions of how to remedy the coinsurance problem.

Response: As a rule, we develop estimates of impacts for legislative proposals that are under consideration by the Congress and for final legislation as we are developing regulations to implement the law. Although we do not have the resources available to model any number of other data analyses that may have merit, our data are made available to the public, so the commenter and any other interested party may perform the coinsurance analysis.

Comment: One commenter stated that the proposed PPS creates new complexities for Medicare beneficiaries in that they will have to wait for hospitals to do the calculations necessary to determine coinsurance. The beneficiaries will also receive multiple bills and explanations of benefits for multiple hospital visits occurring on the same day. The commenter stated that we will need to have an extensive process in place to explain why, in most cases, beneficiaries are paying 50 to 70 percent of their outpatient services and why they are receiving separate statements when they have multiple visits on the same day.

Response: In the proposed rule, we assigned medical visits, that is, clinic and emergency room visits, to APCs based on both the level of visit as defined by a HCPCS code and the diagnosis of the patient. In order to implement that type of APC assignment, we would have to require hospitals to submit a separate bill for each medical visit that occurred on the same day; however, under the final rule, medical visits are assigned to APCs based solely on the HCPCS code, and it will be possible for hospitals to bill for multiple medical visits on the same bill. We agree that the way coinsurance is determined under the PPS is a significant change. We are developing a brochure for beneficiaries that will explain the new system and the policies under the outpatient PPS that will affect them.

Comment: One commenter recommended that we make information available to beneficiaries that compares the average coinsurance for high volume procedures performed at hospitals in a particular geographic area so that beneficiaries can make informed health care decisions about their care.

Response: We believe that beneficiaries will be informed about the coinsurance reductions elected by hospitals in their area through advertisements and other information made available by hospitals.

Comment: One commenter asked whether the EOMB (Explanation of Medicare Benefits) notice to the beneficiary will clearly explain that a hospital's decision to reduce coinsurance applies to a specific service furnished at that specific hospital.

Response: We are reviewing the EOMB in light of the changes in Medicare payments and coinsurance amounts under the PPS, but we have not yet finalized our work. We will take the commenter's suggestion into consideration as we investigate changes we will make to the EOMB.

G. Adjustment for Area Wage Differences

1. Proposed Wage Index

Under section 1833(t)(2)(D) of the Act, the Secretary is required to determine a wage adjustment factor to adjust, in a budget-neutral manner, the portion of the payment rate and the coinsurance amount that is attributable to labor-related costs for relative differences in labor and labor-related costs across geographic regions. As stated in the proposed rule, we considered several options and we proposed using the hospital inpatient PPS wage index as the source of an adjustment factor for geographic wage differences for the hospital outpatient department PPS. We believe that using the hospital inpatient PPS wage index is both reasonable and logical, given the inseparable, subordinate status of the outpatient department within the hospital overall. Use of a hospital outpatient-specific wage index was not required by the Congress and we did not have either the time or resources necessary to construct one. We explained in our proposed rule that there are several possible versions of the hospital inpatient wage index that can be developed by extracting the basic wage and salary data from hospital cost reports, depending on the methodology that is applied to the data. For the hospital outpatient PPS, we proposed to adopt the same version that is used to determine payments to hospitals under the hospital inpatient PPS to adjust for relative differences in labor and labor-related costs across geographic areas. This version reflects the effect of hospital redesignation under 1886(d)(8)(B) of the Act and hospital reclassification under 1886(d)(10) of the Act.

By statute, we implement the annual updates of the hospital inpatient PPS on a fiscal year basis. However, we proposed to update the hospital outpatient department PPS on a calendar year basis. Therefore, the hospital inpatient PPS wage index values that are updated annually on October 1 would be implemented for the hospital outpatient department PPS on the January 1 immediately following. We proposed this schedule so that wage index changes will be implemented on a calendar year basis concurrently with other revisions and updates, such as the conversion factor update or changes in the APC groups resulting from new or deleted CPT codes. Subsequent to our proposal, section 201(h) of the BBRA 1999 amended section 1833(t)(8)(A) of the Act (as redesignated by section 201(a) of the BBRA 1999) to require the Secretary to review and revise the outpatient PPS wage index adjustment factor at least annually rather than on a periodic basis. (This section of the Act was further redesignated as section 1833(t)(9)(A) by section 202(a) of the BBRA 1999.)

2. Labor-Related Portion of Hospital Outpatient Department PPS Payment Rates

We proposed to recognize 60 percent of the hospital's outpatient department costs as labor-related costs that would be standardized for geographic wage differences. We initially estimated this percentage by comparing the percentage of costs attributed to labor by other systems (that is, hospital inpatient PPS and ASC) and by considering health care market factors such as the shift in more complex services from the inpatient to the outpatient setting, which could influence labor intensity and costs. We stated that 60 percent represented a reasonable estimate of outpatient costs attributable to labor, as it fell between the hospital inpatient PPS operating cost labor factor of 71.1 percent and the ASC labor factor of 34.45 percent, and is close to the labor-related costs under the hospital inpatient operating cost PPS attributed directly to wages, salaries, and employee benefits (61.4 percent) under the rebased 1992 hospital market basket that was used to develop the fiscal year 1997 update factor for inpatient PPS rates (published August 30, 1996 at 61 FR 46187).

We confirmed our estimate through regression analysis. Using this approach, we analyzed the percentage change in hospital costs attributable to a 1 percent increase in the wage index as expressed by the hospital wage index coefficient. The coefficient from a fully specified payment regression of the hospital cost per unit, standardized for the service mix on the wage index, disproportionate share patient percentage, modified teaching, rural, and urban variables, is approximately 0.60, suggesting a labor share of 60 percent. Even though we decided not to propose additional adjustments, we believed that the coefficient from this specification provided the best estimate of the labor share for the proposed PPS. This judgment was based on a policy to use a labor share that reflects the relationship between the wage index and costs, rather than the effects of correlated factors.

After calculating 60 percent of each hospital's total operating and capital costs, we divided that amount by the hospital's FY 1998 hospital inpatient PPS wage index value to standardize costs to remove the differences that are attributable to geographic wage differences. Therefore, as we explained in the proposed rule, the total cost of performing a procedure or visit would include standardized operating and capital costs, as well as related costs (for example, operating room time, medical/surgical supplies, anesthesia, recovery room, observation) and minor ancillary procedures such as venipuncture that we packaged.

Comment: Some commenters urged that we annually update the wage index applied to the outpatient PPS as we do under the hospital inpatient PPS.

Response: We proposed to update the wage index annually, on a calendar year basis. In addition, section 1833(t)(9)(A) of the Act, redesignated and amended by the BBRA 1999, requires us to review and revise the wage adjustment at least annually.

Comment: A professional society recommended eliminating the ''regional variation for radiologic technologists working in small and rural practices'' and applying the ''same wage scale'' used for their urban counterparts. The commenter asserted that our wage index methodology is biased against rural hospital radiology departments that must compete with the urban areas to attract and retain radiologic technologists. The commenter stated that hospitals are operating in a very competitive labor market in which rural facilities are forced to match or exceed wages paid in the urban areas for reduced workloads. The commenter further stated that the impact of higher hourly technologist wages does not result in a corresponding increase in a higher wage index for radiologic technologists in rural hospitals because these wages are averaged with those for all other hospital inpatient personnel working in the same area.

Response: The commenter is correct that the wage index is calculated based upon all of the wages paid and hours worked of hospital personnel within areas of the hospital that are paid under the inpatient PPS. The wages and hours are then totaled for a particular labor market area (defined as a Metropolitan Statistical Area [MSA] or all of the counties of a State that are not part of an MSA). We believe the inpatient wage index is an appropriate measure of the relative costs of labor across geographic areas for purposes of outpatient PPS.

Currently, we do not have data available that would allow us to calculate the wage index for the costs of employing staff in particular occupational categories. Collecting these data would require significant recordkeeping and reporting efforts for hospitals, and the impacts of adjusting the wage index using the data are uncertain. Although some analyses have indicated that the wage indices of rural areas could rise as a result of such an adjustment, these findings are limited by the lack of a national database through which to fully assess the impacts.

Comment: Several commenters viewed our proposal to establish a 60 percent labor share as an arbitrary decision for which we provided no rational support. One commenter stated that ''Congress did not expect HCFA to invent a number.''

Response: As we explained in the proposed rule (63 FR 47581), we used a statistical tool, that is, regression analysis, to validate the percentage of costs that we had initially estimated could be attributed to labor and, therefore, subject to the wage adjustment. We adopted this approach because we did not have adequate and appropriate data readily available through a reputable source from which we could derive a hospital outpatient labor share within the time allotted to develop our new system. While hospital outpatient costs, including labor costs, are reported annually on the hospital cost report, they are not reported in a manner and format that allow us to capture the statistical and cost data necessary to calculate a precise hospital outpatient labor share. Therefore, we decided to use regression analysis to test our estimate of that labor share. Within the constraints imposed by a lack of accessible, reliable data and the compressed timeframe under which we were working to develop the outpatient PPS, we believe our approach was appropriate and the best available option.

Comment: Several commenters urged us to use more current hospital cost report data to determine the appropriate hospital outpatient labor share.

Response: As stated above, at this time the Medicare hospital cost report is not a feasible data source for determining a hospital outpatient labor share.

Comment: One commenter asserted that setting the labor-related share at 60 percent fails to recognize all labor costs associated with the delivery of hospital outpatient services. The commenter stated that the labor-related percentage for the outpatient PPS should be the same as that used for the hospital inpatient PPS, that is, 71.1 percent. Another commenter supported 60 percent as a ''maximum'' labor percentage on an interim basis and suggested that we reconsider our decision to use the inpatient PPS hospital wage index to adjust the outpatient PPS payments because of the commenter's concerns about flaws inherent in the system used to derive the inpatient PPS wage index values. A third commenter proposed that the

labor-related portion should be closer to the 34.45 percent currently applied to adjust ASC payment for wage variation. The latter commenter contended that apportioning 60 percent of the outpatient PPS payment rate for wage adjustment would adversely affect rural hospitals because the wage index values for these areas are generally below 1.0.

Response: We note that commenters' opinions regarding an appropriate labor percentage are mixed. However, beyond expressing a preference for a percentage other than 60 percent, none of the commenters provided data to assist us in re-evaluating our proposal. We realize that rural hospitals would benefit from using a labor share that is less than 60 percent and that some other hospitals would derive advantages from a labor share greater than 60 percent. However, we believe the approach that we used to determine the labor share that will be applied to all hospitals paid under our new system is reasonable and the best option available at this time. We will re-evaluate our decision as we gain more experience with the new system and as new data become available.

3. Adjustment of Hospital Outpatient Department PPS Payment and Coinsurance Amounts for Geographic Wage Variations

In the proposed rule, we noted our intent to use fiscal year 1999 hospital inpatient PPS wage index values to compute the initial outpatient PPS rates. However, we have decided to use fiscal year 2000 inpatient PPS wage index values in determining the payment rates set forth in this final rule. The rationale for using the fiscal year 2000 wage index includes availability of the more recent wage index, that it is more current than the 1999 wage index would have been, and that it is being used to calculate FY 2000 payments under the hospital inpatient PPS.

We proposed to use the annually updated hospital inpatient PPS wage index values to adjust both program payment and coinsurance amounts under the outpatient PPS for area wage variations. Under our proposal, when intermediaries calculate actual payment amounts, they would multiply the prospectively determined APC payment rate and coinsurance amount by that labor-related percentage to determine the labor-related portion of the base payment rate and coinsurance amount that is to be adjusted using the applicable wage index factor. We proposed that the labor-related portion would then be multiplied by the hospital's inpatient PPS wage index factor, and the resulting wage-adjusted labor-related portion would be added to the nonlabor-related portion, resulting in wage-adjusted payment and coinsurance rates. The wage-adjusted coinsurance amount would then be subtracted from the wage-adjusted APC payment rate, and the remainder would be the Medicare payment amount for the service or procedure. Note that even if a hospital elects to reduce the coinsurance or if the coinsurance is capped at the inpatient deductible, the full coinsurance is assumed for purposes of determining the Medicare payment percentage. (See section III.F.3 for a discussion on how Medicare program payments are calculated when the Part B deductible applies.)

The following is an example of how an intermediary would calculate the Medicare payment for a surgical procedure with a hypothetical APC payment rate of $300 that is performed in the outpatient department of a hospital located in Heartland, USA. The coinsurance amount for the procedure is $120. The hospital inpatient PPS wage index value for hospitals located in Heartland, USA is 1.0234. The labor-related portion of the payment rate is $180 ($300 × 60 percent), and the nonlabor-related portion of the payment rate is $120 ($300 × 40 percent). The labor-related portion of the unadjusted coinsurance amount is $72 ($120 × 60 percent), and the nonlabor-related portion of the unadjusted coinsurance amount is $48 ($120 × 40 percent). It is assumed that the beneficiary deductible has been met.

Wage-Adjusted Payment Rate (rounded to nearest dollar):
= ($180 × 1.0234) + $120
= $184 + $120
= $304

Wage-Adjusted Coinsurance Amount (rounded to nearest dollar):
= ($72 × 1.0234) + $48
= $74 + $48
= $122

Calculate Medicare Program Payment Amount:
$304 − $122 = $182

4. Special Rules Under the BBRA 1999

We issued the federal fiscal year (FY) 2000 hospital inpatient PPS wage index values in the **Federal Register** on July 30, 1999, in a final rule titled ''Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2000 Rates'' (64 FR 41490). Subsequent to that publication, section 152 of the BBRA 1999 reclassified certain counties and labor market areas for purposes of payment under the Medicare hospital inpatient PPS; section 153 of the BBRA 1999 enacted a ''wage index correction''; and section 154 of the BBRA 1999 provided for the calculation and application of a wage index floor for a specified area. These changes are effective for FY 2000 and will be explained in detail in an interim final rule with comment that we expect to issue in the **Federal Register** shortly. The wage index values in Addendum H, Addendum I, and Addendum J reflect the changes made by the BBRA 1999.

H. Other Adjustments

1. Outlier Payments

Section 1833(t)(2)(E) of the Act, as enacted by the BBA 1997, authorized, but did not require, an outlier adjustment. In the proposed rule, we discussed our reasons for not implementing an outlier adjustment policy. We explained that we had reached that decision after carefully evaluating several factors. For the following reasons, we believed an outlier policy was not necessary: (a) in the proposed PPS, unlike the hospital inpatient PPS, we would use limited packaging of services and allow payment for multiple services delivered to a given patient on a given day; (b) payment for critical care services would reflect the intensity and higher costs associated with providing this type of medical care; and (c) we would make higher payment for serious medical cases even if critical care were not provided and additional payments would be made for any other laboratory work, x-rays, or surgical interventions resulting from medical visits to the emergency room.

Section 201(a) of the BBRA 1999 amended section 1833(t) of the Act by adding an outlier adjustment provision, section 1833(t)(5). Under this new provision, the statute now requires that we make an additional payment (that is, an outlier adjustment) for outpatient services for which a hospital's charges, adjusted to cost, exceed a fixed multiple of the outpatient PPS payment as adjusted by pass-through payments. The Secretary determines this fixed multiple and the percent of costs above the threshold that is to be paid under this outlier provision. The statute sets a limit on projected aggregate outlier payments. Under the statute, projected outlier payments may not exceed an ''applicable percentage'' of projected total payments. The applicable percentage means a percentage specified by the Secretary (projected percentage of outlier payments relative to total payments), subject to the following limits: for years before 2004, the projected percentage that we specify cannot exceed 2.5 percent; for 2004 and later, the projected percentage cannot

exceed 3.0 percent. Section 201(c) of the BBRA 1999 amended section 1833(t)(2)(E) of the Act to require that these payments be budget neutral.

Section 1833(t)(5)(D) of the Act grants the Secretary authority until 2002 to identify outliers on a bill basis rather than on a specific service basis and to use an overall hospital cost-to-charge ratio (CCR) to calculate costs on the bill rather than using department-specific CCRs for each hospital.

To set the threshold or fixed multiple and the payment percent of costs above that multiple for which an outlier payment would be made, we first had to determine what specified percentage of total program payment, up to 2.5 percent, we should select. We decided to set the outlier target at 2.0 percent. In order to set the fixed multiple outlier threshold and payment percentage, we simulated PPS payments, as described below in section G of the preamble. As explained further below, we calibrated the threshold and the payment percentage applying an iterative process so that the simulated outlier payments were 2.5 percent of simulated total payments. *For purposes of the simulation,* we set a ''target'' of 2.5 percent (rather than 2.0 percent), because we believe that *a given set of numerical criteria* would result in a higher percentage of outlier payments under the simulation using 1996 data than under the PPS. This is because we believe that the 1996 data reflects undercoding of services, which means simulated total payments would likely be understated and it in turn means the percentage of outlier payments would be overstated. In addition, we are unable to fully estimate the amount and distribution of pass-through payments using the 1996 data. Our inability to make these estimates further understates the total payments under the simulation. We believe that a set of numerical criteria that results in simulated outlier payments of 2.5 percent using the 1996 data would result in outlier payments of 2.0 percent under PPS. The difference arises from the effect of undercoding in the historical data and the payment of pass-throughs under PPS. Under the budget neutrality requirement in section 1833(t)(2)(E) of the Act, as amended by section 201(c) of the BBRA 1999, we make a corresponding 2.0 percent reduction to the otherwise applicable conversion factor. We will monitor outlier payment and make any necessary refinements to the outlier methodology when we set outlier policies for CY 2002.

After setting the outlier target percentage and reducing the unadjusted conversion factor to reflect the 2 percent outlier reduction and the 2.5 percent pass-through adjustment (see discussion in section III.D), we identified those claims in our 1996 database with at least one payable service under the PPS system. For these bills, we first calculated the total PPS payment for the bill using the reduced conversion factor. Next, we calculated for each claim the total charges attributed to services being paid under the PPS system. These charges were then adjusted to cost, using a hospital-specific CCR. We used the sum of the hospital's total operating CCR and total capital CCR as the hospital specific CCR. These CCRs were calculated from the most current cost report data available and were adjusted to calendar year 1996.

We also identified all bills for the 1,800-plus hospitals that we had previously identified as having coded only the lowest level clinic visit code (CPT code 99201) for all visits. For these hospitals, we isolated those claims with at least one service with the CPT code 99201 and one or more additional PPS covered service. Due to the undercoding on these bills and the inherent problem in determining a possible outlier condition, we excluded these bills from the calculation process but set aside a proportional amount of outlier payments based on the proportional cost of these bills to the total cost of all bills used in the outlier calculation.

After determining the PPS payment and the cost for all 42 million claims for which there was at least one billable service under the PPS system, we experimented with several combinations of thresholds or fixed multiples and payment percent of costs over these multiples. We found that the combination of using a multiple of 2.5 for the threshold and the use of a payment percent of 75 percent of cost over this threshold achieved our target of a 2.5 percent outlier payment. Approximately 1.6 million claims in our 1996 claims database had calculated bill costs that exceeded the PPS payments on the claim by more than 2.5 times and thus qualified for an outlier payment in our model.

Comment: We received several comments that supported our proposal not to create outlier payments. However, most commenters opposed it and supported including an outlier policy. Several commenters disagreed that multiple payment for multiple services furnished during a given visit would absolve the need for outliers. One commenter stated that outlier payments are necessary because of the limited number of APC groups. Several commenters believe that outlier payments are necessary to recognize variability in APC groups stemming from treatment options and patient complexity. Some argued that our own data demonstrate that an outlier policy is necessary to ensure equitable payments. Several commenters stated that the data trimming algorithm that we used, excluding from our PPS database claims that were greater than three standard deviations from the geometric mean, probably eliminated claims that included high cost items and services that should have been reflected in our data and that may have been associated with the later technologies. A professional association noted that an examination of our PPS data indicated that ''20 percent of outpatient services subject to the PPS (excluding clinic and emergency room visits) include maximum costs that are at least 10 times higher than the corresponding rate; 100 services have maximum costs that are at least 40 times higher than the corresponding payment rate.''

One commenter believes that an outlier policy is necessary for a payment system based on averaging to provide additional payments for potentially variable and expensive items such as pharmaceuticals and supplies. Several commenters suggested that outlier payments would be necessary if we did implement their option to carve out all pharmaceuticals and certain supplies from the hospital outpatient PPS and pay them separately based on reasonable costs or average wholesale price (AWP). Most commenters who urged establishing outlier payments advocated them for high cost drugs, supplies, and new technologies. Some commenters advised that a drug such as Activase administered to a cardiac patient in the emergency room prior to inpatient admission or transfer to another hospital for inpatient admission would be costly. One commenter estimated that the cost for two doses of the drug would exceed $4,000. One commenter urged an outlier policy that would adequately pay for iodine I 131 tositomomab. Another commenter recommended that we make an outlier payment for Hemophilia Factor Concentrate that could be packaged in APC 906 (Infusion Therapy, except Chemotherapy) or APC 907 (Intramuscular Injections) and Tissue Plasminogen Activator (TPA) and IV therapy drugs as outliers.

A professional association expressed the need for an outlier policy for tests whose costs exceed a reasonable range of costs for similar procedures. They identified CPT codes 95951 and 95956 as examples of those tests. Another association recommended adoption of

an outlier policy to recognize higher costs associated with new technologies. The commenter suggested that the policy remain in effect a full year after the hospital outpatient PPS is implemented to allow us adequate time to collect the appropriate data for use in updating the payment rates. Several other commenters believe that we may need to adopt an outlier policy on an interim basis while data are collected to determine the appropriate assignment of certain services and items to an APC. One commenter advocated outlier payments for hospitals whose aggregate costs exceed total payments under the hospital outpatient PPS in a given year. A number of other commenters stated that the hospital outpatient PPS outlier policy should be similar to that currently used for the inpatient PPS.

Response: As we discussed above, section 201(a) of the BBRA 1999 amended the Act by adding a new section 1833(t)(5). This provision now requires the Secretary to make an additional outlier payment for outpatient services for which a hospital's or a CMHC's charges, adjusted to cost, exceed a fixed multiple of the new PPS payment as adjusted by pass-through payments. The Secretary is required to determine the fixed multiple and the percent of costs above the threshold that is to be paid under the outlier provision. As we explain above, to implement the outlier adjustment, we have determined that an outlier payment will be made when calculated bill costs exceed the PPS payments on a claim by more than 2.5 times. In addition, the provision of transitional pass-throughs under section 201(b) of the BBRA 1999, which requires the Secretary to make an additional payment for certain high cost medical devices, drugs, and biologicals, constitutes a kind of outlier adjustment (see section III.D of this preamble), and our decision to create special transitional payments for new technology items and services (see section III.C.8) will also provide additional payments to hospitals that incur higher costs under the outpatient PPS.

2. Transitional Corridors/Interim Payments

As we developed the proposed rule, we conducted extensive regression analysis of the relationship between outpatient hospital costs and several factors that affect costs, such as teaching intensity and disproportionate share percentage, as part of the analysis to determine whether payment adjustments should be proposed for the outpatient PPS. Ultimately, we did not propose any adjustments other than the wage index used to adjust for local variation in labor costs. One of the main reasons we did not propose any special adjustments was that the estimated effects of measured factors on costs were small and, in most cases, not statistically significant. In addition, we believe that the negative impacts estimated in the proposed rule for certain classes of hospitals were partially attributable to undercoding and coding variations in the data because coding did not affect the payment of many services under the current payment system, especially medical visits.

Since publication of our proposed policy, section 202(a)(3) of the BBRA 1999 added new paragraph (7) to section 1833(t) of the Act to require the Secretary to make payment adjustments during a transition period to limit the decline in payments under PPS for hospitals. These additional payments are to be implemented without regard to budget neutrality and are in effect through 2003.

Under paragraphs (A), (B), and (C) of section 1833(t)(7) of the Act, the amount of the payment adjustment for an individual hospital depends on the difference between the hospital's ''PPS amount'' and the hospital's ''pre-BBA amount.'' Section 1833(t)(7)(E) of the Act defines the ''PPS amount'' as the amount payable under PPS for the hospital's covered outpatient department services, excluding the effects of the transitional corridor and including coinsurance and deductibles. For purposes of calculating the PPS amount, we include the full copayment amounts; if a hospital chooses to reduce the copayment for some or all of the services that it furnishes, we will count the full copayment amounts rather than the reduced copayment amounts. Section 1833(t)(7)(F) of the Act defines the ''pre-BBA amount'' for a period as the amount equal to the product of (1) the hospital's reasonable cost for covered outpatient department services, and (2) the base outpatient department payment-to-cost ratio for the hospital. The statute defines ''base payment-to-cost ratio'' as the ratio of (1) the hospital's reimbursement for covered outpatient department services during the cost reporting period ending in 1996, to (2) the reasonable cost of the services for the period. The base payment-to-cost ratio will be calculated as if the amendments to sections 1833(i)(3)(B)(i)(II) and 1833(n)(1)(B)(i) of the Act made by section 4521 of the BBA 1997, to require that the full amount beneficiaries paid as coinsurance under section 1862(a)(2)(A) of the Act are taken into account in determining Medicare Part B Trust Fund payment to the hospital, were in effect in 1996.

