adjustment factor that, when multiplied by the applicable CY 2010 ESRD wage index value, would result in aggregate payments to ESRD facilities that would remain within the target amount of composite rate expenditures. When making this calculation, the final ESRD wage index floor value of 0.6500 is applied whenever appropriate. The final wage BN adjustment factor is 1.057735 for CY 2010.

To ensure BN, we also must apply the wage index BN adjustment factor to the wage index floor of 0.6500 which results in an adjusted wage index floor of 0.6875 (0.6500 x 1.057735) for CY 2010.

General Comments

Comment: One commenter supports our proposal to maintain the existing case-mix adjusters and believes it will be important to maintain consistency in the current composite rate by preserving the current case-mix adjustors, given the anticipated shift to a bundled payment system.

Response: As explained earlier in this section, we did not propose any changes to the current basic case-mix composite rate payment system. We have maintained the current basic case-mix adjusters for CY 2010. We have proposed a number of patient-level adjusters in the new bundled ESRD PPS system, which are explained in detail in the ESRD PPS proposed rule (74 FR 49925 and 49926).

l. ESRD Wage Index Tables

The CY 2010 ESRD wage index tables are located in Addenda F and G of this final rule with comment period.

J. Discussion of Chiropractic Services Demonstration

1. Background

Section 651 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) requires the Secretary to conduct a 2-year demonstration to evaluate the feasibility and advisability of expanding coverage for chiropractic services under Medicare. Medicare coverage for chiropractic services is limited to manual manipulation of the spine to correct a subluxation described in section 1861(r)(5) of the Act. The demonstration expanded current Medicare coverage to include ‘‘care for neuromusculoskeletal conditions typical among eligible beneficiaries and diagnostic and other services that a chiropractor is legally authorized to perform by the State or jurisdiction in which such treatment is provided’’ and was conducted in four geographically diverse sites, two rural and two urban regions, with each type including a Health Professional Shortage Area (HPSA). The two urban sites were 26 counties in Illinois and Scott County, Iowa, and 17 counties in Virginia. The two rural sites were the States of Maine and New Mexico. The demonstration, which ended on March 31, 2007, was required to be budget neutral as section 651(f)(1)(B) of the MMA mandates the Secretary to ensure that ‘‘the aggregate payments made by the Secretary under the Medicare program do not exceed the amount which the Secretary would have paid under the Medicare program if the demonstration projects under this section were not implemented.’’

In the CY 2006, 2007, and 2008 PFS final rules with comment period (70 FR 70266, 71 FR 69707, 72 FR 66325, respectively), we included a discussion of the strategy that would be used to assess BN and the method for adjusting chiropractor fees in the event the demonstration results in costs higher than those that would occur in the absence of the demonstration. We stated BN would be assessed by determining the change in costs based on a pre-post comparison of Medicare costs for beneficiaries in the demonstration and their counterparts in the control groups and the rate of change for specific diagnoses that are treated by chiropractors and physicians in the demonstration sites and control sites. We also stated that our analysis would not be limited to only review of chiropractor claims because the costs of the expanded chiropractor services may have an impact on other Medicare costs. If the demonstration was not budget neutral, we anticipated making reductions in the CY 2010 and CY 2011 physician fee schedules. We indicated that if we determined that the adjustment for BN was greater than 2 percent of spending for the chiropractor fee schedule codes, we would implement the adjustment over a 2-year period. However, if the adjustment was less than 2 percent of spending under the chiropractor fee schedule codes, we would implement the adjustment over a 1-year period.

2. Analysis of Demonstration

Brandeis University, the demonstration evaluator, used two approaches in examining BN. The ‘‘All Neuromusculoskeletal Analysis (NMS)’’ reflects an intent-to-treat approach whereby the utilization of all beneficiaries who received any Medicare covered services for neuromusculoskeletal conditions in the demonstration areas was examined. This method is potentially subject to large external forces because of its inclusion of all beneficiaries including those who did not use chiropractic services and who would not become users of chiropractic services, even with expanded coverage for them. Therefore, a second analysis, termed the ‘‘Chiropractic User Analysis’’ was conducted to examine only the subset of beneficiaries who used chiropractic services for the treatment of their neuromusculoskeletal conditions. Both approaches use hierarchical linear modeling of costs over 3 years—1 year prior to the demonstration and the 2 years of the demonstration. We posted a report describing these analyses on CMS Web site at *http://www.cms.hhs.gov/reports/downloads/MMA651_BudgetNeutrality.pdf.*

The results of both analyses indicate that the demonstration was not budget neutral. In the ‘‘All NMS Analysis,’’ which compared the Medicare costs associated with NMS conditions for *all* beneficiaries in the demonstration areas with those of beneficiaries with similar characteristics from similar geographic areas that did not participate in the demonstration, the total effect of the demonstration to Medicare was $114 million. In the ‘‘Chiropractic User Analysis,’’ which compared the Medicare costs associated with NMS conditions for beneficiaries who used expanded chiropractic services in the demonstration areas, with those of beneficiaries with similar characteristics who used chiropractic services as currently covered by Medicare to treat a neuromusculoskeletal condition from similar geographic areas that did not participate in the demonstration, the total effect of