For calendar years 2000 and 2001, payment to hospitals whose PPS payment is less than 100 percent, but is at least 90 percent, of the pre-BBA payment, is increased by 80 percent of the difference. Hospitals whose PPS payment is less than 90 percent, but is at least 80 percent, of the pre-BBA payment, will receive additional payment equal to the amount by which 71 percent of the estimated pre-BBA payment exceeds 70 percent of the PPS payment. Hospitals whose PPS payment is less than 80 percent, but is at least 70 percent, of the pre-BBA payment will receive additional payment equal to the amount by which 63 percent of the pre-BBA payment exceeds 60 percent of the PPS payment. Payments to hospitals whose PPS payment is less than 70 percent of the pre-BBA payment will be increased by 21 percent of the pre-BBA payment. For calendar years 2001 through 2003, the number of corridors and the associated percentage increases decline over time. As required by statute, interim payments will be made subject to retrospective adjustments. Section 1833(t)(7) of the Act provides special transition payments for cancer centers and small rural hospitals, which are discussed below in section III.H.3.

Comment: Hundreds of commenters, including associations, hospitals, and entities providing goods and services to hospitals, expressed grave concerns about the estimated impact of our proposed system on certain classes of hospitals. Many commenters noted that the case mix and service mix for specific classes of hospitals such as rehabilitation, cancer, children's, rural, and teaching hospitals are different than for other hospitals. They argued that a number of these hospitals deal with patients who typically require more resources. The commenters noted that we have authority under the statute to make adjustments for specific classes of hospitals. Some reasoned that given our estimates of substantial losses for certain classes of hospitals under the proposed hospital outpatient PPS, we should use our authority to exclude these classes of hospitals from the outpatient PPS for 2 years, require proper coding of bills from those hospitals, and have an opportunity to analyze the results of the improved coding. These commenters urged that we examine reasons other than coding that may contribute to the disparity. Many commenters recommended that a separate conversion factor be developed

for the hospitals whose payments are adversely affected by the new system.

Response: As discussed above, section 1833(t)(7) of the Act, as added by section 202(a) of the BBRA 1999, provides that, for several years, additional payments be made to any facility for which the PPS payment is less than an estimate of the hospital's pre-PPS payment and that these payments are in addition to the total payments under the PPS. Our estimate of the impacts of this change in policy along with other payment-related provisions of the BBRA 1999 (discussed in further detail in section IX) show improved payments under PPS relative to pre-BBRA law for nearly all classes of hospitals. Our simulations show that hospitals overall receive an additional 4.6 percent in payments under PPS compared to pre-PPS law. Long-term care and children's hospitals show losses (1.7 percent and 3.2 percent, respectively). Moreover, urban hospitals with no indirect teaching or disproportionate share inpatient adjustments show a loss of 0.3 percent. In addition, we reexamined and reestimated the multivariate regression specifications described in the proposed rule to reflect the changes described in this rule. Based on the results of regression analysis, we believe further adjustments are not warranted at this time. We found, for example, the disproportionate share percentage did not have a statistically significant effect on unit costs standardized by service mix. In addition, positive and significant results did not occur for most teaching variables that we specified. For instance, positive and significant results did not occur for hospitals whose ratio of residents to inpatient and outpatient days was less than .28. Hospitals with a large number of residents to inpatient and outpatient days did demonstrate slightly higher standardized costs, but only when the regression model included independent variables for urban/rural location. Moreover, the parameter estimate was small and payment was not greatly improved when a corresponding adjustment was made to these teaching hospitals. Therefore, we are not making such adjustments for these hospital groups. We do not believe that this action will restrict beneficiary access to care because the projected losses are relatively small and could reflect undercoding on the part of these hospitals before PPS.

We will begin comprehensive analyses of cost and payment differentials between different classes of hospitals as soon as there is a sufficient amount of claims data submitted under the PPS. We will use data from the initial years of the PPS to conduct regression and simulation analyses. In addition, we will carefully track and analyze the additional payment made to hospitals under section 1833(t)(7) of the Act. These analyses will be used to consider and possibly propose adjustments in the system, particularly beginning in 2004 when the BBRA 1999 transition provisions expire.

Comment: Commenters from organizations representing teaching hospitals recommended that we include a budget-neutral payment adjustment for certain classes of hospitals such as teaching hospitals. For example, the concern is that PPS payments are not adequate for academic medical centers because they provide more resource-intensive outpatient services than other hospital types.

Response: As noted above, we are not making adjustments for specific classes of hospitals in this final rule. The primary reason for this decision is that section 1833(t)(7) of the Act requires additional payments through 2003 to all hospitals whose PPS payment falls below estimates of pre-PPS payment. We will conduct analyses and studies of cost and payment differential among different classes of hospitals, including teaching facilities, when sufficient data under the PPS have been submitted. We will carefully consider whether permanent adjustments should be made in the system once the BBRA 1999 transition provisions expire.

3. Cancer Centers and Small Rural Hospitals

Cancer Centers

In the BBA 1997, the Congress did not exclude from the hospital outpatient PPS the 10 cancer centers that are currently excluded from the inpatient PPS, but section 1833(t)(8) of the Act (as enacted in the BBA 1997) provides special consideration for these hospitals under the outpatient PPS. More specifically, that section provides that the outpatient PPS would not apply to the 10 cancer centers before January 1, 2000, and that the Secretary may establish a separate conversion factor for cancer centers to take into account the unique costs they incur due to their patient population and the intensity of their services.

In the proposed rule, we stated that, because we had no choice but to delay implementation of the PPS for all hospitals until sometime after January 1, 2000 due to Y2K concerns, we would begin paying cancer centers under hospital outpatient PPS at the same time. Also, we did not propose a separate conversion factor for cancer centers. Although our proposed impact analysis indicated that, under the PPS, the cancer centers could lose 32 percent of their current outpatient Medicare payments, we proposed to do additional work to try to explain the impact before we provided for a separate conversion factor or other payment adjustment.

Section 1833(t)(7)(D)(ii) of the Act, as added by the BBRA 1999, provides that the 10 cancer centers excluded from the inpatient PPS are permanently held harmless with respect to their pre-BBA 1997 amount.

Comment: The cancer centers commented that they are unlike other hospitals in that they treat the most difficult cases (patients often referred by community hospitals) and they are usually the first hospitals to use the latest technology related to cancer treatments. They also pointed out that their clinic visits often involve consultations with a number of physicians and therefore are longer and require more hospital resources than clinic visits in other hospitals. They believe that our proposed payments for clinic visits would seriously underpay them for their more comprehensive visits. The cancer centers also stated that any delay in recognizing and paying appropriately for new technology would affect them more adversely than it would other hospitals.

During the comment period for the proposed rule, the cancer centers submitted for our consideration an alternative payment methodology. Under their methodology, we would calculate a separate conversion factor for each of the 10 centers based on their individual base year Medicare payments and service mix. Subsequently, the conversion factors would be updated using the Congressionally determined update factor applicable to all hospitals. Hospitals would be paid interim payment amounts during the year, but payment would ultimately be based on the lesser of—

- The PPS payments they would receive using their individual conversion factor; or
- The payments they would receive based on their cost reports by applying the current (that is, pre-PPS) outpatient services payment methodology.

Capital costs would be excluded from this comparison and be paid on a reasonable cost pass-through basis. The proposal also envisioned some payment penalties and incentives similar to the penalties and incentives provided under the reasonable payment cost limit methodology applicable to hospitals excluded from the inpatient PPS.

Response: As noted above, new section 1833(t)(7)(D)(ii) of the Act holds cancer centers harmless on a permanent basis by providing that, in instances where Medicare payment to a cancer center under the hospital outpatient PPS would be lower than a specified pre-BBA Medicare payment for the same services, we are to pay the full pre-BBA amount. Therefore, an alternative approach to paying cancer centers under the hospital outpatient PPS is no longer needed.

Small Rural Hospitals

We noted in the proposed rule that rural hospitals generally receive a relatively high percentage of their Medicare income from outpatient services (greater than the national average), which compounds the impact of the reduction in Medicare payments to rural hospitals that we projected would result upon implementation of the hospital outpatient PPS. We attributed these reduced revenues to undercoding, lack of economies of scale, and reliance on the median instead of the geometric mean in the calculation of APC weights. Because our impact analysis revealed that low-volume rural hospitals that are sole community hospitals or Medicare-dependent hospitals could experience a considerable reduction in revenues under the outpatient PPS, we solicited comments in the proposed rule on two possible approaches to phasing in the outpatient PPS for these types of hospitals.

Section 1833(t)(7)(D)(i) of the Act provides that hospitals located in a rural area with 100 or fewer beds are held harmless with respect to their pre-BBA 1997 amount for outpatient services furnished before January 1, 2004. For purposes of implementing this provision, bed size will be determined in the same way it is for inpatient PPS for the indirect medical education adjustment as defined in § 412.105(b), Determination of number of beds. A hospital's location in a rural area will also be determined as it is in the inpatient PPS; see § 412.63(b), Geographic classifications.

Comment: Many commenters were concerned that the projected negative impact of the proposed outpatient PPS on rural hospitals would be magnified because outpatient revenues make up such a large part of rural hospitals' total revenues. Some commenters believe that our proposed PPS ratesetting method favors high volume, urban hospitals. Some commenters supported phasing in the outpatient PPS for rural disproportionate share hospitals because those facilities may not have the resources to improve their coding in the near future. One association opposed phasing in the PPS because doing so would postpone but not resolve the financial jeopardy imposed on rural hospitals by the hospital outpatient PPS. Some commenters recommended that we provide an ''add-on'' to the prospective rate for emergency services in low-volume sole community and rural disproportionate share hospitals. One commenter expressed concern about the numerous factors contributing to rural hospitals' negative margins that limit their ability to absorb losses, including a disproportionately high share of Medicare, Medicaid, and indigent patients, significant problems recruiting practitioners, low population density, and limited patient volume. Numerous commenters recommended that we establish a payment floor for low-volume rural hospitals. One association requested that we either revise the payment methodology or put in place a payment floor that guarantees health care services will continue to be available to Medicare beneficiaries served by rural hospitals.

Response: As we discuss above, in order to limit potential reductions in payment to hospitals under the outpatient PPS, section 1833(t)(7) of the Act, as added by section 202(a)(3) of the BBRA 1999, requires us to establish payment adjustments for hospitals whose PPS payments are less than our estimate of the hospital's pre-BBA payments. These additional payments are to be implemented in a non-budget neutral manner and are to be paid through 2003. Section 1833(t)(7)(D)(i) of the Act includes a special ''hold harmless'' provision, which is to be paid through 2003, for hospitals that are located in a rural area and that have no more than 100 beds. Under section 1833(t)(7)(D)(i) of the Act, as added by the BBRA 1999, small rural hospitals will be paid a predetermined pre-BBA amount for services covered under the outpatient PPS if payment under the PPS would be less than the pre-BBA amount. This hold harmless provision establishes a payment floor until January 1, 2004 for small rural hospitals. During this period, we will collect and analyze data under the PPS in order to assess whether any special adjustments will need to be made for rural hospitals once the hold harmless provision expires.

I. Annual Updates

1. Revisions to APC Groups, Weights and the Wage and Other Adjustments

Prior to enactment of the BBRA 1999, section 1833(t)(6)(A) of the Act required the Secretary to periodically review and revise the APC groups, the relative payment weights, and the wage and other adjustments to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors.

In the proposed rule, we described our plan to update the various components of the outpatient PPS. We proposed to keep the composition of all the APC groups essentially intact from one year to the next, with the exception of the few changes that may be necessary as a consequence of annual revisions to HCPCS and ICD–9–CM (International Classification of Diseases, Ninth Edition, Clinical Modification) codes. We stated that we did not plan to routinely reclassify services and procedures from one APC to another. We proposed to make these changes based on evidence that a reassignment would improve the group(s) either clinically or with respect to resource consumption. However, we specifically solicited comments on how frequently to recalibrate the APC weights and on the method and data that should be used. We defined recalibration as the updating of all the APC group weights based on more recent information.

We proposed to update the wage index values used to calculate program payment and coinsurance amounts on a calendar year basis, adopting, effective for services furnished each January 1, the wage index value established for a hospital under the inpatient PPS the previous October 1. The first update to the wage index values will be effective for calendar year 2001 beginning January 1, 2001.

Section 201(h)(1)(A) of the BBRA 1999 amended section 1833(t)(8)(A) of the Act (as redesignated by section 201(a) of the BBRA 1999) to require the Secretary to review the components of the outpatient PPS not less often than annually and revise the groups, the relative payment weights, and the wage and other adjustments to take into account changes in medical practice, changes in technology, and the addition of new services, new cost data, and other relevant information and factors. (Section 202(a) of the BBRA 1999 further redesignated section 1833(t)(8) as section 1833(t)(9).)

Section 201(h)(1)(B) of the BBRA 1999 further amended this section of the Act to require that the Secretary consult

with an expert outside advisory panel composed of an appropriate selection of representatives of providers to review (and advise the Secretary concerning) the clinical integrity of the groups and weights. This provision allows these experts to use data other than those collected or developed by us during our review of the APC groups and weights. Section 201(h)(2) of the BBRA 1999 requires the Secretary to initiate the annual review process beginning in 2001 for the PPS payments that would take effect January 1, 2002.

Comment: A number of commenters urged that we adopt an annual update cycle for APC recalibration. Some commented that the APC update frequency should not be less often than the annual cycles that we have instituted for both the hospital inpatient PPS and physician fee schedule payment system. Many commenters maintained that annual updating is necessary to ensure that the APCs appropriately reflect changes in new technologies, standards of care, and other marketplace patterns. Several commenters stated that an annual update cycle is needed to take into account changes in drug prices and appropriately reflect advancements in nuclear medicine. Some commenters believe that updating the APCs less frequently than annually would adversely impact hospitals that would incur financial losses attributable to inappropriate payment for new technologies. Some commenters contended that infrequent updating would be a disincentive for manufacturers to develop new outpatient therapies.

Response: In accordance with the amendments enacted by the BBRA 1999, we will review and update annually, for implementation effective January 1 of each year, the APC groups, the relative payment weights, and the wage and other adjustments that are components of the outpatient PPS, beginning with the update to be effective January 1, 2002.

2. Annual Update to the Conversion Factor

We stated in the proposed rule that section 1833(t)(3)(C)(ii) of the Act requires us to update annually the conversion factor used to determine APC payment rates. Section 1833(t)(3)(C)(iii) of the Act provides that the update be equal to the hospital inpatient market basket percentage increase applicable to hospital discharges under section 1886(b)(3)(B)(iii) of the Act, reduced by one percentage point for the years 2000, 2001, and 2002. The Secretary also has the option (under section 1833(t)(3)(C)(iii) of the Act) of developing a market basket that is specific to hospital outpatient services. We advised in our proposed rule that we are considering this option, and specifically invited comments on possible sources of data that are suitable for constructing a market basket specific to hospital outpatient services. We did not receive any comments regarding potential data sources for constructing a hospital outpatient-specific market basket. Therefore, we will update the conversion factor annually by the hospital inpatient market basket increase (as specified in section 1886(b)(3)(B) of the Act), reduced by one percentage point for the years 2000, 2001, and 2002.

3. Advisory Panel for APC Updates

As stated above, section 1833(t)(9)(A) of the Act (as redesignated by section 201(a) of the BBRA 1999 and further redesignated by section 202(a) of the BBRA 1999) requires the Secretary, beginning in 2001, to consult with an expert outside advisory panel of appropriately selected provider representatives when annually reviewing and updating the APC groups and the relative group weights. The statute specifies that the expert panel will act in an advisory capacity on matters pertaining to the clinical integrity of the groups and weights and that it may use data other than those developed or collected by us in executing this function. We will initiate this review process in 2001 for the hospital outpatient PPS payments that will take effect for services furnished on or after January 1, 2002. We will adopt a process for identifying and appropriately selecting provider representatives to serve as members of an expert advisory panel. We anticipate informing the hospital community of the formation of an expert advisory panel through timely notice in the **Federal Register**.

J. Volume Control Measures

Section 1833(t)(2)(F) of the Act requires the Secretary to develop a method for controlling unnecessary increases in the volume of covered outpatient department services. Section 1833(t)(6)(C) of the Act, as added by the BBA 1997, authorizes the Secretary to adjust the update of the conversion factor if we determine that the volume of services paid for under the outpatient PPS increases beyond amounts we establish under section 1833(t)(2)(F) of the Act.

In the proposed rule, we proposed a volume control measure for services furnished in CY 2000 only. We discussed several long-term alternatives to control volume for services furnished in subsequent years, and we solicited comments on those options. We stated that we would propose an appropriate volume control mechanism for services furnished in CY 2001 and beyond after we completed further analysis. Given the complexities of developing an appropriate volume control mechanism for hospital outpatient services, we believed additional study was necessary.

For CY 2000, we proposed to use a modified version of the physician sustainable growth rate system (SGR), which is required under section 1848(d)(3) of the Act, for purposes of the hospital outpatient PPS. As we stated in the proposed rule, this appeared to be the most feasible initial approach. Using this approach, we proposed to update the target amount specified under section 1833(t)(3)(A) for CY 1999 as an expenditure target for services furnished in CY 2000. We stated that we would update the CY 1999 target for inflation (based on the projected change in the hospital market basket minus one percentage point), estimate changes in the volume and intensity of hospital outpatient services, and estimate Part B fee-for-service changes in enrollment. If volume exceeded the target for CY 2000, we proposed to adjust the update to the conversion factor for CY 2002. We further stated that we would compare the CY 2000 target to an estimate of CY 2000 actual payments to hospitals as determined by our Office of the Actuary using the best available data. We proposed that if unnecessary volume increases, as reflected by expenditure levels, caused payment to exceed the target, we would determine the percentage by which the target is exceeded, and adjust the CY 2002 update to the conversion factor by the same percentage.

We indicated that we would respond in the final rule to comments on our proposed volume control measure for services furnished in CY 2000, but not to comments about volume control options for services furnished after CY 2000, which will be addressed in a later proposed rule.

Comment: We received many comments opposing our proposed use of an SGR-like system to control unnecessary volume increases under the hospital outpatient PPS. Most commenters strongly urged us to exercise the discretionary authority allowed under section 1833(t)(9)(C) of the Act (as redesignated) not to adjust the update to the conversion factor. A few commenters endorsed the provision

of the ''President's Plan to Modernize and Strengthen Medicare for the 21st Century'' (issued July 2, 1999) to delay adoption of a volume control measure in order to give hospitals additional time to adjust to the new system. Several commenters, including one national physicians' association, contended that we did not have the statutory authority to establish and use an expenditure target in the manner that we had proposed. The physicians' association stated that the law limits use of the SGR system to physician services. Some commenters believe that we lack the expertise needed to set an accurate target amount. Others argued that an expenditure target is not a reliable way to distinguish the growth of necessary versus unnecessary services and that our proposal would therefore have consequences not intended by the statute (that is, affecting all services rather than only those that would be considered unnecessary). Some commenters stated that expenditure caps only work when they directly affect those who control the volume. These commenters contended that a volume control measure is unfair to hospitals because it is physicians, not hospitals, who order services and therefore control volume. Some commenters were concerned that adopting a volume control measure would penalize hospitals for increases in outpatient volume attributable to technological changes that appropriately shift service delivery from the inpatient to outpatient setting. In addition, numerous organizations recommended that we not implement the volume expenditure targets and control measures because payments would be reduced to inadequate levels and affect beneficiary access to care.

Response: We are delaying implementation of a volume control mechanism as suggested by the ''President's Plan to Modernize and Strengthen Medicare for the 21st Century'' (the statute does not specify an implementation date). This delay gives hospitals time to adjust to the PPS, and it gives us additional time to study appropriate methods of controlling outpatient volume over the long term. We are currently working with a contractor to study options for volume control measures for outpatient services. In the future, before we make any final decision, we will publish a notice in which we will discuss our proposal and will provide a public comment period.

K. Claims Submission and Processing and Medical Review

Comment: Numerous commenters expressed a variety of concerns related to information exchange processes required by the new PPS. Several commenters stated that the remittance advice documents will need to reflect all of the components used in calculating payment for each claim, as well as possible coinsurance reductions. The commenters also were concerned that, with the complexity of the APC system, hospitals will need the ability to verify payment. One health system that had experience with 3M's APGs offered the experience of their member hospitals to assist us by providing input on the data needed by hospitals to manage APCs. This same commenter stated that hospitals must be given detailed instructions on claims submission, changes to the UB–92, and changes to the Correct Coding Initiative (CCI) in advance to ensure that systems and personnel can comply with Medicare requirements.

Response: We released specific hospital billing instructions that address line item reporting and reporting of service units on December 23, 1999 (Transmittals 1787 and 747). We will be issuing final instructions for implementation of this PPS in a program memorandum to fiscal intermediaries. The program memorandum addresses a range of issues such as appropriate use of revenue center/HCPCS codes for compliance with Medicare requirements and changes to Remittance Advice messages and Medicare Summary Notices/EOMBs.

All current correct coding initiative (CCI) edits with the exception of laboratory and anesthesiology edits have been incorporated in the outpatient code editor (OCE) that fiscal intermediaries use to process claims for hospital outpatient services for payment. We will address OCE changes in a program memorandum to fiscal intermediaries. The effective date of these edits is July 1, 2000.

We have decided not to pursue changes to the UB–92 claim form to allow line item diagnosis because, as we discuss in section III.C.3, we will not be using diagnosis to determine payments for clinic and emergency visits when the PPS is first implemented. Diagnosis codes, however, are still required to be reported on hospital outpatient bills.

Medical Review Under the Hospital Outpatient PPS

We have received inquiries regarding the anticipated medical review process for hospital outpatient PPS claims. The methodology of review for outpatient claims does not change under the PPS. The goal of medical review is to identify inappropriate billing and to ensure that payment is not made for noncovered services. Contractors may review any claim at any time, including requesting medical records, to ensure that payment is appropriate. In accordance with this final rule, Medicare will make payment under the PPS for hospital outpatient services including partial hospitalization services; certain Part B services furnished to inpatients who have no Part A coverage; partial hospitalization services furnished by CMHCs; vaccines, splints, casts and antigens provided by HHAs and CORFs that provide medical and other health services; and splints, casts and antigens provided to hospice patients for the treatment of a nonterminal illness. In addition, we expect focused reviews will include the adjustments we have made to the hospital outpatient PPS as a result of the enactment of the BBRA 1999, especially the transitional pass-through payments for innovative drugs, biologicals, and medical devices that are discussed in section III.D. Fiscal intermediaries will continue focused and random review of services such as ambulance, clinical diagnostic laboratory, orthotics, prosthetics, take home surgical dressings, chronic dialysis, screening mammographies, and outpatient rehabilitation (physical therapy including speech language pathology and occupational therapy) even though these services are excluded from the scope of services paid under the hospital outpatient PPS.

L. Prohibition Against Administrative or Judicial Review

Section 1833(t)(9) of the Act, as added by the BBA 1997, prohibits administrative or judicial review of the development of the PPS classification system, the groups, relative payment weights, wage adjustment factors, other adjustments, volume control methods, calculation of base amounts, periodic control methods, periodic adjustments, and the establishment of a separate conversion factor for cancer hospitals. Section 201(a) of the BBRA 1999 redesignates this section as section 1833(t)(11) of the Act, and section 201(d) of the BBRA 1999 amends the section by adding the following to the list of adjustments subject to the limitation on judicial review: the factors used to determine outlier payments, that is, the fixed multiple, or a fixed dollar cutoff amount; the marginal cost of care, or applicable total payment percentage; and the factors used to determine additional payments for certain medical devices, drugs, and biologicals such as the determination of insignificant cost, the duration of the additional payments, the portion of the outpatient PPS

payment amount associated with particular devices, drugs, or biologicals, and any pro rata reduction. Section 202(a) of the BBRA 1999 further redesignates section 1833(t)(11) as section 1833(t)(12).

IV. Provider-Based Status

A. Background

The Medicare law (section 1861(u) of the Act) lists the types of facilities that are regarded as providers of services, but does not use or define the term ''provider-based.'' However, from the beginning of the Medicare program, some providers, which we refer to in this section as ''main providers,'' have owned and operated other facilities, such as SNFs or HHAs, that were administered financially and clinically by the main provider. The subordinate facilities may have been located on the main provider campus or may have been located away from the main provider. In order to accommodate the financial integration of the two facilities without creating an administrative burden, we have permitted the subordinate facility to be considered provider-based. The determination of provider-based status allowed the main provider to achieve certain economies of scale. To the extent that overhead costs of the main provider, such as administrative, general, housekeeping, etc., were shared by the subsidiary facility, these costs were allowed to flow to the subordinate facility through the cost allocation process in the cost report. This was considered appropriate because these facilities were also operationally integrated, and the provider-based facility was sharing the overhead costs and revenue producing services controlled by the main provider.

Before implementation of the hospital inpatient PPS in 1983, there was little incentive for providers to affiliate with one another merely to increase Medicare revenues or to misrepresent themselves as being provider-based, because at that time each provider was paid primarily on a retrospective, cost-based system. At that time, it was in the best interest of both the Medicare program and the providers to allow the subordinate facilities to claim provider-based status, because the main providers achieved certain economies, primarily on overhead costs, due to the low incremental nature of the additional costs incurred.

In the proposed rule, we pointed out the increase of provider-based facilities and the financial and organizational incentives for that increase since 1983. A variety of factors such as the emergence of integrated delivery systems and the pressure to enhance revenues have combined to create incentives for providers to affiliate with one another and to acquire control of nonprovider treatment settings, such as physician offices.

We noted in the proposed rule that it is essential that we make decisions regarding provider-based status appropriately, and that we have clear rules for identifying provider-based entities. By failing to distinguish properly between provider-based and free-standing facilities or organizations, we risk increasing program payments and beneficiary coinsurance with no commensurate benefit to the Medicare program or its beneficiaries and we jeopardize the delivery of safe and appropriate health care services to our beneficiaries.

Although there is no direct statutory requirement to maintain explicit criteria for determination of provider-based status, there are statutory references acknowledging the existence of this payment outcome. For example, section 1881(b) of the Act provides for separate payment rates for hospital-based ESRD facilities. There is currently no general definition of ''provider-based facility'' in the CFR. However, in the proposed rule, we cited issuances that do contain provisions for recognition of specific types of entities as provider-based, including Program Memorandum A–96–7, published on August 27, 1996, which pulled together instructions for specific entity types from previously published documents and consolidated them into a general instruction for the designation of provider-based status for all facilities or organizations. That Program Memorandum was subsequently reissued, without substantive change, as Program Memoranda A–98–15 and A–99–24 and, in October 1999, was manualized by the Provider Reimbursement Manual, Part I, Transmittal 411 (adding new section 2446), and the State Operations Manual, Transmittal 11 (replacing previous section 2003 and adding new section 2004). Our policy will continue to follow the principles we articulated in Program Memorandum A–96–7 and the Provider Reimbursement Manual and State Operations Manual sections cited above until October 10, 2000. After that date, we shall apply the policies set forth in these final regulations.

B. Provisions of the Proposed Rule

We announced our intention to implement §§ 413.24(d)(6)(i) and (ii), 413.65, 489.24(b), and 498.3, as revised based on our consideration of public comments, with respect to services furnished on or after 30 days following publication of a final rule. We describe these sections below and explain that we have now provided a 6-month delay in the effective date of the regulations on provider-based status.

We proposed to add a new § 413.65 on the determination of provider-based status. In paragraph (a), we proposed to define the following terms: department of a provider, free-standing facility, main provider, provider-based entity, and provider-based status. In paragraph (b), we proposed that a facility or organization would not be entitled to be treated as provider-based simply because it or the provider believe it to be provider-based. The facility or organization, or the provider, would have to contact HCFA and obtain an affirmative provider-based determination before billing of the facility's or organization's costs through the main provider, or inclusion of those costs on the main provider's cost report, is initiated. Further, we proposed to presume a facility not located on the campus of a hospital and used as a site of physician services of the kind ordinarily furnished in physician offices to be a free-standing facility unless we determined it to have provider-based status.

We proposed to require, in paragraph (c), that a main provider that acquires a facility or organization for which it wishes to claim provider-based status must report its acquisition of the facility or organization to us if the facility or organization is off the campus of the main provider, or is located on the campus of the main provider and, if acquired, would increase the main provider's costs by 5 percent or more. The main provider must also furnish all information needed for a determination as to whether the facility or organization meets the criteria in this section for provider-based status. A main provider that has had one or more facilities or organizations determined to have provider-based status also must report to us any material change in the relationship between it and any department or provider-based entity, such as a change in ownership of the entity or entry into a new or different management contract, that could affect the provider-based status of the department or entity.

In paragraph (d), we proposed the requirements for a determination of provider-based status. In paragraph (d)(1), we proposed to set forth licensure requirements for facilities or organizations seeking provider-based status.

In paragraph (d)(2), we proposed to require that a facility or organization be

under the ownership and control of the main provider.

In paragraph (d)(3), with respect to administration and direct supervision of the main provider, we proposed to require that a facility or organization seeking provider-based status have a reporting relationship to the main provider that is characterized by the same frequency, intensity, and level of accountability that exists in the relationship between the main provider and one of its departments.

In paragraph (d)(4), we proposed that a facility or organization seeking provider-based status and the main provider share integrated clinical services, as evidenced by privileging of the professional staff of the department or entity at the main provider, and the main provider's maintenance of the same monitoring and oversight of the department or entity as of other departments. Also, the medical director of the department or entity would be required to maintain a day-to-day reporting relationship with the chief medical officer (or equivalent) of the main provider, and be under the same supervision as any other director of the main provider.

In paragraph (d)(5), we proposed to require that the department or entity and the main provider be fully financially integrated within the main provider's financial system, as evidenced by the sharing of income and expenses. The department's or entity's costs should be reported in a cost center of the provider, and the department's or entity's financial status should be incorporated into, and readily identifiable in, the main provider's trial balance.

In paragraph (d)(6), we proposed to require that the main provider and the facility seeking status as a department of the provider be held out to the public as a single entity, so that when patients enter the department they are aware that they are entering the provider and will be billed accordingly. (This requirement would not apply to a provider-based entity that is itself a provider, such as a SNF.)

In paragraph (d)(7), we proposed to require that the department of a provider or provider-based entity and the main provider be located on the same campus, except where requirements relating to service to the same patient population are met.

Paragraph (e) would specifically prohibit the approval of provider-based status for any proposed department or entity that is owned by two or more providers engaged in a joint venture.

In proposed paragraph (f), we proposed to state that facilities or organizations operated under management contracts would be considered provider-based only if specific requirements are met related to: Staff employment, administrative functions, day-to-day control of operations, and holding of the management contract by the provider itself rather than by a parent organization.

In proposed paragraph (g), we proposed to specify nine obligations of hospital outpatient departments and hospital-based entities. We explained that these obligations ensure that facilities seeking recognition as hospital outpatient departments or hospital-based entities are in fact what they represent themselves to be, and are not simply the private offices of individual physicians or of physicians in group practices.

We also proposed to preclude any facility or organization that furnishes all services under arrangements from qualifying as provider-based. We believe the provision of services under arrangement was intended to be allowed only to a limited extent, in situations where cost-effectiveness or clinical considerations, or both, necessitate the provision of services by someone other than the provider's own staff. The ''under arrangement'' provision in section 1861(w)(1) of the Act and § 409.3 is not intended to allow a facility merely to act as a billing agent for another.

Proposed paragraph (h) states that, if we learn of a provider that has inappropriately treated a facility or organization as provider-based, before obtaining our determination of provider-based status, we would reconsider all payments to that main provider for those periods subject to reopening, and we would investigate to determine whether the designation was appropriate.

In proposed paragraph (i), we would apply the principles in paragraph (h) to situations involving inappropriate billing for services furnished in a physician's office or other facility or organization as if they had been furnished in a hospital outpatient or other department of a provider or in a provider-based entity.

We also proposed to add a new paragraph (j) that would allow us to review past determinations. If we find that a designation was in error, and the facility or organization in question does not meet the requirements of this section, we will notify the main provider that the provider-based status will cease as of the first day of the next cost report period following notification of the redetermination.

In addition, we proposed to add to § 413.24(d) new paragraphs (6)(i) and (6)(ii) to clarify that main providers, in completing their Medicare cost reports, may not allocate overhead costs to the provider-based or other cost centers that incur similar costs directly through management contracts or other arrangements. These changes are needed to prevent misallocation of management costs, which would result in excessive payment to those types of providers paid on a reasonable cost basis.

To provide an administrative appeals process for entities that have been denied provider-based status, we proposed to revise the regulations on provider appeals at § 498.3. As revised, these rules would specify that a provider seeking a determination that a facility or an organization is a department of the provider or a provider-based entity under proposed § 413.65 would be included in the definition of ''prospective provider'' for purposes of part 498, and would be afforded the same appeal rights as a prospective provider, such as a hospital or SNF, that we have found not to qualify for participation as a provider.

C. Comments and Responses

In response to our proposals, we received approximately 120 letters of comment, most of which raised a number of issues. Included among the commenters were hospitals and hospital and other provider associations, physicians, attorneys, and other individuals. Here we respond to comments submitted on the proposed rule.

General Comments

Many comments were not directed to a specific provision or criterion, but concerned the implementation of the regulations or the application of provider-based criteria to specific types of facilities. These are summarized below.

Effective Date

Comment: A commenter requested clarification as to when the parts of the final rule setting forth criteria for provider-based status would be effective, and a number of commenters requested an extended grace period or a delay in effective date of the final rules, with some commenters requesting delays as long as 12 to 18 months. Various reasons were cited, including the pressures on providers to prepare their systems and staff for the outpatient PPS, the need to bring operations into compliance with the provider-based criteria, and the anticipated workloads of HCFA regional offices that may

receive a large number of requests for provider-based determinations. Commenters argued that it is unrealistic to expect that a hospital would engage in a full-blown analysis of its provider-based arrangements and modify each arrangement until it knows against which exact criteria it is measuring those arrangements. Any changes in status will require hospitals to implement billing and other operational changes. Thus, commenters argued that it is not reasonable to expect hospitals to complete such steps within a 30-day period.

Response: We agree, and are providing a delay in the effective date until October 10, 2000. Moreover, as stated in our response to comments on proposed § 413.65(j) below, any redetermination of provider-based status that finds the facility or organization not to be provider-based will not take effect for at least 6 months after the date the provider is notified of the redetermination.

Application to Specific Facilities

Comment: One commenter stated that under the Balanced Budget Act of 1997 (the BBA 1997) long-term hospitals established on or before September 30, 1995 are entitled to retain their long-term hospital classification notwithstanding their location in the same building or campus of another hospital. In the commenter's view, these hospitals should not now have this classification revoked by this proposed regulation.

Response: The provision referred to by the commenter, section 4417(a) of the BBA 1997, is codified in section 1886(d)(1)(B) of the Act and is implemented under regulations at § 412.22(f). That provision authorizes certain hospitals to continue being excluded from the Medicare hospital inpatient prospective payment system (PPS) based on their exclusion status and configuration on or before September 30, 1995, even though they would not otherwise qualify for this exclusion. The criteria for provider-based status do not conflict with or even directly relate to the section 4417(a) provision, and we have therefore not made any change in the regulations based on this comment.

Comment: The commenter believes that rural health clinics (RHCs) should be exempted from provider-based designation requirements if they meet the intent of the enabling regulation. The commenter requested that an RHC be granted provider-based status if it meets one of the following criteria: Is the sole source of primary care for the community; has traditionally served the community with an open door policy; or treats a disproportionate share of the community's Medicare and Medicaid population.

Response: We share the commenter's concern, but believe the criteria suggested are overly inclusive and could lead to a proliferation of RHCs in areas where there are no true shortages of care. While we do not believe a blanket exemption from the criteria is warranted, we have developed a special provision for RHCs affiliated with small rural hospitals, as described below in our responses to comments on § *415.65(d)(7), Location in immediate vicinity.*

Comment: A commenter stated that there may be instances where the Medicare regulations related to provider-based definitions conflict with the Medicaid provider-based regulations, and asked whether Medicaid will be required to comply with the new Medicare provider-based regulations.

Response: Because hospitals under Medicaid are required to meet the same standards as Medicare facilities, these final rules would affect the Medicaid definition of these facilities as well as the Medicare definitions.

Comment: Commenters stated that the reasons cited for establishing provider-based requirements that are found in the preamble do not apply to clinical laboratories and thus these requirements should not apply. The commenters asked that we explicitly state in the final regulations that the provider-based requirements are not applicable to clinical laboratories. They believe the regulations have little bearing where, as with clinical laboratory services, reimbursement is under a fee schedule amount, and neither the Medicare program nor the beneficiary will pay anyone differently as a result of the treatment of the laboratory in the manner proposed.

Response: As explained more fully in the preamble to the proposed rule, our objective in issuing specific criteria for provider-based status is to ensure that higher levels of Medicare payment and increases in beneficiary liability for deductibles or coinsurance (which can all be associated with provider-based status) are limited to situations where the facility or organization is clearly and unequivocally an integral and subordinate part of a provider. Under this principle, we agree with the commenter's view that it would not be either necessary or appropriate to make provider-based determinations with respect to facilities or organizations if by law their status (that is, provider-based or free-standing) would not affect either Medicare payment levels or beneficiary liability. However, we believe that it is not necessary to specify in the regulations that specific facility types are excluded, since these facilities or organizations are unlikely to seek a provider-based determination. We will be careful to clarify this policy in program operating instructions.

Comment: A commenter stated that the proposed provider-based requirements seem to preclude the possibility of a Comprehensive Outpatient Rehabilitation Facility (CORF) meeting these new requirements. The commenter believes that in the past, CORFs have been permitted to be either provider-based or free-standing and asked whether the final rules will give CORFs the option of being either free-standing or provider-based.

Response: As explained more fully in the preamble to the proposed rule, our objective in issuing specific criteria for provider-based status is to ensure that higher levels of Medicare payment and increases in beneficiary liability for deductibles or coinsurance (which can all be associated with provider-based status) are limited to situations where the facility or organization is clearly and unequivocally an integral and subordinate part of a provider. We are aware that, under the cost-based payment system that applied to CORFs prior to January 1, 1999, approximately 17 percent of participating CORFs claimed provider-based status. However, effective January 1, 1999, in accordance with the BBA 1997, payment for all CORF services is made no longer on the basis of cost reimbursement but on the basis of the physician fee schedule. Beneficiary liability is also determined under the fee schedule, regardless of the organizational structure or affiliations of the CORF. The switch to fee schedule payment from a cost-based system eliminates or removes any payment incentives to be a provider-based rather than a free-standing CORF. Thus, as in the case of the preceding comment, we agree with the commenter's view that it would not be either necessary or appropriate to make provider-based determinations with respect to facilities or organizations if by law their status (that is, provider-based or free-standing) would not affect either Medicare payment levels or beneficiary liability. We also note that existing regulations at § 413.174 specify rules for determining whether ESRD facilities are independent or hospital-based, and we have revised § 413.65(a) to state that determinations with respect to ESRD facilities will continue to be made under § 413.174,

not § 413.65. However, we believe that it is not necessary to specify in the regulations that most specific facility types are excluded, since these facilities or organizations are unlikely to seek a provider-based determination. We will be careful to clarify this policy in program operating instructions.

Application to Specific Facilities—Indian Health Service (IHS)

Comment: Several commenters requested an exception or exemption from the rules for IHS and tribal facilities. One commenter was concerned that the implementation of these proposed regulations will have the effect of denying Medicare participation as provider-based entities to a number of IHS facilities that are currently operated by Indian tribes under the auspices of Public Law 93–638. They will also cause a disruption of the coordinated health care delivery system(s) that exist between IHS and numerous tribes, and jeopardize statutorily authorized contracting and compacting relationships between the IHS and these tribes due to the conflict between these proposed regulations and the statutory opportunities for self-determination by the Indian tribes. The IHS strongly recommended that these proposed regulations not apply to IHS and tribal health systems as written. Recommendations were also made to deem satellite facilities within a discrete Indian reservation as meeting the definition of a provider-based entity as well as satellite facilities within a historical service unit. Finally, the IHS recommended that the current system be ''grandfathered'' to meet the definition of provider-based entity.

Response: We share many of these concerns and have provided special treatment for IHS and tribal facilities as described below.

Comment: A commenter was concerned that the proposed regulations would severely restrict a number of IHS satellite clinics from receiving reimbursement for the provision of Medicare Part B services. The commenter believes that a number of the requirements that must be met before an entity can be designated as provider-based for Medicare payment purposes are unrealistic for IHS satellite clinics, which are often the only Medicare providers on remote tribal lands. The commenter recommended that HCFA provide for an exemption for IHS satellite facilities that are generally located on a main hospital campus or within a short distance of a hospital. Also, the commenter recommended that the final rule clarify that IHS and tribal outpatient departments or satellite clinics are eligible to receive designation as a department of a provider or a provider-based entity and are eligible for Part B reimbursement.

Response: We share many of these concerns and have provided special treatment for IHS and tribal facilities as described below.

Comment: Many tribes have acquired operations of outpatient facilities and are in the process of acquiring the affiliated hospitals. The commenter stated that this trend, coupled with the complexities of the Indian Self-Determination Act (Pub. L. 93–638), the Indian Health Care Improvement Act (Pub. L. 94–437), and a moratorium on tribal compacting and contracting, requires special consideration by HCFA. The commenter requested that facilities be recognized as provider-based if—

(1) The outpatient facility is owned and operated by the tribe that owns the majority of the tribal shares utilized in funding the main hospital;

(2) The tribe has previously compacted programs that were historically administered by the hospital and are now administered through a committee or board comprised of medical staff of both facilities;

(3) The outpatient facility is in the same State as the hospital;

(4) There is coordination and integration of services, to the extent practicable, between the outpatient facility seeking provider-based status and the main provider.

Response: We recognize that the provision of health services to members of Federally recognized Tribes is based on a special and legally recognized relationship between Indian tribes and the United States Government. To address this relationship, the IHS has developed an integrated system to provide care that has its foundation in IHS hospitals. Because of these special circumstances, not present in the case of private, non-Federal facilities and organizations that serve patients generally, we agree that it would not be appropriate to apply the provider-based criteria to IHS facilities or organizations or to most tribal facilities or organizations. Therefore, we have revised the final rule to state that facilities and organizations operated by the IHS or Tribes will be considered to be departments of hospitals operated by the Indian Health Service or Tribes if, on or before April 7, 2000, they furnished only services that were billed as if they had been furnished by a department of a hospital operated by the Indian Health Service or a Tribe and they are: (1) owned and operated by the IHS; (2) owned by the Tribe but leased from the Tribe by the IHS under the Indian Self-Determination Act in accordance with applicable regulations and policies of the Indian Health Service in consultation with Tribes: or (3) owned by the IHS but leased and operated by the Tribe under the Indian Self-Determination Act in accordance with applicable regulations and policies of the Indian Health Service in consultation with Tribes. Facilities or organizations that are neither leased nor owned by the IHS would not be eligible for this special treatment, even if operated on Tribal land by members of the Tribe. These facilities would, of course, be eligible to participate in Medicare as FQHCs if applicable requirements in our regulations at 42 CFR part 405, subpart X are met. We did not adopt the conditions recommended by one commenter because we believe they may not apply to all Tribes.

Application to Specific Facilities—Federally Qualified Health Centers (FQHCs)

Comment: A commenter stated that despite specific acknowledgment of the eligibility of FQHCs to qualify as provider-based entities, certain proposed ownership, governance, and supervision criteria in connection with the determination of provider-based status would effectively prohibit entities from maintaining concurrent provider-based and FQHC designations. The commenter believe the criteria should be modified, or some other special provision created, to allow FQHCs to be departments of a provider.

Response: We understand the commenter's concerns and have provided special treatment for FQHCs as described below.

Comment: The commenter, a hospital that is affiliated with a number of off-site community health centers, believes the criteria in the proposed rule would deny provider-based status to community controlled, urban tax-exempt health centers operated under the license of a ''main provider.'' Several of the commenter's health centers are FQHCs that must fulfill certain criteria to maintain this status. In the commenter's view, it is not feasible to require the ''main provider'' to own and control these health centers or to require that the health centers and the ''main provider'' strictly meet all of the requirements set forth in the proposed rule. The commenter asked that the final rule be revised to take into account these historical relationships and ''grandfather'' the provider-based status of health centers that have been on the license of a disproportionate share hospital for at least 10 years. The recommended ''grandfathering''

provisions also could, in the commenter's view, require common Joint Commission on Accreditation of Healthcare Organizations (JCAHO) accreditation, integration of clinical care committees, main provider approval of clinical guidelines and protocols, and financial oversight and review by the main provider.

Response: We share many of these concerns and have provided special treatment for FQHCs as described below.

Comment: A commenter requested that we provide a transition period of at least five years for health centers that have been treated as provider-based entities for a significant period of time (for example, 10 years or more), so that the centers will have adequate time to achieve compliance with the provider-based criteria. In the commenter's view, an extended time period for compliance would permit continuity of care to the populations served by the health centers while granting the affected health centers an opportunity to find alternative funding streams.

Response: We recognize that FQHC qualification criteria effectively require these facilities to be governed by community-based boards independent of hospitals and other providers, while our provider-based criteria require facilities seeking provider-based status to be operated under the ownership and control of the main provider, and to be under the direct supervision of that provider. This does not preclude an FQHC from participating in Medicare as a free-standing entity; on the contrary, this participation is entirely appropriate. However, it does preclude the facility from qualifying as a department of a hospital or other provider under our criteria.

Despite the difference between HRSA and HCFA requirements, we are aware that some FQHCs may have been treated by hospitals as departments for purposes of Medicare and Medicaid billing, and we are concerned that an abrupt change in status for them could force some or all to close, leading to shortages of care in some areas. Therefore, we plan to establish special provisions for FQHCs and FQHC ''look-alikes'' (facilities that are structured like FQHCs and meet all requirements for grant funding, but have not actually received these grants). Specifically, we have revised the regulations to state that if a facility has since April 7, 1995 furnished only services that were billed as if they had been furnished by a department of a provider and either (1) received a grant before 1995 under section 330 of the Public Health Service Act or, before 1995, received funding from such a grant under a contract with the recipient of such a grant and meets the requirements to receive a grant under section 330 of the Public Health Service Act; or (2) based on the recommendation of the PHS, was determined by HCFA before 1995 to meet the requirements for receiving such a grant, the facility will continue to be treated, for purposes of this section, as a department of the provider without regard to whether it complies with the criteria for provider-based status in § 413.65. We note that both types of facilities would be obligated, for as long as they are treated as a department of a provider, to comply with the applicable requirements for departments of providers as stated in § 413.65(g).

Application of Standards

Comment: One commenter believes that the proposed rule did not make clear how it would apply to existing entities, because some language in the rule could be read to require that existing entities would not receive provider-based status until we have issued a determination letter. Another commenter requested that we clarify whether we expect to review all clinics prospectively or just new clinics. The commenter stated that requirements that only new clinics seek designation does not preclude us from auditing currently designated clinics. Another commenter asked if there will be a set time frame during which current providers with provider-based departments or entities under Program Memorandum A–96–7 must contact us and receive an official designation in order to continue billing as they currently do. More specifically, the commenter asked whether, if there is such a time frame, compliance with the criteria in the Program Memorandum would constitute a good faith effort as referred to in § 413.65(i)(2). Additional guidance was also requested as to what providers should do now to demonstrate that they have made a good faith effort.

Response: We plan to review all new requests for provider-based status. At present, we have no plans to systematically review all providers to determine whether they may be claiming provider-based status for some facilities or organizations inappropriately. However, we will review the status of specific facilities or organizations in response to complaints or any other credible information that indicates that provider-based status requirements are not being met. If the regional office determines that this is the case, it will take action in accordance with the rules in new § 413.65(h) and (i). In response to the comment about possible retroactive application of the new regulations, we note that they will apply only on or after their effective date of October 10, 2000. We will not apply the provider-based criteria in the new regulations to periods prior to that date; on the contrary, decisions for such periods will be reviewed only under the criteria in effect at the time, as stated in Program Memoranda and the Provider Reimbursement Manual and State Operations Manual.

Comment: Two commenters pointed out the proposed rules do not state whether the required approval status is retroactive to when the provider applied or to when we granted approval. These commenters believe it should be retroactive to the date of the provider's application for the determination.

Response: We plan to make provider-based status applicable as of the earliest date on which a request for provider-based status has been made and all requirements for provider-based status are shown to have been met, not on the date of our determination. Thus, if a provider requests provider-based status for a facility on May 1 and demonstrates that applicable criteria were met on that date, but the regional office did not make a formal determination until June 1, the determination would be effective on May 1.

Comment: The commenter stated that we should not have published important provider-based policies in a **Federal Register** document that some providers, such as skilled nursing facilities and home health agencies, may not have read. The commenter recommended that we re-issue these proposed rules separately from the proposed hospital outpatient prospective payment rules.

Response: We do not agree that the proposed rules were published in an obscure location. On the contrary, the number of written comments received, many of them from providers other than hospitals, indicates that our proposals were widely known among providers that could be affected. Therefore, we do not intend to republish the proposed rules.

Comment: A commenter expressed concern that these provider-based provisions are unnecessarily restrictive and will unreasonably limit practice arrangements. The commenter went on to state that in the current health care environment, physicians and hospitals need flexibility to adapt to local market conditions and participate in a variety of practice arrangements to provide cost effective, high quality care. An unnecessary strict definition of

''provider-based entity'' could have a chilling effect on the evolution of new care delivery structures that would expand access to care, especially in rural areas.

Response: We share the commenter's concern with preserving Medicare beneficiaries' access to care, but do not agree that the provider-based rules will limit access. We note that the rules do not prohibit hospitals from purchasing physician practices or taking other actions to enhance access to care in remote rural areas; they only set minimum standards for the type of affiliations that will be recognized for provider-based designation.

For example, an institutional provider such as a hospital or SNF may elect to use part of its institutional complex to house physician offices or other facilities that provide services complementing those of the provider. Those facilities'costs will have to be included in the trial balance of the institutional complex, in order to allow costs to be allocated accurately to all parts of the complex, and permit the costs of the provider to be determined. However, inclusion of such facilities' costs on the institutional complex trial balance does not make the facilities provider-based. On the contrary such facilities would have to meet the criteria in § 413.65 to qualify for provider-based status.

Comment: Different views were expressed on how much

discretion regional offices should have in applying the provider-based criteria. One commenter asked that we make the rules as clear and concise as possible. The commenter argued that rules allowing for great latitude in interpretation could be dangerous for the provider community. On the other hand, another commenter stated that we should allow Medicare regional offices greater latitude for determining when sufficient integration exists for a facility to qualify as provider-based, and should avoid adopting regulations that ''micro-manage'' a hospital's operations. Another commenter suggested that rather than requiring that *all* criteria must be met to achieve provider-based status, we change the test to *substantially all*. There may be circumstances where criteria are not fully met, but an overall assessment supports a provider-based determination. This same commenter recommended that a ''pending'' status be incorporated into the evaluation process, whereby hospitals not meeting the criteria for provider-based status would be afforded an opportunity to make the modifications necessary. Another commenter asked that instead of meeting all criteria, we permit the regional offices to evaluate a facility's status with respect to the main provider with input from local government and the fiscal intermediary. Another commenter also suggested that the standards only be enforced to the extent that they are applicable and relevant, consistent with state laws, and relate to practices that are subject to the control of the particular provider.

Response: We have tried to balance the need to apply standards that can be adapted to fit particular circumstances, and agree that the standards should not be overly prescriptive, but rely on regional judgment to ensure appropriate decision making. Because provider-based status is a matter of extreme importance to many facilities, published standards provide a basis for advance assessment and planning of particular organizational and financial arrangements. Therefore, we have decided that a facility or organization will be found to be provider-based only when it is in compliance with *all* standards set forth in these final rules.

With respect to the comment regarding situations in which all but a few criteria for provider-based status are met, we note that nothing prohibits the main provider from re-applying for approval of provider-based status for a facility or organization after having made the changes necessary to come into compliance. Regional offices would in such cases only need to verify compliance with whatever criteria had not been previously met, unless the amount of time that elapses between requests, or other factors, make a full re-evaluation necessary. Because facilities have this flexibility under the rules as proposed, we did not make any changes based on this comment.

Comment: One commenter believes that we had not fully addressed the impact of these rules on service delivery. The commenter suggested that changes would affect deemed status, survey and certification requirements, state licensure requirements, physician referral requirements, and a host of related issues. Another commenter stated that the new requirement regarding administration and supervision found in § 413.65(d)(3) could impact more than our estimated 105 providers. The commenter believes that if providers are required to convert management firm employees to hospital employees and then revert back when outpatient PPS becomes effective, this could impact 5,000 inpatient PPS hospitals.

Response: We again reviewed our requirements, but do not believe they will have the far-reaching effects envisioned by these commenters. In particular, to the extent a facility or organization that claims to be a department of a provider must be accredited, surveyed, or licensed as a part of that provider, or must adapt to the physician referral requirements of the main provider, that result does not flow from the existence of criteria for provider-based status, but instead is a direct result of the provider's decision to claim the facility or entity as a department. We also do not think it is reasonable to assume that any significant number of hospitals will restructure themselves repeatedly because of the final rules set forth below. As noted earlier, both the proposed and final rules closely parallel policies that have been stated explicitly on program instructions since 1996, and we are providing a 6-month delay in effective date for the final rule. Thus, hospitals and other providers have had ample time to assess the impact of any changes and to make necessary adjustments in an orderly way.

Comment: A commenter requested clarification as to how the proposed rules would apply to two hospitals seeking consolidation into a single provider. The commenter also asked whether two small PPS hospitals located approximately 15 to 25 miles apart in separate towns within a metropolitan statistical area (MSA) who wish to consolidate would be prohibited from doing so because of patient population or licensure requirements. Furthermore, if these two hospitals are already certified as a single provider, would the proposed rules require them to separate and create separate providers? Another commenter requested that the final regulatory text state that the provider-based requirements do not apply to any facility where there are inpatient beds since such a facility would be viewed as a ''main provider.'' The provider-based requirements should apply only to facilities or organizations other than main providers.

Response: Although the Program Memorandum and proposed rules were issued in response to situations primarily involving outpatient facilities, we believe the policies set forth in these documents are equally applicable to inpatient facilities, and should be applied in the many cases in which a determination about inpatient facilities must be made. The rules would not prohibit two previously separate hospitals from merging to become a single provider. However, for either facility to be considered provider-based with respect to the main provider, the facility would have to meet the criteria

in this final rule. To clarify the scope of application of these regulations, we have added a definition of ''remote location of a hospital'' and a reference to hospital satellite facilities to § 413.65(a) Definitions, and have clarified the wording of several later sections by including references to remote locations and satellites. We have defined a ''remote location of a hospital'' as 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 may not be licensed to provide inpatient hospital services in its own right, and Medicare conditions of participation do not apply to a department as an independent entity. 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). Hospitals may acquire remote locations by various means, but often do so by mergers or acquisitions, in which a single hospital purchases other, previously separate hospitals, and operates them as remote locations that are not separately organized as departments, but instead furnish the same types of services as the original hospital. For example, a long-term care or other specialty hospital might acquire one or more other hospitals, terminate their separate participation in Medicare, but continue to use them as sites of the same type of care as the original hospital. Satellite facilities are currently defined in our regulations at § 412.22(h)(1) (for hospitals) and § 412.25(e)(1) (for units). In general, a satellite facility is a part of a hospital (or of a hospital unit) that provides services in a building also used by another hospital, or in one or more buildings on the same campus as buildings also used by another hospital. Satellite status always involves co-location with another hospital, while remote locations are not co-located with other hospitals' facilities.

Comment: A commenter requested clarification that the provider-based requirements apply only to providers who are paid under the reasonable cost methodology. The preamble language in section VI implies that these requirements would also apply to providers under the outpatient PPS. The commenter believe that if this were the case, the requirements found in §§ 413.24(d)(6) and 413.65 would be appropriately placed in Subchapter E (for example, Part 482, Conditions of Participation for Hospitals).

Response: The rules set forth below are not limited in their scope to providers paid on a reasonable cost basis but, except where specifically stated in the text of the rules, apply to all providers and facilities seeking Medicare payment. While many of the problems associated with inappropriate accordance of provider-based status relate to cost reimbursement, the different payment systems used for various providers may produce some unintended incentives for one type of facility to gain an unfair payment advantage by misrepresenting itself. The specific requirements cited do not, like the Medicare conditions of participation, implement section 1861(e) of the Act, nor do they primarily concern patient health and safety. Therefore, we did not adopt the suggestion that the section be relocated to part 482.

Comment: A commenter would support a provision that prohibits hospitals from acquiring free-standing physician practices and converting them to hospital-based entities.

Response: We understand the commenter's concern, but do not have authority under the Medicare law to prohibit this practice. We do believe that the rules set forth below will keep hospitals from misrepresenting physicians' practices as hospital outpatient departments.

Section 413.24(d)(6) Adequate cost data and cost finding: Management contracts

Comment: The proposed cost reporting requirements state that if an overhead administrative cost center does not perform services for the off-site clinic or department, no costs should be allocated to that function. The commenter pointed out that this contradicts generally established Medicare cost reporting principles that have always required that the administrative costs be allocated to allowed and nonallowed cost centers.

Response: Our position, as expressed in the Provider Reimbursement Manual, Part II, Chapter 36 for hospitals, is to allow the provider to bypass the allocation of overhead through the cost report to avoid inappropriate allocations. An example of this would be lab services under arrangement, where there is obviously no administrative activity by the main provider. Our electronic cost report systems are set up to ''skip'' that particular cost center and to re-allocate the costs to the remaining cost centers. Likewise, where administrative costs such as billing are performed by the subordinate provider, no billing cost from the main provider should be allocated to that cost center from the main provider.

Comment: Several commenters suggested clarification of ''like'' costs by adding a definition or providing examples. Also, a commenter stated that since the main concern is costs, this provision should be applied when management costs exceed the hospital's operating costs of the department by 10 percent on a comparable basis. Another commenter stated that: (1) Management services benefit only the specific department to which they are expensed, and provide no direct services to other hospital departments; (2) A department under the management contract receives necessary services from other hospital overhead departments; (3) such overhead departments do not represent duplicate services provided under the management contract. Since management agreements can be drastically diverse, the commenter believes this clarification would assist in avoiding any confusion, as well as allow for consistency with generally accepted cost finding principles. Another commenter stated that most entities that contract to manage an area of a hospital manage just that area. Therefore, if they offer assistance with a particular function, it is only for that area and not for the whole hospital. The commenter believes the same principles of reimbursement should be applied whether the hospital provides the service directly or contracts for the service to be provided.

Response: Examples of similar costs when management contracts provide services also available through the main provider are the following: billing services, computer services, accounting services, and, possibly, general administrative staff. When the same services are included in the administrative and general costs of the main provider, and allocated down to subordinate cost centers or providers incurring and reporting these same costs in the trial balance, the result is a duplication of costs to the subordinate cost center or provider. As long as the main provider has the ability to identify these ''like'' service costs, these costs should be re-allocated to the remaining reimbursable and non-reimbursable cost centers in proportion to each cost center's total costs as prescribed in the Provider Reimbursement Manual, Part II, Chapter 36. However, if the main provider is not able to identify the costs of these same services to permit the exclusion of allocation to the subordinate providers or cost centers,

the cost of the management contract of the subordinate provider or cost center must be reclassified to the main provider's administrative and general cost center, and allocated down to *all* reimbursable and non-reimbursable cost centers in proportion to each cost center's total cost.

Comment: With regard to the language in paragraph (d)(6)(ii), Medicare principles of reimbursement require that, when two entities are related, and one contracts from the other, reimbursement for these services is at cost due to the ''related party principle.'' The commenter stated that the cost of a service is both direct and indirect; Medicare reimbursement has a longstanding methodology concerning nonrevenue producing costs and their allocation on a provider's cost report. A separate work paper should not be required. The appropriate methodology for stepping down administrative costs should be based on the cost of the entity utilizing the service. The cost of the free-standing entity must be placed on the main provider's cost report to step down cost appropriately. Additional work papers would allow room for error and would delay any necessary adjustments.

Response: The intent of § 413.24(d)(6)(ii) was to require the main provider to report costs of related party entities that would not be reported through their accounting system on the main provider's books and records, for example, trial balance. Consequently, when there is a sharing of administrative services, for example, managerial staff, the related entity escapes any administrative overhead allocation when that same related entity is not reported on the main provider's trial balance of the cost report. While the commenter is correct regarding the proper reporting of related transactions at cost of the related entity, this regulation section goes further to require the main provider to develop the total cost of the related entity, utilizing and maintaining workpapers to justify the amount to be reported, and to report those costs by the main provider on the cost report trial balance.

Section 413.65(a) Definitions (retitled in this final rule as Section 413.65(a) Scope and definitions)

Comment: Two commenters requested that a definition be provided for ''a provider's campus.'' A definition would be important since the proposed regulation specifies additional requirements for off-campus locations.

Response: We agree that location on or off a hospital's campus is important. To provide a clear standard, we have revised the final rule to define ''campus'' as ''the physical area immediately adjacent to the provider's main buildings, other areas and structures that are not strictly contiguous to the main buildings but are located within 250 yards of the main buildings, and any other areas determined on an individual case basis, by our regional office, to be part of the provider's campus.'' This definition would encompass not only institutions that are located in self-contained, well-defined settings, but other locations, such as in central city areas, where there may be a group of buildings that function as a campus but are not strictly contiguous and may even be crossed by public streets. This would also allow the regional offices to determine, on a case-by-case basis, what comprises a hospital's campus. We believe allowing regional office discretion to make these determinations will allow us to take a flexible and realistic approach to the many physical configurations that hospitals and other providers can adopt.

Comment: The commenter expressed concern regarding the definition of provider-based facilities as many hospital-owned outpatient services are often provided with leased employees with ambulatory care experience. It is not clear that such an arrangement would satisfy the intent of the regulation.

Response: The regulations do not explicitly prohibit the use of leased employees, and each situation will be evaluated relative to the criteria in the regulations set forth below.

Comment: One commenter stated that the difference between ''department of a provider'' and ''provider-based entity'' is not clear from the definitions given of those terms. The commenter requested that we clarify in the regulations text whether a provider-based entity must be certified in its own right, and what type of certification this encompasses. The commenter also requested clarification in the regulations text concerning whether the term ''provider'' in the definition is intended to mean only entities that satisfy the Medicare definition of ''provider'' contained in § 400.202.

Response: We have clarified § 413.65(a) to state that a ''department of a provider'' is a facility or organization that could not by itself be qualified to participate in Medicare as a provider under § 489.2, while a ''provider-based entity'' could be so qualified. For example, a skilled nursing facility (SNF) could be a ''provider-based entity,'' whereas an entity that furnishes ambulatory surgical services could not be a provider-based entity, and could participate in Medicare (for example, receive Medicare payment for services furnished to beneficiaries), only as a department of a provider, as a physician office, or as an ambulatory surgical center approved by Medicare under part 416, if at all. We have further revised the final rule to clarify that a department of a provider furnishes services of the same type as the main provider (for example, a department of a hospital furnishes hospital services), while a provider-based entity furnishes services of a different type from those of the main provider (for example, a hospital-based RHC furnishes RHC services, not hospital services).

Comment: A commenter believes the proposed rule should be revised for medically underserved populations and health manpower shortage areas to allow the referral of beneficiaries back to their community for treatment of community-based therapy providers. Therapy services provided under such a referral would be included under the provider-based designation.

Response: We do not oppose use of such referrals where they are medically appropriate, but believe that referral arrangements should not be equated to provider-based status.

Comment: A commenter questioned the requirement that services be furnished ''under the name'' of the main provider entity. The commenter argued that the requirement is inconsistent with the commenter's view that health care in the late 1990s is, and in many markets must be, ''marketed'' in a highly competitive environment. The commenter's view is that having provider-based status turn on the names used will inevitably invite micro-management of the way the main provider's name is used by the department or other hospital-based entity.

Response: We disagree with any suggestion that health care is merely a generic commodity that can be repackaged under another name for marketing purposes. On the contrary, we believe that operating under the name of the main provider, and holding oneself forward to patients under that name, is an important indicator of status as an integral and subordinate part of that provider. Therefore, we did not make any changes in the regulation based on this comment.

Section 413.65(b) Responsibility for obtaining provider-based determinations

Comment: A commenter stated that the proposed rule does not state clearly enough whether our approval is required in order to permit billing each

time a provider sets up a new service, regardless of whether the service is acquired, managed, new, located on the main campus, or off the main campus. Some commenters stated that if approval is required in all instances, it will cause a significant paperwork backlog and will be quite costly to administer.

Response: Section 413.65(b) states explicitly that a determination by us that a facility or organization is provider-based is required before the main provider may treat the facility or organization as provider-based for billing or cost reporting purposes. We recognize that this may generate some administrative cost, but believe the cost will be much less than the amounts that would be spent improperly if payment were made to a free-standing facility as if it were provider-based.

Comment: A commenter urged that the new determination process be applied to all current as well as new hospital-based services.

Response: We have no plans at present to review all hospitals and other providers with respect to provider-based criteria, but will look into any situations that come to our attention in which it appears that a facility does not meet the requirements of the new regulations but is being treated as provider-based. If the facility or organization does not qualify as provider-based, action will be taken as described later in this preamble and in § 413.65(i).

Comment: A commenter stated that there should be some mechanism in place for a long-term hospital (LTH) to seek an advance determination or advisory ruling that a proposed LTH satellite will be granted provider-based status. Because establishing an LTH requires a huge expenditure of time and human resources, an LTH main provider needs to know in advance whether or not its proposed satellite will receive a favorable provider-based determination. It is suggested that we institute a system by which advance rulings or determinations are available before the satellite is established.

Response: We understand the commenter's concern, but do not have the staff or facilities to provide advance approvals of restructuring proposals. We suggest that providers review the new criteria carefully and avoid forms of organization that are not clearly in compliance with them.

Comment: Two commenters suggested that we provide guidance on the application process providers must complete in order to receive a provider-based determination. In addition, time limits for approval of these determinations should be established. Furthermore, existing provider-based entities should not be required to change their billing and accounting procedures. A commenter also asked for clarification as to whether the intermediary and regional office is to be the contact, and who will make the actual determination of provider-based status.

Response: We are developing an application process and intend to have it in place and ready for use before the effective date of the regulation. We expect that determinations of provider-based status will be made by our regional offices. Involvement by other entities, such as fiscal intermediaries or State survey agencies, will be for information-gathering purposes and under the direction of the regional office.

Comment: A commenter suggested that if a determination goes against the provider, the provider should be given the option to come into compliance with the requirements or file an appeal.

Response: As noted earlier, the regulations do not prohibit a provider that meets most but not all criteria from taking action to fully meet the criteria, thus qualifying a facility or organization for provider-based status. In the case of a provider that believes that the determination of the regional office is incorrect, an appeals process is provided under part 498.

Comment: A commenter stated that the requirement in paragraph (b)(3) establishes an adverse presumption against provider status for ''off-campus'' physician practice sites, and that the focus on ''campus'' boundaries will prove elusive, and serve no real policy purpose.

Response: As explained later, we believe location in the immediate vicinity is an important indicator of provider-based status, and that location can be a good basis for identifying facilities for further scrutiny.

Section 413.65(c) Reporting

Comment: Several commenters pointed out that the regulatory language does not reflect the preamble language regarding off-campus entities and the five percent increase in a provider's costs.

Response: We have revised the final rule to correct this oversight.

Comment: One commenter asked whether this language applies only to entities that are applying for provider-based status, or also applies to entities that have already achieved provider-based status.

Response: The requirement applies to both types of providers, but providers that have entities with provider-based status are required to report only newly created or acquired facilities or organizations.

Comment: Two commenters stated that the five percent and off-campus criteria with regard to provider-based status do not take into account the characteristics of rural and frontier areas, and could lead to lower payments to some facilities, thus reducing the flow of Federal money into rural areas and possibly creating a shortage of care. In addition, considering the small budget of RHCs and other rural facilities, 5 percent is an inappropriately low and unreasonable growth limit.

Response: We understand the commenter's concern but do not agree that a 5 percent threshold for reporting is too low. Therefore, we made no change based on this comment.

Comment: A commenter asked whether this reporting requirement also applies to all newly developed services (that is, department on the campus of the hospital).

Response: The requirement applies to all newly developed on-campus services that could increase the costs of the provider by 5 percent or more.

Comment: A commenter requested clarification that a main provider that ''creates'' as well as ''acquires'' a facility or organization is responsible for reporting to us. The commenter also suggested specific items to be included in the reporting and approval process. These include specific data elements to be reported by the main provider, specifying our component with primary responsibility; specifying our approval process; adding a preliminary conditional approval process; adding a specific time period for our approval; and adding requirements for the effective date that the costs of the provider-based entity can be included on the main provider's cost report.

Response: We have revised the regulation to clarify that it applies to facilities or organizations created by the main provider, as well as those ongoing operations acquired by purchase or other means. We have not included the procedural detail requested by the commenter in regulations, but will consider including it in program instructions.

Comment: A commenter stated that the use of the phrase ''any material change'' in paragraph (c)(2) of this section is too vague and open to interpretation. It is suggested that the section be revised to clearly designate changes of ownership and new management agreements as the only two material changes that require reporting by provider-based entities.

Response: We do not agree that the range of reportable events should be limited in this way. On the contrary, we intend to require reporting of any change that could have a significant (''material'') effect on compliance with the provider-based criteria.

Comment: A commenter asked if the reporting requirements are coordinated with the notification of change of ownership requirements at § 489.18(b), where notice is to be given in advance, and whether there should be a cross reference or clarification with respect to the change in ownership regulation and this proposed regulation.

Response: We believe this suggestion has merit, and will consider revising our program instructions to specify that a report under § 489.18(b) should be reviewed for its applicability to provider-based determinations.

Section 413.65(d) Requirements

Comment: A commenter suggested that we clarify whether all requirements, or only a majority of the requirements, must be met to obtain provider-based status.

Response: We have revised the first sentence of paragraph (d) to state that all of the stated requirements must be met by a facility or organization that wishes to be classified as provider-based.

Section 413.65(d)(1) Licensure

Comment: Many commenters objected to the requirement that provider-based facilities share a common license with the main provider unless the State requires separate licensure for the subordinate facility. One commenter listed several reasons for this concern. First, in the commenter's opinion, licensure determinations may be made based on factors that are different from those that would be important for provider-based determinations. Another reason cited by the commenter is that State licensure laws may vary from State to State. Some State hospital licensure definitions are building specific, and do not include off-site outpatient facilities, thus giving what the commenter argues is undue weight to physical location in evaluating provider-based status. Finally, the commenter believes that requiring common licensure will create a situation where some States may have a large number of provider-based entities and others will have few or none, thus leading to inconsistent application of our rules. One commenter recommended that the same licensure requirement be waived for States with idiosyncratic licensure requirements. An alternative would be accreditation with the provider as a deemed status for meeting a common license requirement. The commenter suggested that the proposed language could be reworded to clarify that offsite clinics would not have to be licensed or operated under the same license as the provider in those States that do not license them.

Response: We recognize that licensure may not be an appropriate indicator of provider-based status in all States, and have therefore revised the regulations to require common licensure only in States with laws that permit common licensure of the provider and the prospective provider-based department under a single license. This means that in States that do not allow licensure of certain types of facilities, such as those providing ambulatory care or those located off the provider's main campus, the licensure criterion would not be applied. We do not agree that JCAHO or other accreditation should be accepted in lieu of licensure, since such accreditation may not necessarily reflect an on-site evaluation of the prospective provider-based department. In recognition of the fact that some hospitals are not licensed by the State because they are Indian Health Service (Federal) hospitals or are located on Tribal lands, we also will not apply the licensure requirement to departments of those hospitals.

Comment: Under paragraph (d)(1) as proposed, clinics in another State from the main provider could not be under the hospital's license. Several commenters argued that this requirement would arbitrarily affect rural and urban health care delivery, where the main provider is close to a State line. A commenter recommended that close proximity be used instead, where a hospital-based clinic is in another State from the main provider. For urban hospitals in large metropolitan statistical areas that cross State boundaries, the commenter believes that the market area of the main provider should be the primary determinant of the potential for integration with the main provider.

Response: Under the regulations as revised based on the comments summarized above, common licensure would not be required of facilities located across State lines if the law of the State in which the main provider is located does not allow such licensing. However, see the discussion, later in this preamble, of § 413.65(d)(7)(ii).

Comment: A commenter pointed out that the proposed rule appears to limit the licensure requirement to ''departments'' of the main provider. The commenter asked whether this requirement only applied to ''provider-based entities.'' The commenter also suggested that where a State has two licensure schemes for the same type of facility, we should not prefer one licensure scheme over the other for purposes of determining the provider-based status of the facility.

Response: The commenter is correct in noting that the common licensure requirement in the proposed rule would have applied only to provider-based departments. We did not propose to apply a common licensure requirement to provider-based entities such as SNFs and HHAs, because they are providers of services in their own right, and typically would be separately licensed without regard to their affiliation with the provider. We disagree with the commenter's view that licensure should not be viewed as an indicator of integration. On the contrary, our view is that if a facility could be licensed as part of a main provider but chooses not to be, the facility cannot reasonably be seen as an integral and subordinate part of that provider.

Comment: With regard to the proposed requirement that states that our determination regarding provider-based status will be based on a State health facilities' review commission, one commenter argued that relying on the commission's criteria for purposes of making provider-based determinations is arbitrary and inappropriate. The commenter believes imposing this criterion could disadvantage providers and discourage expansion to off-site locations, thus indirectly leading to shortages of care. Another commenter requested that there be a delay in implementation during which time changes can be made to the commission's definition of what rates it can regulate.

Response: We continue to believe it would be inappropriate for a facility to claim to be separate from the provider for State rate-setting purposes while also claiming to be an integral and subordinate part of the provider for Medicare purposes. To allow this practice would authorize providers to misrepresent their structures and affiliations in whatever way will yield the highest payment. Thus, we did not make changes to reflect the comment.

Section 413.65(d)(2) Operation under the ownership and control of the main provider

Comment: Regarding § 413.65(d)(2), the commenter suggested that the regulations provide a separate set of criteria that would allow a provider that is operated within one legal entity to be provider-based to a provider that is operated within another legal entity, as long as the two entities are under common control. Another commenter

stated that this ownership and control requirement is unnecessarily rigid, since a hospital-based clinic, which was strictly an administrative division of the hospital, might qualify while another similar clinic, wholly owned by the hospital with slightly different governing bodies and documents, would not be eligible.

Response: We do not agree that common control of two separate entities by the same parent organization should be sufficient to meet a requirement for ownership and control by the main provider. While this arrangement may be an appropriate way to manage two separate entities, it does not establish provider-based status for either. With respect to the second comment, we agree that the form of administration of an entity can determine whether or not the entity is found to be provider-based. We believe this would be an appropriate result, since it would help ensure that only facilities that are organized as provider-based entities or departments of a provider are given this status.

Comment: One commenter believes it is unrealistic to require a potential provider-based facility or organization to be owned by the main provider and share bylaws and an identical governing body. The commenter stated that in the present business climate an entity can operate as a provider-based entity without meeting these criteria. It is recommended that we replace the proposed 100 percent ownership standard with a majority standard, require only overlapping governing bodies, and eliminate the requirement for organization under the same organizational documents. Another commenter believes that the key consideration should be whether the provider is in control of the day-to-day operations of that portion of the facility in which the provider seeks provider-based status, and not necessarily whether the building is 100 percent owned by the provider. The commenter believes we should rephrase this provision to require that the operations of that portion of the facility or organization in which the provider is seeking provider-based status be controlled by the provider.

Response: In response to the first comment, we recognize that many organizations enter into business relationships that involve overlapping of ownership, governance, and applicability of bylaws. However, this degree of collaboration does not mean that one facility is an integral and subordinate part of another. Therefore, we made no change based on this comment. Regarding the second comment, we wish to clarify that it is ownership of the business enterprise, not of the buildings or other physical assets of the enterprise, that is required under paragraph (b)(1). We have therefore revised the regulation text to refer to ownership of the business enterprise.

Comment: A commenter stated that the requirements contained in paragraph (d)(2) would preclude entities that are jointly owned through legitimate joint ventures or those separately organized subordinate facilities from qualifying for provider-based status. Additionally, to require the level of integration suggested by our proposed rule would prevent providers from establishing efficient systems of delegation and management, solely to qualify for provider-based status.

Response: We agree that this criterion would have the stated effect. As explained further in our discussion of comments on proposed § 413.65(e), facilities operated jointly by two or more providers cannot appropriately be considered integral and subordinate parts of either provider. With respect to the second comment, we do not oppose systems of operation that stress separate, decentralized operation where this leads to greater efficiency. However, we believe such facilities or organizations should be recognized as the separate enterprises that they are, not considered integral and subordinate parts of another institution.

Comment: A commenter suggested that the requirement under paragraph (d)(2) be modified for medically underserved populations and health manpower shortage areas.

Response: We are also concerned that our criteria not limit access to care for any vulnerable populations and have, to avoid this potential problem, created special provisions for FQHCs and IHS and tribal facilities. As described later in this preamble, we have also created an exception to the location requirements in paragraph (d)(7), which is designed to help avoid restricting access to primary care furnished by RHCs in remote, underserved areas. In view of these provisions, we do not believe it is necessary to also modify our requirement relating to ownership of the facility or organization.

Comment: A commenter stated that the proposed requirements in paragraph (d)(2) are inherently inconsistent with section 330 of the Public Health Service Act statutory and regulatory requirements and the Bureau of Primary Health Care expectations necessary to obtain and maintain section 330 funding (and FQHC status). The commenter believes HCFA should not require FQHCs to be 100 percent owned by the main provider or share a common governing body and common bylaws with the main provider. The commenter also suggested that we accept appropriate reporting relationships and satisfaction of other criteria (for example, licensure, quality assurance, integration of certain administrative and clinical functions, such as billing, purchasing, retention of medical records, quality assurance and utilization review procedures; and public awareness of the relationship between the health center and the main provider) as a sufficient basis for provider-based status.

Response: As described earlier, we have provided a special transition period for FQHCs. We believe this period will be adequate to avoid the problems envisioned in this comment.

Section 413.65(d)(3) Administration and supervision

Comment: A commenter recommended that the daily reporting relationship stated in § 413.65(d)(3) should be replaced with the standard of having the reporting relationships have the same intensity as on-site departments. The commenter stated that in practice at the hospital, there may be very little day-to-day contact between medical directors of various hospital services. Also, the commenter believes it is unlikely that departmental directors report directly to the chief executive officer, but rather to a chief operating officer or other designee. Finally, the commenter argued that under the common governance requirement, while all hospital employees are theoretically accountable to the governing body, the accountability may be directed through the CEO, and multiple executives may not have an independent reporting with the board. Another commenter also believes that the standards for the provider-based entity should mirror those of the main facility; personnel reporting structure needs to be respected within the regulations. Still another commenter found ''intensity'' to be a subjective standard and asked how it will be measured.

Response: We agree that reporting need not be daily in all cases, and have revised the final rule to state that 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 departments. We agree with the commenter that the intensity of supervision will have to be assessed on a case-by-case basis, but do not believe

this will lead to imprecise or poorly reasoned decisions.

Comment: Several commenters believe that this requirement limits the flexibility of the entity to operate efficiently and effectively in the current environment, since hospitals frequently turn to many specialized management companies to operate more efficiently and effectively than with hospital resources. Another commenter stated that whether the administrative department utilizes employees at one location and contracts at another location should be irrelevant as long as the function is integrated with the main provider, follows the policies and procedures of the main provider, and is accountable to the governing body of the main provider as is any other department. Still another disagreed, and believes that it may be appropriate to require that the main provider manage such contracts.

Response: We do not agree that the provision unreasonably limits hospital flexibility. Paragraph (3)(iii)(B) explicitly allows different management contracts to be used for the facility or organization and the main provider, as long as the provider manages the contracts. Thus, we did not make any changes in the proposal based on these comments.

Comment: A commenter asked whether the administrative functions listed in paragraph (d)(3)(iii) are the only services that must be integrated between the main provider and the subordinate facility.

Response: The commenter was correct in understanding that the functions listed are the only administrative functions that must be integrated. There are also requirements for integration of certain financial functions, as described below.

Comment: One commenter posed several questions concerning this proposed requirement. First, in a certain situation, the facility fee is billed to the intermediary by the hospital billing department using the provider number, while the professional fee is billed to the Part B carrier by the faculty practice billing organization under its physician group number. The commenter asked if the different provider number and tax identification impact on the provider-based status, and if there is a more appropriate way to obtain billing numbers for hospital-based clinics. Also, the commenter asked if clinic space can be shared by two clinics, when one is provider-based and one is free-standing, without impacting the provider-based status of the first clinic.

Response: In the circumstances described, the use of separate billing and tax identification numbers for provider and physician services would not adversely affect a facility's request for provider-based status, since such billings are required under Medicare to be separate in the case of services in hospitals. The question regarding sharing of space, however, can be answered only in the context of a specific case, and we expect that such decisions will be made by our regional offices.

Comment: With respect to the oversight of contracts under paragraph (3)(B)(iii)(B), several commenters stated that it is common for hospitals to subcontract out the billing for different departments, especially the hospital outpatient department, due to the complexity and number of claims. These commenters stated that while it may be appropriate to require the main provider to manage such contracts, departments other than the billing department should be permitted to perform this management function. One commenter suggested revising the criterion on billing under the integration of administrative functions to state, ''common billing or the contract for billing services is held by the provider where it is based.''

Response: We agree that departments other than the main provider's billing department may appropriately manage billing contracts, and have revised the criterion to state that the contract for a provider-based facility or organization must be managed by the main provider.

Section 413.65(d)(4) Clinical services

Comment: A commenter asked for clarification of paragraph (4)(iv) of this section, specifically concerning whether this language would require a Medicare certified HHA's improvement activities to be overseen by hospital medical staff, rather than the advisory committee as is now being done. The commenter believes that having the hospital medical staff overseeing the quality assurance activities of a HHA may not be appropriate or cost effective and may even slow the process of performance changes.

Response: The commenter is correct in understanding that compliance with this criterion would require oversight of a hospital-based HHA's quality improvement activities by the hospital's medical staff. We do not agree with the commenter that the outcome would be to substitute the judgment of the hospital for the HHA's own committee or that it would be inappropriate. The hospital conditions of participation contain a number of separate requirements that must be read together to make complete sense of this provision. Conditions spelled out at § 482.12 (Governing body), § 482.21 (Quality assurance), and § 482.22 (Medical staff) establish a chain of accountability in a hospital for the quality of care it provides. The requirements are clearly applicable to any activity (for example, provider-based entity) that is an integral part of the hospital. Thus, a quality improvement activity of the HHA is likely to be firmly grounded in the hospital's operating and governance fabric even when the group is ''established'' by the HHA, and staffed by employees and physicians who work primarily in home health. We would expect the linkages to be formal (that is, known to the governing bodies and medical staffs of both providers), and the quality assurance mechanisms interrelated to the extent that shared patients are the subject of the effort.

Comment: Regarding paragraph (d)(4)(v) of this provision, some commenters requested clarification of what is meant by a ''unified retrieval system,'' or for guidance as to what types of cross referencing are acceptable. Another commenter asked for an explanation of the practical expectations regarding the maintenance of medical records. Finally, a commenter expressed support for the requirement for a unified retrieval system (or cross references), saying the latter system would be used in States that mandate a unified system.

Response: We would like to clarify that what is intended is that a system be maintained under which both the potential provider-based entity or department of a provider and the main provider have access to the beneficiary's record, so that practitioners in either location can obtain relevant medical information about care in the other setting. We did not, however, make any changes in the requirement based on these comments.

Comment: A commenter believes that functions of operations should not be regulated to dissuade cost efficiency, and that laundry and housekeeping would be examples where shared services may not be the most effective manner of operation.

Response: We agree that in some cases it may be less expensive for a facility to obtain services independently, but continue to believe such separateness is an indicator that the facility is not an integral and subordinate part of a provider.

Comment: With regard to paragraph (d)(4)(vi) requiring integration of services of the main and provider-based entity, the commenter expressed concern about the potential impact of

this section on a patient's freedom of choice. The commenter believes that the entity's efforts to meet this standard would limit a patient's freedom of choice. The commenter suggested that we clarify our position so that providers acting in good faith will not be sanctioned for attempting to comply with this requirement.

Response: Paragraph (d)(4)(vi) requires only that patients have access to the services of the main provider and that they be referred to it where the referral is appropriate. We wish to clarify that these criteria are not intended to restrict patient freedom of choice or the practitioner's freedom to refer patients to other locations, where doing so will result in better care for the patient.

Section 413.65(d)(5) Financial integration

Comment: A commenter believes that § 413.65(d)(5), which requires full integration of financial operations, is too rigid. An alternative approach is suggested that would allow managers of provider-based entities to retain some control over both the resources and information required to administer these units.

Response: Section 413.65(d)(5) requires that there be financial integration of the potential provider-based facility or organization and the main provider, but does not preclude normal management control of resources. Thus, we made no change in the regulation based on this comment.

Comment: A commenter stated that the criteria for common resource usage of building, equipment, and service personnel is not even relevant for multi-campus systems or even buildings that are across the street from each other, much less off-site hospital outpatient departments.

Response: Although the provider-based program memoranda required that there be significant common resource usage of buildings, equipment, and service personnel on a daily basis, this requirement does not appear in the proposed rule. Thus, we made no change in the regulation based on this comment.

Comment: One commenter stated that the requirement for financial integration seems unnecessary in light of the requirement for 100 percent ownership by the main provider. The commenter stated that some providers may wish to segregate the operations of certain departments in their financial systems, and expressed the view that as long as the costs of a department can be adequately identified on the cost report, the practice should be acceptable.

Response: We do not believe that these two requirements are duplicative. On the contrary, in some cases a provider may own 100 percent of another facility or organization, but not be financially integrated with it, either because the other facility or organization is engaged in a different, non-health care activity, or because it is organized and operated separately from the main provider. In these circumstances, we believe the criteria on financial integration apply appropriately to deny provider-based status to separate facilities or organizations.

Section 413.65(d)(6) Public awareness

Comment: Section 413.65(d)(6) requires that provider-based entities be identified as part of the main provider organization. The commenter did not understand the importance of this criterion, particularly when the provider-based organization is licensed and Medicare certified separately from the main provider.

Response: The proposed rule would not apply this criterion to provider-based entities (which may participate separately as providers), but only to provider-based departments. In the latter case, we think it is not unreasonable for such a department to be expected to identify itself with the provider of which it claims to be a part.

Section 413.65(d)(7) Location in immediate vicinity

Comment: A commenter stated that if off-site RHCs cannot be considered provider-based, it will be much harder to deliver care in rural areas. The commenter asked that RHCs be allowed to continue as provider-based RHCs even though they are off campus.

Response: We continue to believe close physical proximity is an important indicator of provider-based status. We note, however, that paragraph (d)(7) does allow off-campus facilities to be treated as provider-based if they meet the criterion relating to service to the same patient population.

Comment: Many commenters believe that more specific tests of service to the same patient population are needed. One commenter suggested that an appropriate criterion would be that the proposed provider-based facility or organization be located within the same geographic area that accounts for a high percentage of patients in the main provider. The commenter believes this test is consistent with Program Memorandum No. 96–7 and with the qualification requirements for sole community hospitals. Other commenters suggested that the main provider's geographical service area be considered the area from which the main provider drew 80 percent of its Medicare inpatients for the previous three years.

Response: We agree that more precise criteria are needed. Therefore, we have revised the regulations to provide that a prospective provider-based facility or organization will be considered to serve the same patient population as the main provider if, during the 12-month period immediately preceding the first day of the month in which the application for provider-based status is filed with us, at least 75 percent of the patients served by the facility or organization seeking provider-based status reside in the same zip code areas as at least 75 percent of the patients served by the main provider. As an alternative, we would consider a facility or organization to serve the same patient population if, during the same 12-month period described above, at least 75 percent of the patients served by the prospective provider-based facility or organization who required the type of care furnished by the main provider received that care from the main provider. We require this ''same patient population'' test to be met for the 12-month period used to support an initial determination of provider-based status, and it must continue to be met for each subsequent 12-month period to justify a continuation of provider-based status. Application of population/geographic standards to newly established facilities or organizations is discussed below.

Comment: Commenters suggested we show some flexibility with regard to the definition of patient population for teaching hospitals. The commenter stated that it will not always be the case that the patient populations for the teaching program will be the same as the overall mix or patient population for the main provider.

Response: We recognize that patient populations will not be identical in all cases, and thus have adopted a patient population criterion under which there may be a divergence of up to 25 percent between the main provider and the facility or organization seeking provider-based status. We believe this provides a reasonable allowance for differences in patient population. Moreover, we note that under section 1886 of the Act, Medicare provides much flexibility for teaching hospitals in other ways, for example, under section 1886(h)(4)(E), permitting the counting of residents for purposes of payment to teaching hospitals for the time the residents spend in nonhospital settings.

Comment: Two commenters suggested that the criterion on service to the same patient population be dropped. One commenter believes the criterion is overly vague, could limit access to care as facilities seek to control their service patterns, and, in general, represents a geographically based approach that is out of keeping with modern technology and communications. Another commenter stated that the criterion is unclear, and providers could find it burdensome to assemble the data to show compliance. Other commenters shared the second commenter's concern, but instead of recommending elimination of the criterion, they suggested that a more administrable solution would be to use regional or state standards to define ''same geographic area,'' such as, health systems area, a specified mileage amount, or our wage area.

Response: As described above, we have developed a more precisely stated test of service to the same patient population. We believe that test will be clear and understandable, not impose unrealistic burdens on providers, and allow provider-based designations that parallel service patterns.

Comment: With respect to paragraph (d)(7)(i), a commenter asserted that many currently operating facilities that are treated as provider-based by us provide types of service that are the same as those of the main provider, but serve patient populations from different geographic areas. The commenter believes these entities provide care under the direction of, and utilize substantial services from, the main provider. An example would be the geographically separate campuses of a single parent hospital that are located at various sites throughout a region. The commenter suggested that such campuses be presumed to be provider-based if they provide substantially the same services as the main provider, do not exceed the size of the main provider, and comply with all other provider-based requirements. Another commenter stated that the ''same patient population'' requirement should not apply to multi-campus long term care hospital locations. These locations are fundamentally different from other provider-based entities that the regulation addresses, since a long-term care hospital main provider and its remote campus furnish the same services, and offer the same programs of care, but operate in slightly different geographic areas. The commenter suggested that so long as all of the strict financial and administrative integration requirements of the proposed provider-based regulation are satisfied, the ''same patient population'' requirements should not apply to long-term care hospitals. The result of this criterion would be that satellites will not be established in many underserved areas where long term services are needed. Another commenter believes a specialty facility, such as a long-term care hospital, should be exempt from the geographic proximity requirement if it can demonstrate that it will improve the quality of patient care, and offer services that are not otherwise provided in that area.

Response: We recognize that there may be some cases in which a hospital and another facility seeking provider-based status as a remote location of that hospital may meet most or all other criteria in § 413.65, yet not qualify because the two facilities serve different patient populations. However, we do not agree that this result should lead us to abandon the ''same patient population'' test. On the contrary, we continue to believe that criterion is a valid indicator of provider-based status. Thus, we did not revise the regulation based on this comment. In this context, we note that there is no Medicare rule that would prohibit a hospital from setting up another hospital in another area. We do not agree with the commenter's assumption that because the program memorandum and proposed rule were issued in response to situations primarily involving outpatient facilities, they can apply only to such facilities. On the contrary, we believe the policies set forth in these documents are equally applicable to inpatient facilities, and should be applied in the many cases in which a determination about inpatient facilities must be made. In particular, the rules apply to remote locations of long-term care and other hospitals that are main providers, as well as to satellite facilities of hospitals and hospital units that are excluded from the hospital inpatient prospective payment system. Remote locations and satellite facilities are discussed more fully earlier in this preamble, and ''satellite facilities'' are specifically described in our regulations in §§ 412.22(h) and 412.25(e). (As explained in that document, we are concerned that establishment of satellites by hospitals and units excluded from the inpatient PPS could lead to payment abuses, such as circumvention of certain payment caps mandated by section 4414 of the Balanced Budget Act of 1997, and we have therefore established special payment rules for those facilities. Facilities seeking to qualify as ''satellites'' under the inpatient payment criteria in §§ 412.22(h) and 412.25(e) would first need to comply with the provider-based requirements before being eligible for satellite status.) We have revised the final rule to clarify its application to remote locations of hospitals and satellite facilities.

Comment: The commenter believes that flexibility in the definition of ''located in the immediate vicinity'' needs to be met with additional considerations when viewing rural and underserved areas; for example, it should not be our intention to eliminate the provider-based designation of a rural health clinic (RHC), when the purpose of the RHC is to be an outreach to geographically isolated areas.

Response: We share the commenter's concern and have developed a special provision for RHCs, as described below.

Comment: A commenter believes that the requirement that provider-based entities serve the same population as the main provider could cause significant problems for RHCs. The unique situations addressed by hospital-based RHCs attempting to satisfy the health care needs of medically underserved areas should be considered as exceptions to the proposed rule.

Response: We continue to believe close physical proximity is an important indicator of provider-based status; however, we recognize that small rural hospitals and their RHCs may not be able to demonstrate that a substantial number of clinic patients receive services from the main provider. Small rural hospitals typically provide limited inpatient care compared to their urban counterparts, which may cause the RHC patients to seek inpatient service from other providers. In light of this, we believe small rural hospitals (less than 50 beds) that own and operate RHCs should not be expected to demonstrate that they serve the same patient population as the main provider. Therefore, we are revising the regulation to allow off-campus RHCs affiliated with small rural hospitals (less than 50 beds) to retain their provider-based status without satisfying that requirement.

Comment: Several commenters opposed the inclusion of paragraph (d)(7)(ii), since they view a State border as an arbitrary boundary inhibiting a hospital's ability to serve patients, which seems counterproductive. They also argued that a regulation that fails to recognize the operation of health care systems that function across State lines is unrealistic. Another commenter suggested that we rely on the proposal concerning serving the same patient population. It was also stated that in one case a provider can be located in a city

split by the State border with its related facility located one mile away, but in another state, while in another case, the provider and its subordinate facility can be a mile apart and in the same State. Another commenter believes that, since Medicare beneficiaries often cross borders for health care services, disallowing hospitals in these areas from establishing provider-based entities eliminates choices and prohibits the development of new services. The commenter recommended that we revise or eliminate this criterion. Another commenter suggested that LTHs and their satellites not be subject to this requirement if the main provider and its satellite are located in two contiguous States. Alternatively, the commenter suggested that we consider using the wage index areas as guidelines for the areas to be served by provider-based entities even if that area crosses State lines.

Response: After reviewing these comments, we have decided to revise the regulations to allow providers in one State to have provider-based facilities in an adjacent State, if doing so is not inconsistent with the law of either State, and other criteria are met, including those related to service to the same patient population.

Comment: With regard to paragraph (d)(7)(i), while the proposed rule permits a provider to show that a ''high percentage'' of patients of the main provider and the facility come from the same geographic region, new facilities would not have any historical data upon which to base this assertion, and therefore would fail to be able to demonstrate the criteria prior to operation. Another commenter believes the requirement may pose an impediment to new facilities being located in underserved or outlying areas. Thus, the commenters believe the same patient population requirement should not apply to new facilities, including new long-term care hospital satellites.

Response: We agree that it would be appropriate to establish a criterion that could be met by new facilities or organizations, and therefore have revised the final rule to include a special provision for new facilities or organizations. Under this revision, a new facility or organization, (one that has not been in operation for all of the 12-month period immediately preceding the first day of the month in which the application for provider-based status is filed with us), may be considered to meet the criterion on service to the same patient population, if it is located in a zip code area included among those that (during the 12-month period described above) accounted for at least 75 percent of the patients served by the main provider. We note that this provision would not be limited to long-term care hospitals' satellites or their remote locations, but would be available to all new facilities or organizations.

Section 413.65(e) Provider-based status not applicable to joint ventures

Comment: Several commenters expressed concern that this criterion would prohibit the use of joint ventures for entities that want to participate as provider-based entities, and argued that such a prohibition would unnecessarily restrict hospital flexibility. One believes this provision should be eliminated. Another commenter suggested modification of paragraph (d)(2) of the rule to establish majority ownership as the standard rather than 100 percent ownership. Still other commenters suggested that provider-based status for facilities or organizations run as joint ventures should be permitted, as long as the hospital at which the facility is located has the equipment or service under its control.

Response: We reviewed these comments carefully, but did not make any changes in the regulations based on them. When a facility or organization is run as a joint venture of two or more providers, it is by definition under their joint control, and therefore cannot be an integral and subordinate part of any individual provider. We have no interest in discouraging such ventures, but continue to believe they do not qualify as provider-based.

Section 413.65(f) Management contracts

Comment: Several commenters expressed the view that the criterion under which the staff of the facility or organization must be employed by the provider or another organization other than a management company is too restrictive, and should be deleted. One commenter argued that, if the written contract maintains the responsibility and control for services in the hands of the main provider, the employer of the staff working at the site is not relevant. Another believes the criterion will discourage economic efficiencies. If a provider is able to demonstrate integration and subordination of the off-site facility based upon other provider-based criteria, the fact that a hospital chooses to provide certain services either directly through its own employees or indirectly through an independent contractor/management arrangements is irrelevant. Another commenter argued that the proposed criterion is inconsistent with: the provision of the Medicare statute that expressly permits coverage of ''services under arrangement''; with the hospital conditions of participation that recognize that contractors may be used to furnish patient care services; and with the Provider Reimbursement Manual, which recognizes that providers commonly contract for management services and the costs of the contract services may be allowed under Medicare principles of reimbursement. Still another commenter believes the proposed criterion would negatively impact the therapy profession, and could impact the health and safety of Medicare beneficiaries.

Response: We do not believe the criterion is overly restrictive, nor do we agree that employment of the staff of a facility or organization is irrelevant to the question of whether that facility or organization is an integral and subordinate part of a provider. On the contrary, employment of the staff of such a facility or organization will normally give the provider significant control over it, thus promoting integration. Conversely, if a facility or organization is staffed by personnel who are employed by another entity that has only a contractual relationship with the provider, the facility or organization may well be an integral and subordinate part of the management company, not of the provider.

We also do not agree that the criterion is inconsistent with section 1861(w)(1) of the Act, which permits providers to make arrangements for the provision of specific health services, nor do we believe adopting this criterion will undercut the ability of providers to have selective services provided under arrangements. In this regard, we point out that existing Medicare policy, stated in section 207 of the Medicare Hospital Manual (HCFA Publication 10), emphasizes the need for the hospital to exercise professional responsibility for the arranged-for services, not merely to serve as a billing mechanism for the other party. This is consistent with our view that section 1861(w)(1) was intended to allow specific health care services to be furnished under arrangements, but was never meant to be a vehicle by which a provider could nominally operate a facility or organization, but, in fact, contract out its operation to another entity. Finally, we note that while there are various sections of the hospital conditions of participation and the Provider Reimbursement Manual that recognize the possibility that specialized health care services or management services may be provided under contract, this does not indicate that providers may

contract out entire departments or services while claiming them as provider-based. To clarify the scope of the requirement on contracted services, we have revised it to state that management staff of the facility or organization (rather than health care or support staff) need not be employed directly by the provider. We have also revised the rule to clarify that if staff of the facility or organization (other than management staff) are employed by an organization other than the management company or the provider, it must be the same organization that also employs the staff of the main provider.

Section 413.65(g) Obligations of hospital outpatient departments and hospital-based entities

Section 413.65(g)(1)

Because of the direct relationship between the proposed changes in this section and those in § 489.24(b), comments on both proposals are discussed later, under § 489.24(b), ''Special responsibilities of Medicare hospitals in emergency cases.''

Comment: A commenter requested clarification as to the application of the anti-dumping requirement in the home health setting.

Response: Section 413.65(g)(1) states that the EMTALA requirements apply to hospital outpatient departments. EMTALA requirements would not apply to off-campus provider-based entities that are not hospital departments, such as home health agencies.

Section 413.65(g)(2)

Comment: While one commenter agreed with the requirement under § 413.65(g)(2) for billing of physician services with the appropriate site-of-service indicator, another commenter also believes there should be clarification that correct billing is the responsibility of the entity performing the billing function. Both commenters suggested that the hospital notify physicians who do their own billing that they must use the correct indicator; they agree that it should not be the responsibility of the hospital.

Response: We agree that physicians (or those to whom they assign their billing privileges) are responsible for appropriate billing, but note that physicians who practice in hospitals, including off-site hospital departments, do so under privileges granted by the hospital. Thus, we believe the hospital has a role in ensuring proper billing.

Section 413.65(g)(5)

Comment: Presently, provider-based clinics bill Medicare for the facility charge on a UB–92 form, and the physician fee is billed separately on a HCFA–1500 form, while other payers may accept a single bill for both charges. A commenter believes it is inappropriate to mandate that two bills be submitted for all patients, as long as charges for similar services are uniform regardless of payer.

Response: As explained further below, we have revised the final rule to eliminate the part of this criterion relating to billing of services to non-Medicare patients. We believe this responds to this commenter's concern.

Comment: Many commenters stated that Medicare should treat a facility that claims a facility fee as being provider-based even when other payers do not do so, reasoning that as long as the hospital claims that the patient is an outpatient for Medicare purposes, the practices of other payers, with respect to similar patients, are not significant, and should be ignored. Another commenter believes this requirement should be eliminated, because, in the commenter's view, it has no bearing on the outpatient services delivered to Medicare beneficiaries, and therefore does not affect Medicare reimbursement. To illustrate, a large commercial insurer does not have the capability to accept certain types of outpatient claims from hospitals; therefore, it requires claims for those services to be billed on a physician claim form, so hospitals will receive the proper reimbursement. If this criteria is retained as proposed, many hospital-based departments would not meet our criteria due to the nuances of other payers' policies, that are often contractual issues with providers. Still another commenter believes that we should reexamine the proposal made in paragraph (g)(5), and at a minimum, clarify what it means by its proposal mandating uniform ''treatment of all patients, for billing purposes, as hospital outpatients.'' If we are proposing to mandate that all outpatients be billed on the same basis, this would effectively extend Medicare direct billing or rebundling rules to all payers. In addition, this proposed requirement would not only be contrary to past policy and practice, but would affect departments that have differentiated billing practices. Another commenter stated that payers typically determine payments based upon how they define a particular service or their individual market power; Medicare certification of outpatient departments should not be influenced by how unrelated third parties pay for services to the patients they cover at these sites. Moreover, this criterion would be very difficult to implement, because hospitals can have hundreds of contracts with insurance companies and the providers that subcontract for part of the risk for plans.

Response: After review of the comments on this section, we have decided to revise it to restrict the requirement for uniform billing to Medicare patients only, thus allowing hospitals to bill other payers in whatever manner is appropriate under those payers' rules. As revised, § 413.65(g)(6) states that hospital outpatient departments (other than RHCs) must treat all Medicare patients, for billing purposes, as hospital outpatients. The department must not treat some Medicare patients as hospital outpatients and others as physician office patients.

Comment: A commenter stated that there appears to be some confusion as to whether this requirement applies to ''departments'' or all facilities and organizations seeking provider-based status. Also, the commenter asked if there is a provision of the proposed rule that mandates that a facility fee be charged to patients of facilities and organizations receiving provider-based status.

Response: As noted earlier, the proposed rule would not apply this criterion to provider-based entities (which may participate separately as providers) but only to provider-based departments. Regarding the second issue, we have, as described in response to the preceding comment, revised the final rule to eliminate the criterion regarding billing of payers other than Medicare.

Section 413.65(g)(7)

Comment: A commenter stated that requiring written notice for each patient (presumably signed by the patient), would be an overly burdensome requirement, and requested that the requirement allow for a clear, prominently displayed sign in lieu of individual notice. Another commenter believes that the proposed requirement would apply a standard to hospital outpatient departments that is not applied to any other site of service.

Response: First, we emphasize that notice is required only for Medicare beneficiaries, not for all patients. We recognize that providing notice will generate some burden for the provider, but believe that the protection it affords to patients warrants the requirement. We considered allowing the notice requirement to be satisfied through the posting of signs, as recommended by one commenter, but concluded that use of individual written notices would more effectively ensure that each

beneficiary receives the necessary information. In response to the comment concerning settings other than hospital outpatient departments, we note that in other settings, a patient is unlikely to be misled as to what type of facility is the site of treatment, so provision of notice is not required. To avoid confusion as to when the requirement applies, we have revised the final rule to state that notice is required only if the hospital outpatient department or provider-based entity is not located on the campus of the hospital that is the main provider. We have revised this final rule to specify that the notice must be in writing, must be one the beneficiary can read and understand, and must be given to the beneficiary's authorized representative if the beneficiary is unconscious, under great duress, or for any other reason unable to read a written notice and understand and act on his or her own rights.

Section 413.65(g)(9) (redesignated in this final rule as Section 413.65(h), Furnishing all services under arrangement)

Comment: A commenter observed that § 413.65(g)(9) does not preclude an outpatient facility from obtaining a certain type of service from an off-site supplier. If this is correct, if the service is provided on-site in the hospital's outpatient facility, it is not clear how the proposed regulations are intended to be applied. It would appear that if the facility is looked at as a whole, all services are not provided ''under arrangements''; therefore, paragraph (g)(9) of this section would not preclude the facility from being recognized as provider-based. However, in this case, the commenter stated that both licensure and ownership requirements would be difficult to satisfy. In most cases, that portion of the facility that is operated ''under arrangements'' with the hospital will not be on the hospital's license, nor will that portion necessarily be owned by the hospital. Thus, the commenter urged that the ''under arrangements'' portion of an outpatient facility be excluded from the licensure and ownership analyses.

Response: We agree that where a facility offers a variety of services, provision of a single type of service under arrangement would not prevent the facility from meeting this criterion. The criterion could not, of course, be met by a facility that furnished only a specific type of service (such as physical therapy), and provided that service only under arrangement. In the case envisioned by the second commenter, the facility would be out of compliance with licensure and ownership requirements, as well as the requirement involving services under arrangement, and we would agree that it could not be provider-based.

Comment: A commenter asked for clarification of ''under arrangements'', in reference to our other regulations that contain these terms. Also, the commenter requested clarification on the types of services to which this standard applies, that is, direct patient care as opposed to facility related services.

Response: The term ''arrangements'' is defined in section 1861(w)(1) of the Act and the Medicare regulations § 409.3, in that ''arrangements'' refers to arrangements that provide that Medicare payment made to the provider that arranged for the services discharges the liability of the beneficiary or any other person to pay for the services. We wish to emphasize that the provision will apply to patient care services, not housekeeping, security, billing, or other services that are not patient care services but are needed to support their provision.

Section 413.65(h) Inappropriate treatment of a facility or organization as provider-based (redesignated in this final rule as paragraph (i))

Comment: This section establishes sanctions that may be used to address a main provider that has treated an entity as provider-based without our review and approval. A commenter believes that the investigation phase should precede the review of payments to the main provider. A commenter was also concerned that the individuals involved in these reviews and investigations are properly trained to make the required determinations.

Response: We believe review of payments will encompass two activities—investigation to determine whether applicable provider-based requirements were met, and a calculation of the amount of overpayment if they were not. Thus, investigation necessarily precedes recovery, but is a part of the overall effort, which is to reconsider payment amounts. To respond more effectively to concerns about how the review and recovery activities will occur, and to clarify the specific actions we will take in cases of inappropriate billing, we have reorganized paragraph (i) to deal separately with the processes of determination and review, recovery of overpayments, and the good faith effort exception. With respect to determination and review, we state that if we learn that a provider has treated a facility or organization as provider-based and the provider had not obtained a determination of provider-based status under this section, we will review current payments and, if necessary, take action in accordance with the rules on inappropriate billing in paragraph (j), investigate and determine whether the requirements for provider-based status in paragraph (d) of § 413.65 (or, for periods prior to October 10, 2000, the requirements in applicable program instructions) were met, and review all previous payments to that provider for all cost reporting periods subject to re-opening in accordance with § 405.1885 and § 405.1889 of this chapter. With respect to recovery of overpayments and the good faith exception, we have clarified that we will recover only the difference between the amount of payments that actually were made and the amount of payments that we estimate should have been made in the absence of a determination of provider-based status, and that recovery will not be made for any period prior to the effective date of these final rules if during all of that period the management of the entity made a good faith effort to operate it as a provider-based facility or organization, as described in paragraph (h)(3) of § 413.65. In response to the comment about the competence of individuals involved in these activities, we wish to emphasize that we will ensure that staff involved in these activities have the necessary expertise.

Comment: A commenter believes that it would be unfair to apply the proposed regulations retroactively, that is, to periods before the effective date of the final rule. Even though paragraphs (h) and (i) provide for a good faith exception, it is still unfair to provide that the conditions for this exception will apply prior to the effective date of the final regulation. The commenter requested that these sections be revised to provide that the period of recovery will not extend to any period prior to the effective date of the final regulations. Another commenter also believes that any payment changes be prospective (unless the hospital did not make a good faith effort to operate the site as provider-based).

Response: We agree that it would be inappropriate to apply the rules in paragraph (h) to any period prior to their effective date, and have revised the final rule to clarify that for such periods, we will make determinations based on the program memoranda or other instructions in effect at the time. However, the criteria in paragraph (i) that form the basis for a good faith exception were in effect prior to the issuance of these regulations. Regarding

the last comment, we cannot agree to ignore possible overpayments resulting from noncompliance with published criteria in effect at that time.

Comment: A commenter believes that the term ''good faith effort'' should be defined to provide more direction and opportunity to comply. Also, entities making ''good faith efforts'' should be given an opportunity to correct those factors or criteria that render it out of compliance with the provider-based requirements.

Response: The conditions under which a provider will be found to have made a good faith effort were clarified in § 413.65(i)(2), and have been restated in the final rule.

Section 413.65(i) Inappropriate billing (redesignated in this final rule as paragraph (j))

Comment: A commenter believes that suspending all payments for outpatient services to facilities that have billed inappropriately as provider-based entities until the provider can demonstrate that payments are proper is too onerous. Instead, the commenter suggested that we consider suspending the reimbursement differential between a provider-based entity and a nonprovider-based entity until a determination is made or the facility has had a reasonable opportunity to comply.

Response: We understand the commenter's concern and have revised the final rule to authorize partial suspension of payment (that is, a reduction in payment) to the extent needed to prevent creation of an overpayment to the provider. This rule will allow payment to continue at a reduced rate, thus avoiding creation of financial hardship for the provider. To describe more clearly how we will deal with instances of inappropriate billing, we have reorganized paragraph (j) of § 413.65 to spell out more clearly the actions we will take, and the extent to which payment will be adjusted. Specifically, we state that if we find that a facility or organization is being treated as provider-based without having obtained a determination of provider-based status under this section, we will notify the provider, adjust future payments, review previous payments, determine whether the facility or organization qualifies for provider-based status under this paragraph, and continue payments only under specific conditions. The notice to the provider will explain that payments for past cost reporting periods may be reviewed and recovered, that future payments for services in or of the facility or organization will be adjusted, and that a determination of provider-based status will be made.

We further state that we will not stop all payment in such cases, but instead, will 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 were met. We also explain that we will review previous payments and, if necessary, take action in accordance with the rules on inappropriate treatment of a facility or organization described above. The regulation states that we will determine whether the facility or organization qualifies for provider-based status under the criteria in this section. If we determine that the facility or organization qualifies for provider-based status, future payment for services at or by the facility or organization will be adjusted to reflect that determination. Even if the facility or organization does not qualify for provider-based status, however, we will continue paying, at an appropriately adjusted level, for a limited time period in order to avoid disruption of services to program beneficiaries at that site and to allow an orderly transition to freestanding status.

The notice of denial of provider-based status sent to the provider will ask the provider to notify us in writing, within 30 days of the date the notice is issued, as to 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 in a free-standing facility. If the provider indicates that the facility, organization, or practitioners will not be seeking to enroll, or if we do not receive a response within 30 days of the date the notice was issued, all payment will end as of the 30th day after the date of notice. If the provider indicates that the facility or organization, or its practitioners, will be seeking to enroll and meet other requirements for billing for services in a free-standing facility, payment for services of the facility or organization will continue, at the adjusted amounts described in paragraph (j)(2) of this section for as long as is required for all billing requirements to be met (but not longer than 6 months) if—

- The facility or organization, or its practitioners, submit 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, furnish all other information we need to process the enrollment application and verify that other billing requirements are met.

If the necessary applications or information are not provided, we will terminate all payment to the provider, facility, or organization as of the date we issue notice that necessary applications or information have not been submitted. We have clarified the final rule to state that these reductions will occur where inappropriate billing is or has been taking place.

Comment: A commenter believes that there are already existing mechanisms for overpayment and recoupment that may be used in the situations described in this section. At the very least, administrative actions of this type should be subject to time frames in order to protect providers from the impact of extended investigations.

Response: We plan to conduct any recovery efforts in accordance with applicable law and regulations on overpayment recovery. However, investigations may be complex and require examination of many records, and we do not agree that they should be limited by additional, self-imposed restrictions.

Comment: A commenter stated that a facility or organization that requests a provider-based determination prior to the effective date of the final rule, and meets the good faith requirements, should not be subject to recovery of overpayment for periods either before or after the effective date of the final rule. This will prevent disruptions to existing arrangements that meet the good faith exception during the time that the request is being processed.

Response: If we were to adopt this proposal, we would be guaranteeing an overpayment to providers who, for a specific time period, knowingly billed for services as those of provider-based entities, even though they met only a few of the provider-based criteria. Thus, we did not adopt this comment.

Comment: A commenter requested that the requirement found at paragraph (i)(2)(iii) be clarified to state that management is only responsible for professional services billed by the hospital.

Response: As explained earlier, we believe hospitals' privileging mechanisms give them adequate leverage to prevent inappropriate billing by practitioners using their facilities. Therefore, we did not adopt this comment.

Comment: As to the good faith criteria found in paragraph (i)(2), a commenter questioned why requirements related to public awareness were chosen for inclusion. An organization can represent itself to the public in any number of inaccurate ways in order to mislead our officials and others. The

commenter believes that we should focus our attention on more tangible expressions of good faith efforts to operate a provider based entity.

Response: We believe inclusion of this requirement is needed to help ensure that beneficiaries are protected from unexpected deductible and coinsurance liability. While we agree with the commenter that some providers may misrepresent the status of off-site facilities, we believe such providers cannot reasonably be said to have acted in good faith, and should not receive favorable treatment with respect to past overpayments.

Section 413.65(j) Correction of errors (redesignated in this final rule as paragraph (k))

Comment: A commenter disagreed with the language in this subsection that would allow us to review and rescind, if appropriate, any past determinations. The commenter believes that this subsection should be removed and any previous determinations should be grandfathered in under the new regulations. Other commenters recommended that we grandfather facilities or organizations that had previously been determined by the regional office to be provider-based, or that have not received such a determination but have been billing as provider-based without a determination for a period of at least ten years, so that those facilities or organizations could retain provider-based status even though they do not meet the criteria in the regulations.

Response: We do not agree that it would be appropriate to grandfather existing facilities or organizations, since this would in effect create an ongoing double standard, under which some facilities or organizations are held to higher standards than others. Moreover, the fact that improper billing may have continued undetected for a long period is not a reason to continue to permit such billing. As explained in the response to the following comment, however, any adverse determination regarding provider-based status of facilities or organizations which we previously determined were provider-based will not be effective until the start of the cost reporting period after the period in which the provider is notified of the redetermination, or for at least 6 months, whichever date is later.

Comment: A commenter believes that our proposal that we may review past provider-based determinations inserts needless uncertainty into the process for making provider-based designations. The commenter is concerned that providers may file before the final rule is published in order to avoid a crush of applications and subsequent disruption in payment, if they do not have a determination within 30 days of the rule becoming final. The commenter stated that providers need to be able to receive prompt determinations on which they can rely.

Response: We understand the concern about avoiding the need to process a large number of applications in a short time, and agree that it would not be appropriate to make abrupt changes in provider-based status. To avoid a possible crush of applications within a 30-day period, as envisioned by the commenter, we are providing the delayed effective date described earlier in this document. In addition, under § 413.65(j) of these regulations, when a facility or organization that previously was determined to be provider-based is found to no longer qualify for provider-based status, treatment of the facility or organization as provider-based will not cease until the first day of the first cost reporting period following notification of the redetermination, but not less than 6 months after the date the provider is notified of the redetermination. If there has been no prior determination of provider-based status, and a facility or organization is later found not to meet the criteria, that determination may be effective up to 6 months after the date the provider is notified of the determination, if within 30 days of the determination, the provider indicates that the facility or organization, or its practitioners, will enroll separately and, within 90 days, the facility or organization, or its practitioners, take other necessary action to enroll.

Section 489.24(b) Special responsibilities of Medicare hospitals in emergency cases

Comment: One commenter disagreed strongly with the proposed revisions to the regulation defining ''comes to the emergency department,'' and in particular expressed the view that patients arriving on the campus, sidewalk, driveway, or parking lot of hospital facilities should not be considered to have come to the emergency department. The commenter stated the view that an obligation under section 1867 of the Act (sometimes referred to as the Emergency Medical Treatment and Active Labor Act (EMTALA), after the original title of the legislation adding section 1867) and our regulations at §§ 489.20(l), (m), (q), and (r), and § 489.24 should be triggered only by a presentation to the emergency department, and that only in exceptional situations should EMTALA apply to someone not technically in the emergency department. The commenter recommended that the regulations be revised to state that in these cases, the hospital may rely on a variety of transport options, consistent with the individual's condition and established policies that are applied in a nondiscriminatory manner. The commenter also recommended that the statute be interpreted as requiring only that hospitals with emergency departments have policies and procedures to assure that a person who presents to the hospital requesting emergency services is provided a medical screening examination and, if needed, stabilization or an appropriate transfer.

Another commenter raised several arguments against the proposed change. The commenter stated that there is a legal and ethical conflict in requiring hospital personnel to leave an area of patient care and furnish assistance to another patient in a remote area of the hospital. The commenter also believes that ED personnel are not well-trained or practiced in immobilization or scene safety, and patients and staff may be put at risk if staff are asked to go into the field and render aid to a victim who needs the expert care and experience for which field emergency medical services (EMS) personnel are trained. Finally, the commenter expressed concern about possible increases in the liability insurance cost to hospitals as a result of the proposed change.

Response: We do not agree that the proposed language inappropriately extends the scope of hospitals' EMTALA responsibilities. On the contrary, existing regulations at § 489.24 make it clear that EMTALA applies to hospitals that offer services for emergency medical conditions, and we believe it would defeat the purpose of EMTALA if we were to allow hospitals to rely on narrow, legalistic definitions of ''comes to the emergency department'' or of ''emergency department'' to escape their EMTALA obligations. We would also note, as discussed further below, that there is no requirement that all areas of the hospital be equipped to provide emergency care or that treatment always be provided outside the emergency area or department. Similarly, there is no prohibition of appropriate transfers to other facilities where such a transfer is conducted in accordance with § 489.24. On the contrary, the intent of the revised regulation is to ensure that patients who come to the hospital and request examination or treatment for what may be an emergency medical condition are not denied EMTALA protection simply because they enter the

wrong part of the hospital or fail to make their way to the emergency room.

Comment: Two commenters recommended clarification of the applicability of section 1867 of the Act regarding transfer requirements to scheduled patients at an ''off-campus'' hospital site, to ensure that the movement of scheduled patients unexpectedly requiring a higher level of care to another site of the same hospital is not construed as a ''transfer'' under the emergency access law, and that only those patients taken from one hospital's off-campus facility to another hospital's emergency department or inpatient unit be considered ''transfers'' that must be in accordance with the requirements of section 1867.

Response: We agree that movement of a patient from one part of a hospital to another, including movement from a remote location to a main hospital campus, does not constitute a ''transfer'' for EMTALA purposes, nor does it require compliance with the appropriate transfer requirements in § 489.24(d). The final regulations at § 489.24(i)(3)(i) clarify this policy.

Comment: A commenter expressed the view that the proposed revision to § 489.24 does not recognize the role that EMS personnel play in emergency situations and the true medical benefit provided by EMS personnel to patients in emergency situations. The commenter recommended that language be included in the regulation to authorize hospitals' use of EMS in responding to emergency situations on hospital grounds.

Response: We agree that EMS personnel can play a valuable role in transporting patients to appropriate sources of emergency care. A hospital may not, however, meet its EMTALA obligations merely by summoning EMS personnel. EMS may be used appropriately in conjunction with an appropriate hospital response to treat and move an individual who is already on hospital property. We therefore did not make any change to these regulations to authorize exclusive use of EMS to respond to emergency situations on hospital property.

Comment: A number of commenters stated that the anti-dumping rules implemented under section 1867 of the Act (EMTALA requirements) and our regulations at §§ 489.20(l), (m), (q), and (r), and § 489.24 should apply to the hospital's main campus and to all emergency departments. However, they argued that it is not reasonable to apply these rules to outpatient departments located off-campus that would not be set up to provide emergency services. In the commenters' view, it should suffice that patients in an emergency situation be directed to the hospital's emergency room. Another commenter stated that EMTALA obligations should be limited to those hospital entities that hold themselves out as providing emergency services, and should not be enforceable anywhere outside the emergency department or anywhere on hospital property, including an outpatient department or provider-based entity. Another commenter stated that the enforcement of this requirement would lead to the elimination of service-specific outpatient departments located off a main campus, and asked that we reconsider our policy. One commenter expressed concern that patients identifying a facility as a hospital-based department could mistakenly assume it is equipped to handle emergency cases. Another commenter believes that hospitals should be required to have policies and procedures in place to assure that all parts of the hospital are prepared to deal with getting an individual the appropriate medical screening.

Response: Existing regulations at § 489.24(b) define ''hospital with an emergency department'' to include all hospitals that offer services for emergency medical conditions, not just those that have organized emergency rooms or departments. To the extent a hospital acquires or creates an off-campus location, identifies it to us and to the public as a part of that hospital, and claims payment for services at that location as hospital services, we believe it is not unreasonable to expect that hospital also to assume the obligations, including compliance with EMTALA requirements, which flow from hospital status. This principle does not mean, of course, that a hospital must have a fully equipped and staffed emergency department at each location. It also does not mean that every appearance by an individual at an off-campus hospital department that does not offer services for emergency medical conditions will necessarily trigger an EMTALA obligation on the part of the hospital. Individuals come to these departments for many medical purposes which may not involve potential emergency medical conditions. Under these circumstances, the hospital would not have an EMTALA obligation with respect to that individual. This principle does mean, however, that if an individual comes to an off-campus department of a hospital and a request is made for examination or treatment for a potential emergency medical condition, the hospital incurs an obligation to provide, *within its capability,* an appropriate medical screening examination and necessary stabilizing treatment. In some cases, the patient may need to be taken back to the main hospital campus for a full screening and/or stabilizing treatment. Under these circumstances, the hospital is responsible for moving the patient or arranging his or her safe transport, but this movement would not be considered a ''transfer'' under § 489.24(b), since the patient is merely going from one part of the hospital to another. If it is necessary to transfer the patient to another medical facility, the hospital must provide an appropriate transfer in accordance with § 489.24(d).

After review of the comments on this issue, we have decided to revise the regulations to state more clearly the extent of a hospital's EMTALA obligations with respect to patients who come to a hospital department located off the hospital's main campus. Provider-based entities, such as SNFs or HHAs, located off the hospital campus would not, of course, be subject to EMTALA since a patient coming to such an entity would not have come to the hospital. We will require that each off-campus hospital department, during its regular hours of operation, have in effect procedures for: (1) assessing the possibility that an emergency medical condition exists, and providing such screening (as defined in § 489.24(a) and (b)) and necessary stabilization (as defined in § 489.24(c)) at the off-campus site); (2) transporting the patient to the hospital's emergency room or department for screening and necessary stabilization meeting the requirements of § 489.24; or (3) providing an appropriate transfer to another facility in accordance with the requirements in § 489.24(c). To meet these requirements, the hospital will need to develop procedures that permit staff of the off-campus department to contact emergency physicians or other qualified emergency practitioners at the main hospital campus, to obtain advice and direction regarding the handling of any potential emergencies, and to obtain prompt medical transport, by hospital-owned or other ambulance or other appropriate vehicle, either to the main hospital campus or, where an appropriate transfer is being provided, to another medical facility.

Specifically, we are adding new paragraph (i) to § 489.24 to describe a hospital's obligations. The paragraph states that, if an individual comes to a facility or organization that is located off the main hospital campus as defined in § 413.65(b), but has been determined under § 413.65 of this chapter to be a department of the hospital, and a

request is made on the individual's behalf for examination or treatment of a potential emergency medical condition as otherwise described in paragraph (a) of § 489.24, the hospital is obligated to provide the individual with an appropriate medical screening examination and any necessary stabilizing treatment.

The capability of the hospital includes that of the hospital as a whole, not just the capability of the off-campus facility or organization. Except for cases described in paragraph (i)(3)(iii) (those in which the main hospital campus does not have the specialized capability or facilities needed to treat the individual, or the individual's condition is deteriorating so rapidly that transport to the main campus would significantly jeopardize the life or health of the individual), the obligation of a hospital under this section must be discharged within the hospital as a whole. However, the hospital is not required to locate additional personnel or staff to off-site locations to be on standby for possible emergencies.

In § 489.24(i)(2), Protocols for off-campus departments, we further state that the hospital must establish protocols for the handling of potential emergency cases at off-campus departments. These protocols must include provision for direct contact between personnel at the off-campus department and emergency personnel at the main hospital campus, and may provide for dispatch of practitioners, when appropriate, from the main hospital campus to the off-campus department to provide screening or stabilization services. The intent of these requirements is to ensure timely exchange of information between the two sites, and to allow the hospital the flexibility to bring emergency personnel to the patient, rather than the opposite, where doing so is the best medical approach to meeting the patient's needs.

Under the final rule, if the off-campus department is an urgent care center, primary care center, or other facility that is routinely staffed by physicians, RNs, or LPNs, these personnel must be trained, and given appropriate protocols, for the handling of emergency cases. At least one individual on duty at the off-campus department during its regular hours of operation must be designated as a qualified medical person as described in paragraph (d). The qualified medical person must initiate screening of individuals who come to the off-campus department with a potential emergency medical condition, and may be able to complete the screening and provide any necessary stabilizing treatment at the off-campus department, or to arrange an appropriate transfer.

The final rule further states that if the off-campus department is a physical therapy, radiology, or other facility not routinely staffed with physicians, RNs, or LPNs, the department's personnel must be given protocols that direct them to contact emergency personnel at the main hospital campus for direction. Under this direction, and in accordance with protocols established in advance by the hospital, the personnel at the off-campus department must describe patient appearance and reported symptoms and, if appropriate, arrange transportation of the individual to the main hospital campus (if the main hospital campus has the capability required by the individual, and movement to the main campus would not significantly jeopardize the individual's life or health), or assist in an appropriate transfer. Movement of the individual to the main campus of the hospital is not considered a transfer under this section, since the individual is simply being moved from one department of a hospital to another department or facility of the same hospital.

Finally, specific rules apply if the individual's condition warrants movement to a facility other than the main hospital campus, either because the main hospital campus does not have the specialized capability or facilities required by the individual, or because the individual's condition is deteriorating so quickly that taking the time required to move the individual to the main hospital campus could place the life or health of the individual in significant jeopardy. Under these circumstances, personnel at the off-campus department must, in accordance with protocols established in advance by the hospital, assist in arranging an appropriate transfer of the individual to a medical facility other than the main hospital. The hospital must have protocols to ensure that the movement is an appropriate transfer in accordance with paragraph (d)(2) of this section. The protocol must include procedures and agreements established in advance with other hospitals or medical facilities in the area of the off-campus department to facilitate these anticipated transfers. We note that the interpretive guidelines for enforcement of EMTALA requirements will be revised to conform to these new rules.

Section 498.3 Scope and applicability

Comment: A commenter asked for clarification as to whether appeal rights would be available in the event of revocation by us of provider-based status.

Response: We have revised § 489.3(b)(2) to specify that a determination that a facility or organization no longer qualifies for provider-based status is an initial determination, thus providing an administrative appeals mechanism for these decisions.

D. Requirements for Payment

We proposed to revise § 410.27, Outpatient Hospital Services and Supplies Incident to a Physician Service: Conditions, to require that services furnished at a location other than an RHC or an FQHC that we designate as having provider-based status under § 413.65 must be under the direct supervision of a physician as defined in § 410.32(b)(3)(ii).

Comment: Several commenters requested clarification of what we mean by ''direct supervision.'' One commenter asked that we further define the nature and extent of the supervision needed to comply with our proposal. One commenter asked whether the supervision requirement would be met if a physician is in the hospital or whether the physician must be in the department while the procedure is being performed. The same commenter asked whether the physician billing for the incident to services must be of the same specialty as the procedure being performed. A large trade association stated that we appear to be replacing our current policy in section 3112.4(A) of the Intermediary Manual, which states that we assume the physician supervision requirement to be met when incident to services are furnished on hospital premises, with a policy requiring direct physician supervision at all times, in all outpatient departments, regardless of whether or not they are located on the hospital campus. The commenter recommended that if we retain a direct supervision requirement, it should be limited to outpatient departments located off-site of the main provider. One commenter stated that facilities and organizations accorded provider-based status that are located on the main provider's campus should be subject to the same physician supervision requirements that apply to ''incident to'' services provided elsewhere on the campus.

Response: We regret that our proposal to define ''direct supervision'' by referring to the definition of ''direct supervision of a physician'' given at § 410.32(b)(3)(ii) may have been confusing to some commenters. Section 410.32(b)(3)(ii) defines ''direct supervision'' within (a physician) office

setting as meaning that the physician must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure. The definition at § 410.32(b)(3)(ii) goes on to state that ''direct supervision'' does not mean that the physician must be present in the room when the procedure is performed.

Our intention in the proposed rule was to define ''direct supervision'' of hospital outpatient services incident to physician services when they are furnished at a department of a hospital to mean that a physician must be present on the premises of the entity accorded status as a department of the hospital and, therefore, immediately available to furnish assistance and direction for as long as patients are being treated at the site. By ''direct supervision'' we do not mean that the physician must physically be in the room where a procedure or service is furnished. Nor does the supervising physician necessarily have to be of the same specialty as the procedure or service that is being performed. We emphasize that our proposed amendment of § 410.27 to require direct supervision of hospital services furnished incident to a physician service to outpatients applies to services furnished at an entity that is located off the campus of a hospital that we designate as having provider-based status as a department of a hospital in accordance with the provisions of § 413.65. Our proposed amendment of § 410.27 to require direct supervision of hospital services furnished incident to a physician service to outpatients does not apply to services furnished in a department of a hospital that is located on the campus of that hospital. For hospital services furnished incident to a physician service to outpatients in a department of a hospital that is located on the campus of the hospital, we assume the direct supervision requirement to be met as we explain in section 3112.4(A) of the Intermediary Manual. The requirement at § 410.27 does not affect the definition of physician supervision in section 3112.4(A) of the Intermediary Manual. In response to these comments, we have revised our definition of ''direct supervision by a physician'' in the final regulation.

Comment: A major trade association asserted that requiring a physician to be on-site at a provider-based entity throughout the performance of all ''incident to'' services would be burdensome and costly for hospitals where there are a limited number of physicians available to provide coverage, particularly in rural settings. Another commenter believes that entities with provider-based status should not be subject to physician supervision requirements that are more stringent than those applicable to free-standing facilities. A third commenter believes that this requirement is unnecessary because the requirements for integration with the hospital and other requirements for provider-based status include adequate checks and balances to ensure quality care. The commenter recommended that this proposal be omitted from the final rule with the potential for a separate, better defined, proposal at a later date.

Response: We disagree with commenters who believe the proposed supervision requirement is not necessary or that it would be burdensome to the hospital. First, the supervision requirement is separate from and independent of the provider-based requirements, and hospitals and physicians already have to meet a direct supervision of ''incident to'' services requirement that is unrelated to provider-based issues. That is, we require that hospital services and supplies furnished to outpatients that are incident to physician services be furnished on a physician's order by hospital personnel and under a physician's supervision (Intermediary Manual, section 3112.4(A)). We assume the physician supervision requirement is met on hospital premises because staff physicians would always be nearby within the hospital. The effect of the regulations in this final rule is to extend this assumption to a department of a provider that is located on the campus of a hospital. However, the regulation *does not* extend the assumption of supervision to a department of a hospital that is located off the campus of the hospital. We would not extend this assumption to a provider-based entity, regardless of its location, because the ''incident to'' requirement in § 410.27(a)(1)(iii) applies only to hospitals. Also, as we state above, satisfying the requirements to be designated provider-based is unrelated to our requirement that hospital services furnished incident to a physician service to outpatients at an entity that has provider-based status be under the direct supervision of a physician. Finally, this supervision requirement is entirely consistent with the direct supervision requirements currently set forth in the Medicare Carriers Manual, Part 3, section 2050.1(B).

Comment: One commenter suggested that partial hospitalization services furnished by a hospital to its outpatients be exempt from the outpatient department ''incident to'' requirements, or that other requirements be drafted that would, in the commenter's opinion, be more appropriate to the nature of this care.

Response: Section 1861(s)(2)(B) restricts coverage of partial hospitalization services furnished by a hospital to its outpatients to services that meet ''incident to'' requirements. We do not have the discretion to ignore this statutory restriction.

Comment: One commenter asked that we provide an exception to the direct supervision requirement in the case of physical therapy services. The commenter questioned why therapists who furnish the same services in a provider-based entity that they would furnish in an independent practice should be subject to direct physician supervision in one setting and not the other.

Response: The provision on coverage for outpatient physical therapy and occupational therapy services does not require that they be ''incident to'' physician services (see section 1861(s)(2)(D) of the Act). Therefore, there is no need to exempt them from the supervision requirement for outpatient hospital services incident to a physician service that is furnished at a provider-based entity. We therefore made no change in the final regulation based on this comment.

Comment: One commenter suggested that we modify our proposed regulation to waive the direct supervision requirement in entities with provider-based status for certain procedures for which we already waive the direct supervision requirement when the procedures are performed on homebound patients, as set forth in section 2051 of the Medicare Carriers Manual. The commenter believes that general supervision is sufficient for these waived services, for example, the physician need not be present, but the services must be performed under a physician's overall supervision and control, and ordered by a physician.

Response: Under section 2050.2 of the Medicare Carriers Manual, subject to certain requirements, we waive the direct supervision requirement when the following services are furnished to homebound patients: injections; venipuncture; EKGs; therapeutic exercises; insertion and sterile irrigation of a catheter; changing of catheters and collection of catheterized specimen for urinalysis and culture; dressing changes, for example, the most common chronic conditions that may need dressing changes are decubitus care and gangrene; replacement and/or insertion of nasogastric tubes; removal of fecal

impaction, including enemas; sputum collection for gram stain and culture, and possible acid-fast and/or fungal stain and culture; paraffin bath therapy for hands and/or feet in rheumatoid arthritis or osteoarthritis; and, teaching and training the patient for the care of colostomy and ileostomy, the care of permanent tracheostomy, testing urine and care of the feet (diabetic patients only), and blood pressure monitoring. While we believe the commenter's suggestion has merit, we do not believe it would be appropriate to adopt it before we have had time to analyze the issue further. Therefore, we did not revise the final rule based on this comment.

In our proposed rule, we proposed to require that the same supervision levels established for diagnostic x-ray and other diagnostic tests in accordance with § 410.32(b)(3) be required when these tests are furnished at an entity that has been accorded provider-based status by us.

Comment: A large industry federation generally favored our requiring that diagnostic tests be furnished at provider-based entities under levels of physician supervision that we specify, consistent with the definitions of general, direct, and personal supervision established at § 410.32(b)(3). The commenter suggested that we modify the definition of general supervision to make it clear that the training of nonphysician personnel and the maintenance of necessary equipment and supplies are the responsibility of the hospital, not the physicians.

Response: We agree and we will modify our regulation accordingly.

Comment: Numerous commenters, including radiology and imaging specialty groups, neurologists, vascular technologists, and sonographers, questioned the level of supervision required for various specific diagnostic tests and services.

Response: Our model for this proposed requirement was the requirement for physician supervision for diagnostic tests payable under the Medicare physician fee schedule that was issued in the October 31, 1997 physician fee schedule final rule (for CY 1998) (62 FR 59048). There have been issues raised about the appropriate level of supervision for some specific diagnostic services, similar to the comments we received about our proposed regulation. We have not yet resolved these issues, and this final rule is not the place to convey decisions about appropriate supervision levels for specific diagnostic tests and services by individual HCPCS code. In January 1998, we sent a memorandum to all Associate Regional Administrators advising them to instruct carriers to follow their existing policies on physician supervision of diagnostic tests until we provide further instruction. We intend to instruct hospitals and intermediaries to use the October 31, 1997 physician supervision requirements as a guide, pending issuance of updated requirements. In the meantime, fiscal intermediaries, in consultation with their medical directors, will define appropriate supervision levels for services not listed in the October 31, 1997 final rule when those services are furnished at an entity with provider-based status in order to determine whether claims for these services are reasonable and necessary.

V. Summary of and Response to MedPAC Recommendations

The following are additional recommendations contained in the report on Medicare payment policy that the Medicare Payment Advisory Commission submitted to the Congress in March 1999. (MedPAC, *Report to the Congress: Medicare Payment Policy,* March 1999.) We respond to recommendations that are specifically related to a particular component of the hospital outpatient PPS in the appropriate section of this preamble.

MedPAC Recommendation: MedPAC recommends that the Secretary evaluate payment amounts under the hospital outpatient PPS and the ambulatory surgical center (ASC) PPS along with the practice expense payments under the Medicare physician fee schedule for services furnished in physicians' offices to ensure that the differing payments made under the three payment systems do not create unwarranted financial incentives regarding site of care.

Response: We agree that the three payment systems should avoid creating unnecessary financial incentives to deliver care in particular settings. We will consider this matter further and evaluate differences in payments.

MedPAC Recommendation: MedPAC recommends that the Secretary study means of adjusting base prospective payment rates across ambulatory settings for patient characteristics such as age, frailty, comorbidities and coexisting conditions, and other measurable traits. Under this approach, payment would be less dependent on the type of facility and more dependent on the relative costliness of furnishing specific services to individual patients. MedPAC notes that no viable patient-level adjuster currently exists that could be used in this fashion.

As an interim measure, MedPAC recommends, with reservations, that HCFA evaluate facility-level adjustments in order to preserve access to care for particularly vulnerable segments of the Medicare population.

Response: The underlying premise in this recommendation, as MedPAC states, is that HCFA should move toward development of a more unified and rational payment system for ambulatory care. Many powerful arguments favor such a system, but the challenges of creating and implementing it are substantial. We will give further consideration to the recommendation to study possible adjustments that could be used in various settings.

We agree that we should evaluate the need for facility-level adjustments. We believe the best course is to evaluate the need for these adjustments during the next several years as we gain actual experience with the operation of the hospital outpatient PPS and are able to observe the effects on particular provider groups. In consideration of the transitional protections provided by the BBRA 1999, we have not adopted facility-level adjustments, other than an adjustment for local labor costs, at this time.

MedPAC Recommendation: MedPAC recommends that the Secretary seek legislation to develop and implement a single update mechanism that would link conversion factor updates to volume growth across all ambulatory care settings. These settings include hospital outpatient departments, physicians' offices, and ASCs, as well as other specific settings mentioned.

Response: We believe that this proposal requires further study to determine its feasibility and possible impact. Therefore, we are not prepared to seek legislation at this time.

MedPAC Recommendation: MedPAC recommends that we not use patient diagnosis to calculate relative weights or make payments for medical visits, ''given the current state of the available data and the lack of definitive rules for reporting patients' diagnoses under the proposed system.''

Response: As discussed in section III.C.3, we have dropped diagnosis from our characterization of medical visit APCs. We hope to develop procedure codes for medical visits that are more descriptive of hospital outpatient resource use, rather than physician services. Once we revise procedure coding to better reflect hospital services, we will assess whether accurate diagnosis coding further improves recognition of resources.

MedPAC Recommendation: MedPAC recommends that the Secretary closely

monitor the use of hospital outpatient services to ensure that beneficiary access to care is not compromised.

Response: We plan to evaluate the operation of the new PPS to address a variety of issues, including beneficiary access to care. We note that the provisions of the BBRA 1999 should mitigate substantially any payment reductions and hence the possibility of reduced access.

MedPAC Recommendation: MedPAC recommends that the Secretary consider making payment adjustments in addition to the proposed adjustment for local area wages under the new system. These adjustments should be tied to patient characteristics. The facility-level adjustments that are made until the time that a patient-level adjuster is available should reflect the population of Medicare patients treated by facilities identified to receive the adjustments.

MedPAC points out that HCFA, in setting Medicare payment rates for hospital inpatient services, adjusts payments based on the costs or provider characteristics of hospitals (for example, sole community hospitals). Rather than continuing this practice in the outpatient setting, MedPAC recommends that HCFA move toward making adjustments based on patient characteristics and the relative costliness of resources required in furnishing care to differing patients. Any differences in the payment of the same ambulatory care service should be based on patient characteristics, rather than on the setting. MedPAC recommends that HCFA evaluate any relationships between immutable patient characteristics and the cost of furnishing care.

Response: Other than those adjustments specified in sections 201 and 202 of the BBRA 1999, we have made no additional adjustments in this final rule. We will consider the possibility of adjustments in the future once we have actual experience with operation of the hospital outpatient PPS and can examine its effects. The extent to which adjustments at the level of patient characteristics will be feasible is unclear and would require further study.

VI. Provisions of the Final Rule

The provisions of this final rule reflect the provisions of the September 8, 1998 proposed rule, except as noted elsewhere in this preamble. Following is a synopsis of the major changes we have made, either in response to comments or in order to implement provisions of the BBRA 1999 that apply to the hospital outpatient prospective payment system.

For our proposal to adjust the CY 2002 update of the conversion factor by the percentage that actual CY 2000 payments exceed the estimated CY 2000 expenditure target, we are delaying implementation of the volume control mechanism for 2 years.

For our proposal to package costs that are directly related and integral to performing a procedure or furnishing a service on an outpatient basis, we are making the following changes:

- We are creating separate APC groups to pay for blood, blood products, and anti-hemophilic factors, for splints and casts, and for certain very costly drugs that are not included in the transitional pass-through payment provision.
- We are paying separately, at cost, for the acquisition of corneal tissue.
- As required by section 201(e) of the BBRA 1999, we are *not* paying for certain implantable items under the DMEPOS fee schedule, but are including them as covered outpatient services. We are packaging the costs of these items into the APC payment rate for the procedures or services with which they are associated. These include implantable items used in connection with diagnostic tests, implantable DME, and implantable prosthetic devices.

For our proposal to base payment for medical visits to clinics and emergency departments on diagnosis codes as well as HCPCS codes, we are not using diagnosis codes at this time.

For our proposal to classify a new technology procedure or service within the APC group that it most closely resembles in terms of clinical characteristics and resource utilization, pending collection of additional pricing data, we are creating separate APC groups to which we can temporarily classify new technology services while we gather additional data and gain pricing experience. We are also creating a process under which interested parties may submit requests for consideration of services that may be eligible for payment as new technology.

For our proposal to pay for drugs, pharmaceuticals, and biologicals (except for cancer therapy drugs and certain infrequently used but very expensive drugs) as part of the APC payment for the service or procedure with which they are used, we are establishing transitional pass-through payments, as directed by section 201(b) of the BBRA 1999. Under this provision, an additional payment will be made for current orphan drugs, current cancer therapy drugs, biologicals, and brachytherapy, and current radiopharmaceutical drugs and biological products.

For our proposal to classify a new or innovative medical device, drug or biological (for which we were not making payment as of December 31, 1996) within the APC group that it most closely resembles in terms of clinical characteristics and resource utilization, pending collection of additional pricing data, we are establishing transitional pass-through payments. Under this provision, as directed by section 201(b) of the BBRA 1999, an additional payment will be made for new or innovative devices, drugs, and biologicals whose cost is not insignificant in relation to the APC payment for the group of services with which they are used.

For our proposal not to establish an outlier adjustment, as directed by section 201(a) of the BBRA 1999, we will make an outlier payment when calculated bill costs exceed 2.5 times the PPS payment for a service.

For our proposal to determine comparability of resources and clinical characteristics among the codes within an APC group based on our claims data and the analyses and judgment of our medical advisors, supported by comments from medical specialty societies and trade associations, as provided in section 201(g) of the BBRA 1999, we are limiting the variation so that the highest median cost of an item or service in an APC group is no more than two times the lowest median cost of an item or service within that group. We will also consult with an expert outside advisory panel regarding the clinical integrity of the APC groups and weights as part of our update of the PPS.

For our proposal to periodically review and update payment weights, APC groups, and other elements of the hospital outpatient PPS, as required by section 201(h) of the BBRA 1999, we will annually review the groups, relative payment weights, and the wage and other adjustments that are a part of the PPS.

For our proposal to implement the hospital outpatient PPS fully and in its entirety for all hospitals beginning as early as possible in CY 2000, with no phase-in period, as required by section 202(a) of the BBRA 1999, we are establishing transitional corridors for services furnished before January 1, 2004 to limit losses facilities might otherwise face.

For our proposal not to make any adjustments for any specific classes of hospitals, we are holding small rural hospitals harmless through CY 2003 in accordance with the requirements set by section 202(a)(3) of the BBRA 1999,

which added section 1833(t)(7)(D)(i) to the Act. Also, we are holding cancer centers permanently harmless in accordance with the requirements set by section 202(a)(3) of the BBRA 1999.

For our proposal on beneficiary coinsurance payment amounts, we are limiting the coinsurance amount for a procedure to be no more than the hospital inpatient deductible, as specified in section 204(a)(3) of the BBRA 1999.

The following is a synopsis of the principal changes that we are making in the provider-based requirements:

For our proposal to require main providers and provider-based entities to share a common license, we will require common licensure only where State law permits it. Where State law prohibits it or is silent, we will not apply the licensure requirement. We will also exempt IHS facilities and facilities located on Tribal lands from this requirement.

For our proposal requiring a main provider and a provider-based entity to serve a common service area indicated largely by overlapping patient populations, we have redefined ''common service area'' to mean a 75 percent threshold of patients who reside in a zip code area that is common to the main provider and the provider-based entity.

For our proposal to require provider-based entities to be in the same State as the main provider, we will allow providers in one State to have provider-based facilities in an adjacent State, if doing so is consistent both with the law of the affected States and with other criteria, including those related to a common service area.

For our proposal to require that a provider-based outpatient department bill all payers as an outpatient department, we have rescinded this requirement.

For our proposal to require FQHCs that have been billing Medicare as hospital outpatient departments to comply with the provider-based requirements, we are grandfathering both FQHCs and FQHC ''look-alikes'' (facilities that are organized as FQHCs but do not receive grants) so that these facilities will be considered departments of providers without having to meet § 413.65 requirements.

For our proposal to apply the provider-based requirements to Indian Health Service (including tribally operated) entities, we are creating a permanent exception for those entities that were billing as departments of IHS or Tribal hospitals on or before October 10, 2000.

For our proposal to consider provider-based entities to be part of the hospital for Emergency Medical Treatment and Active Labor Act (EMTALA) (''anti-dumping'' purposes), we are maintaining the principle that off-site hospital facilities are subject to EMTALA. We have clarified the obligations of hospitals with respect to these locations to ensure they are consistent with staffing patterns and resources.

For our proposal to apply provider-based criteria to inpatient facilities such as multi-campus hospitals created by mergers and satellites of PPS-excluded hospitals that are created by hospitals leasing space in other hospitals, we have clarified the applicability of provider-based criteria to remote locations of hospitals and hospital satellite facilities.

VII. Collection of Information Requirements

Under the Paperwork Reduction Act (PRA) of 1995, we are required to provide 30-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 PRA 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.

We are soliciting public comment on each of these issues for the provisions summarized below that contain information collection requirements:

Section 413.24 Adequate cost data and cost finding

Section 413.24(d)(6)(ii) states that a provider must develop detailed work papers showing the exact cost of the services (including overhead) provided to or by the free-standing entity and show those carved out costs as nonreimbursable cost centers in the provider's trial balance. While these information collection requirements are subject to the PRA, the burden associated with these requirements is captured under §§ 413.65(c)(1) and (c)(2) below.

Section 413.65 Requirements for a determination that a facility or an organization is a department of a provider or a provider-based entity

Section 413.65(b)(2) states that a provider or a facility or organization must contact HCFA and the facility or organization must be determined by HCFA to be provider-based before the main provider begins billing for services of the facility or organization as if they were furnished by a department of the provider-based entity, or before it includes costs of those services on its cost report. While these information collection requirements are subject to the PRA, the burden associated with these requirements is captured under §§ 413.65(c)(1) and (c)(2) below.

Sections 413.65(c)(1) and (c)(2) state that a main provider that acquires a facility or organization for which it wishes to claim provider-based status, including any physician offices that a hospital wishes to operate as a hospital outpatient department or clinic, must report its acquisition of the facility or organization to HCFA and must furnish all information needed for a determination as to whether the facility or organization meets the requirements in paragraph (d) of this section for provider-based status, if the facility or organization is located off the campus of the provider or would increase the provider's total costs by at least 5 percent. Furthermore, a main provider that has had one or more entities considered provider-based also must report to HCFA any material change in the relationship between it and any provider-based facility or organization, such as a change in ownership of the facility or organization or entry into a new or different management contract that could affect the provider-based status of the facility or organization.

The burden associated with this requirement is the time for the main provider to report its acquisition to HCFA, furnish all information needed for a determination, report to HCFA any material change in the relationship between it and any provider-based facility or organization, such as a change in ownership of the facility or organization or entry into a new or different management contract that could affect the provider-based status of the facility or organization. It is estimated that 105 main providers will take 10 hours for a total of 1,050 hours.

Section 413.65(d)(4)(v) states that medical records for patients treated in a facility or organization must be integrated and maintained into a unified retrieval system (or cross reference) of the main provider. The burden

associated with this requirement is the time required for the main provider to maintain medical records in a unified retrieval system. While this requirement is subject to the PRA, we believe this requirement is a usual and customary business activity and 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(d)(7)(i) requires that for a facility or organization and the main provider that is not located on the same campus, the facility or organization must demonstrate 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 HCFA, and for each subsequent 12-month period meet the requirements of paragraphs (d)(7)(i)(A), (B), or (C) of this section. While the information collection requirements listed below are subject to the PRA, the burden associated with these requirements is captured under §§ 413.65(c)(1) and (c)(2).

Section 413.65(g)(7) states that when a Medicare beneficiary is treated in a hospital outpatient department or hospital-based entity, the hospital has a duty to notify the beneficiary, prior to the delivery of services, of the beneficiary's potential financial liability (that is, a coinsurance liability for a facility visit as well as for the physician service).

The burden associated with this requirement is the time for the provider to disseminate information to each beneficiary of the beneficiary's potential financial liability (that is, a coinsurance liability for a facility visit as well as for the physician service). It is estimated that 750 providers will make on average 667 disclosures on an annual basis, at 3 minutes per disclosure, for a total annual burden of 25,013 hours.

Section 413.65(j)(5) requires that upon notice of denial of provider-based status sent to the provider by HCFA, the notice will ask the provider to notify HCFA in writing, within 30 days of the date the notice is issued, of 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 in a free-standing facility. This requirement is exempt from the PRA as stipulated under 5 CFR 1320.4(a)(2).

Further, if the provider indicates that the facility or organization, or its practitioners, will be seeking to meet enrollment and other requirements for billing for services in a free-standing facility, the facility or organization must submit 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, furnish all other information needed by HCFA to process the enrollment application and verify that other billing requirements are met. The requirements and burden associated with the provider enrollment process are currently approved under OMB control number 0938–0685, with a current expiration date of September 30, 2001.

Section 424.24 Requirements for Medical and Other Health Services Furnished by Providers Under Medicare Part B

Section 424.24(e)(3)(i) requires that when a partial hospitalization service occurs the physician recertification must be signed by a physician who is treating the patient and has knowledge of the patient's response to treatment. While this signature requirement is subject to the PRA, the overall requirements associated with physician recertification, as currently referenced in HCFA regulation number HCFA–1006, published in the **Federal Register** on June 5, 1998, have not yet been approved by OMB under the PRA. Therefore, we continue to solicit comment on all of the requirements and associated burden referenced in § 424.24.

Section 419.42 Hospital Election To Reduce Copayment

Sections 419.42(b) and (c) state that a hospital must notify its fiscal intermediary of its election to reduce copayments no later than June 1, 2000 prior to the date the PPS is implemented or for subsequent calendar years, beginning with elections for calendar year 2001, no later than December 1 of the preceding calendar year. The hospital's election must be properly documented. It must specifically identify the ambulatory payment classification to which it applies and the coinsurance amounts (within the limits identified within this regulation) that the hospital has elected for each group.

The burden associated with these requirements is the time it takes a hospital to compile, review, and analyze data for both revenues and coinsurance; prepare and present the data to the hospital board; make a business decision as to whether the hospital would elect to reduce coinsurance; and then notify its fiscal intermediary of its election. A hospital would notify its fiscal intermediary of its election to reduce coinsurance only if there were other providers, in close proximity, that would attract a majority of the hospital's business if they did not reduce their coinsurance. Since hospitals do not want to lose money by absorbing coinsurance, we anticipate that this requirement will affect 750 hospitals and take them 10 hours each for a total of 7,500 hours.

Section 419.42(e) states that the hospital may advertise and otherwise disseminate information concerning the reduced level(s) of coinsurance that it has elected. All advertisements and information furnished to Medicare beneficiaries must specify that the coinsurance reductions advertised apply only to the specified services of that hospital and that these coinsurance reductions are available only for hospitals that choose to reduce coinsurance for hospital outpatient services and are not applicable in any other ambulatory settings or physician offices.

The burden associated with this requirement is the time for the hospital to disseminate information concerning its coinsurance election. It is estimated that 750 hospitals will each take 10 hours annually to disseminate this information via newsletters and information sessions at senior citizen centers for a total of 7,500 hours.

We have submitted a copy of this final rule to OMB for its review of the information collection requirements. These requirements are not effective until they have been approved by OMB. A notice will be published in the **Federal Register** when approval is obtained.

If you comment on any of these information collection and record keeping requirements, please mail copies directly to the following:

Health Care Financing Administration, Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards, Room C2–26–17, 7500 Security Boulevard, Baltimore, MD 21244–1850, Attn: John Burke HCFA–1005–FC/R–240,

and

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn.: Allison Herron Eydt, HCFA–1005–FC.

VIII. Response to Comments

Because of the large number of items of correspondence we normally receive on **Federal Register** documents published for comment, we are not able to acknowledge or respond to them individually. Comments on the provision of this final rule that implement provisions of the BBRA 1999 will be considered if we receive them by the date and time specified in the DATES section of this preamble. We will not consider comments concerning provisions that remain unchanged from the September 8, 1998 proposed rule or that were changed based on public comments.

IX. Regulatory Impact Analysis

A. Introduction

Section 804(2) of title 5, United States Code (as added by section 251 of Pub. L. 104–121), specifies that a ''major rule'' is any rule that the Office of Management and Budget finds is likely to result in—

- An annual effect on the economy of $100 million or more;
- A major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or
- Significant adverse effects on competition, employment, investment productivity, innovation, or on the ability of United States based enterprises to compete with foreign-based enterprises in domestic and export markets.

We estimate, based on a simulation model, that the effect on hospitals participating in the Medicare program associated with this final rule would be to increase Medicare payments by $600 million in calendar year 2000. This figure includes beneficiary copayments. We estimate that the additional expenditures to hospitals from the Part B Trust Fund associated with this final rule will be $490 million in fiscal year 2000. Therefore, this rule is a major rule as defined in Title 5, United States Code, section 804(2).

We have examined the impacts of this final rule as required by Executive Order 12866, the Unfunded Mandates Reform Act of 1995, and the Regulatory Flexibility Act (RFA) (Public Law 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more annually). Because the projected spending resulting from this final rule is expected to exceed $100 million, it is considered a major rule for purposes of the RFA.

The Unfunded Mandates Reform Act of 1995 also requires (in section 202) that agencies prepare an assessment of anticipated costs and benefits for any rule that may result in an expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million. This final rule does not mandate any requirements for State, local, or tribal governments.

We generally prepare a regulatory flexibility analysis that is consistent with the RFA (5 U.S.C. 601 through 612), unless we certify that a final rule will not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, we consider all hospitals to be small entities.

Also, section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis for any final rule that may have a significant impact on the operations of a substantial number of small rural hospitals. Such an analysis must conform to the provisions of section 604 of the RFA. With the exception of hospitals located in certain New England counties, for purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital with fewer than 100 beds that is located outside of a Metropolitan Statistical Area (MSA) or New England County Metropolitan Area (NECMA). Section 601(g) of the Social Security Amendments of 1983 (Pub. L. 98–21) designated hospitals in certain New England counties as belonging to the adjacent NECMA. Thus, for purposes of the proposed prospective payment system, we classify these hospitals as urban hospitals.

B. Estimated Impact on the Medicare Program

Our Office of the Actuary projects that the additional benefit expenditures from the Part B Trust Fund resulting from implementation of the hospital outpatient PPS for hospital outpatient services furnished on or after July 1, 2000, and the hospital outpatient provisions enacted by the BBRA 1999, are as follows:

Fiscal year	Impact (In millions of dollars)
2000	490
2001	3,030
2002	3,520
2003	4,230
2004	4,670

C. Objectives

The primary objective of the hospital outpatient prospective payment system is to simplify the payment system and encourage hospital efficiency in providing outpatient services, while at the same time ensuring that payments are sufficient to compensate hospitals adequately for their legitimate costs. Another important goal of the new system is to reduce beneficiaries' share of outpatient payment to hospitals by freezing coinsurance amounts at an absolute level until they equal 20 percent of the total payment amounts.

We believe that implementation of the final PPS will ultimately further each of these goals while maintaining the financial viability of the hospital industry and ensuring access to high quality health care for Medicare beneficiaries. We expect that the provisions of this final rule with comment period will ensure that the outcomes of the PPS are reasonable and equitable while avoiding or minimizing unintended adverse consequences.

D. Limitations of Our Analysis

The following quantitative analysis presents the projected effects of our policy changes resulting from comments, as well as statutory changes enacted by the BBRA 1999, on various hospital groups. We use the best data available. In addition, we do not make adjustments for future changes in such variables as volume and intensity. For this final rule with comment period, we are soliciting comments and information about the anticipated effects of the changes on hospitals resulting from implementation of the hospital outpatient provisions of the BBRA 1999, and our methodology for estimating them.

E. Hospitals Included In and Excluded From the Prospective Payment System

The outpatient prospective payment system encompasses nearly all hospitals that participate in the Medicare program. However, Maryland hospitals that are paid under a cost containment waiver in accordance with section 1814(b)(3) of the Act are excluded from the PPS. Critical access hospitals (CAHs) are also excluded and are paid at cost under section 1834(g) of the Act.

F. Quantitative Analysis of the Impact of Policy Changes on Payment Under the Hospital Outpatient PPS: Basis and Methodology of Estimates

We have analyzed the impact on hospital payment under the outpatient PPS. Our analysis compares the payment impact of PPS compared to current law. The definition and calculation of current law used in the impact analysis is the same used in estimating the conversion factor. That is, current law reflects pre-PPS payment methodologies in effect on January 1, 2000, and prior to July 1, 2000, which include the elimination of the formula-driven overpayment and application of the capital and operating cost reductions. A detailed explanation of the current law calculation can be found in section III.E.2.a.

The data used in developing the quantitative analyses presented below are taken from the CY 1996 cost and charge data and the most current provider-specific file that is used for payment purposes. Our analysis has several qualifications. First, we draw upon various sources for the data used to categorize hospitals in Table 2, below. In some cases, there is a degree of variation in the data from the different sources. We have attempted to construct these variables with the best available source overall. For individual hospitals, however, some miscategorizations are possible.

Using CY 1996 cost and charge data, we simulated payments using the pre-PPS and PPS payment methodologies. Although we used only single-procedure/visit bills to determine APC relative payment weights, we used both single and multiple-procedure bills in the conversion factor and service mix calculations, regressions, and impact analyses. Both pre-PPS and PPS payment estimates include operating and capital costs, adjusted to the calendar year 1996 cost reporting period. We excluded Kaiser, New York Health and Hospital Corporation, and all-inclusive providers because reported charges on their cost reports are not actual charges. Cost-to-charge ratios for these hospitals are not comparable to all other hospitals. The excluded Maryland hospitals were not included in the calculation of the conversion factor and the simulations; however, we did include the 10 cancer hospitals that will be paid under the PPS.

We also trimmed outlier hospitals from the impact analysis because inclusion of hospitals with extremely high and low unit costs would not allow us to assess the impacts among the various classes of hospitals accurately. First, we identified all of the outlier hospitals by using an edit of 3 standard deviations from the mean of the logged unit costs. Trimming the data in this manner ensures that only the hospitals with aberrantly high and low costs are eliminated from the impact analysis. In doing this, we removed 97 hospitals of which 41 hospitals had extremely low unit costs and 56 hospitals had extremely high unit costs. We conducted a thorough analysis of these hospitals to ensure that we did not remove any particular type of hospital (for example, teaching hospitals) that would further harm the integrity of the data. We speculate that many of these hospitals are not coding accurately, and we will continue to perform further analysis in this area following implementation of the PPS.

After we removed the 58 excluded Maryland hospitals, the all-inclusive rate hospitals, the statistical outlier hospitals, and hospitals for which we could not identify payment variables, we used the remaining 5,362 hospitals as the basis for our analysis. Table 2, Annual Impact of Outpatient Prospective Payment System in CY2000–CY2001, below, demonstrates the results of our analysis. The table categorizes hospitals by various geographic and special payment consideration groups to illustrate the varying impacts on different types of hospitals. The first column represents the number of hospitals in each category. The second column shows the hospitals' Medicare outpatient payments under the current (non-PPS) payment system as a percentage of the hospitals' total Medicare payment. The third and fourth columns show the impact of the PPS *excluding* the transitional corridor payments enacted by the BBRA 1999. Column three shows the percentage change in total Medicare outpatient payments comparing pre-PPS payments with payments under the PPS. The fourth column shows the change in *total* (outpatient and inpatient) Medicare payments resulting from implementation of the PPS for outpatient services. The fifth and sixth columns show the impact of the PPS *including* the transitional corridor payments enacted by the BBRA 1999. Column five shows the percentage change in Medicare outpatient payments comparing pre-PPS payments with payments under the PPS. Column six shows the change in total (outpatient and inpatient) Medicare payments resulting from implementation of the PPS for outpatient services.

The first row of Table 2 shows the overall impact on the 5,362 hospitals included in the analysis. We included as much data as possible to the extent that we were able to capture all the provider information necessary to determine payment. Our estimates include the same set of services for both pre-PPS and PPS payments so that we could determine the impact of the PPS as accurately as possible. Because payment under the hospital outpatient PPS can only be determined if bills are accurately coded, the data upon which the impacts were developed do not reflect all CY 1996 hospital outpatient services, but only those that were coded using valid HCPCS codes.

The second row of Table 2 shows the overall impact of the PPS on the 4,828 hospitals that remain when we exclude psychiatric, long-term care, children's, and rehabilitation hospitals.

The next four rows of the table contain hospitals categorized according to their geographic location (all urban, which is subdivided into large urban and other urban, and rural). We include 2,665 hospitals located in urban areas (MSAs or NECMAs) in our analysis. Among these, 1,505 hospitals are located in large urban areas (populations over 1 million), and 1,160 hospitals are located in other urban areas (populations of 1 million or less). In addition, we include 2,160 hospitals located in rural areas in our analysis. The next two groupings are by bed-size categories, shown separately for urban and rural hospitals. The next category groups urban and rural hospitals by volume of outpatient services. We then show the distribution of urban and rural hospitals by regional census divisions.

The next three categories group hospitals according to whether or not they have residency programs (teaching hospitals that receive an indirect medical education (IME) adjustment), receive disproportionate share hospital (DSH) payments, or some combination of these two adjustments. In our analysis we show the impact of the PPS on the 3,738 nonteaching hospitals, the 821 teaching hospitals with fewer than 100 residents, and the 269 teaching hospitals with 100 or more residents.

In the DSH categories, hospitals are grouped according to their DSH payment status. The next category groups hospitals considered urban after geographic reclassification, in terms of whether they receive the IME adjustment, the DSH adjustment, both, or neither. The next five rows examine the impacts of the changes on rural hospitals by special payment groups (rural referral centers (RRCs), sole community hospitals/essential access community hospitals (SCHs/EACHs), Medicare dependent hospitals (MDHs), and hospitals that are both SCHs and

RRCs), as well as rural hospitals not receiving a special payment designation. The RRCs (164), SCH/EACHs (634), MDHs (358), and SCH and RRCs (56) shown here were not reclassified for purposes of the standardized amount.

The next grouping is based on type of ownership. These data are taken primarily from the FY 1996 Medicare cost report files, if available; otherwise, earlier cost report data are used.

The final two groups are specialty hospitals. The first set includes eye and ear hospitals, trauma hospitals (hospitals having a level one trauma center), and cancer hospitals, which are TEFRA hospitals. The last group lists all other TEFRA hospitals, specifically, rehabilitation, psychiatric, long-term care, and children's hospitals.

G. Estimated Impact of the New APC System (Includes Table 2, Annual Impact of Hospital Outpatient Prospective Payment System in CY2000–CY2001)

Column 3 compares our estimate of PPS payments without application of the BBRA 1999 transitional corridors, but incorporating policy changes and all other BBRA 1999 provisions contained in this final rule, to our estimate of payments under the current system. The percent differences shown in columns 3 and 4 between current and PPS payment (without the BBRA 1999 transitional corridors) reflect the impact of the BBRA 1999 outlier and pass-through payment adjustments and nonbudget-neutral hold-harmless provisions for cancer hospitals, as well as distributional differences attributable to variation in cost and charge structures among hospitals.

The percent changes in columns 5 and 6 are the result of comparing our estimate of PPS payments with application of the BBRA 1999 transitional corridors, as well as the statutory and policy changes contained in this final rule, to our estimate of payments under the pre-PPS system. Percent differences between the pre-PPS and the PPS payment (with the BBRA 1999 transition) reflect the combined impact of the transitional corridor adjustments, outlier and pass-through payment adjustments and the hold-harmless provision for cancer hospitals, in addition to distributional differences attributable to variation in cost and charge structures among hospitals.

Basing the conversion factor on pre-PPS program and pre-PPS beneficiary payments and on budget-neutral outlier and pass-through adjustments results in no net change in payments to hospitals overall relative to pre-PPS payments. (As noted above, in section III.E.2 of this preamble, pursuant to section 201(l) of the BBRA 1999, we set the conversion factor by estimating pre-PPS rather than PPS copayments.) However, the BBRA hold-harmless provision for cancer hospitals results in a 0.2 percent increase in payments to hospitals overall because this provision is not budget neutral. Including the BBRA 1999 transitional corridor adjustments further increases payment to hospitals overall. We estimate that in calendar year 2000, payment will increase by an annual rate of 4.6 percent under the PPS compared to the pre-PPS payments.

Without the BBRA 1999 transitional corridor payments, the impact on short-term acute care hospitals is negative for a substantial number of hospital classifications. That is, for certain groups of hospitals, payments under the PPS without the transitional corridor payments would be several percentage points below pre-PPS payments. For nearly all of these hospital groups, the BBRA 1999 transitional corridor payments mitigate this negative impact. In addition, hospital groups that experience net gains without the BBRA 1999 transitional corridor payments experience even greater gains with them. The reason is that even though the average impact for hospitals in these groups is positive, some individual hospitals experience net losses in payments and, thus, benefit from the transitional corridor payments. The hospital groups that gain without the transitional corridor payments receive even greater increases in payments with the transitional corridor payments. The following discussion highlights some of the changes in payments among hospital classifications.

Comparing the pre-PPS and PPS payment estimates, payment to low-volume hospitals would decrease substantially without the BBRA 1999 transitional corridor payments (12.2 percent annually for rural and 7.7 percent annually for urban hospitals with fewer than 5,000 units of service). These hospitals experience a net gain with the BBRA 1999 transitional corridor payments (2.5 percent annually and 0.2 percent annually for low-volume rural and urban hospitals, respectively), although these payment increases are relatively small compared to the 4.6 percent annual increase for hospitals overall. We believe several factors contribute to this outcome, including undercoding, lack of economies of scale, and the reliance on the median instead of the geometric mean in the calculation of APC weights. The majority of these hospitals (about 75 percent) are rural. For these small hospitals, some of the higher standardized unit costs could be attributed to economies of scale. These low-volume rural hospitals also receive a greater percentage of their Medicare income (18.5 percent) from outpatient services than the national average (9.9 percent).

Major teaching hospitals, whose payments would decrease annually by 3.7 percentage points without the BBRA 1999 transitional corridor payments, gain 2.6 percent annually with the BBRA 1999 transitional corridor payments relative to pre-PPS payments. Major teaching hospitals receive less of their total Medicare income (9.1 percent) from outpatient services than the national average. This results in a 0.2 percent annual gain in their total Medicare payments. Minor teaching and nonteaching hospitals would experience marginal gains in outpatient payment without the BBRA 1999 transitional corridor payments. Payment to both hospital groups increases by 5.0 percent annually relative to the pre-PPS payment system.

Without the BBRA 1999 transitional corridor payments, hospitals with a high percentage of low-income patients (disproportionate share patient percentage greater than or equal to 0.35) would have a 2.5 percent annual decrease in payment relative to pre-PPS payments. But payments to these hospitals increase annually by 3.5 percent relative to pre-PPS payments with the BBRA 1999 transitional corridor payments. These hospitals have lower than average volume, and, like major teaching hospitals, receive a smaller than average percentage of their Medicare income from outpatient services. Thus, their total Medicare payments increase marginally, by 0.3 percent, with the BBRA 1999 transitional corridor payments.

Without the BBRA 1999 adjustments, payment to rural hospitals would decrease 1.8 percent annually and payment to large urban hospitals would decrease 0.3 percent annually, while payment to other urban hospitals would increase 1.8 percent annually relative to pre-PPS payments. These hospitals all experience net gains in PPS payment with the BBRA 1999 transitional corridor payments, at an annual rate of 4.4 percent, 4.3 percent, and 5.1 percent, respectively. Even though rural hospitals receive a greater percentage of their Medicare income (14.7 percent) from outpatient services compared to the national average, their total Medicare payments increase by only a fraction, 0.6 percent.

Negative impacts for urban hospitals in the Mid-Atlantic and the West North Central regions are also reversed under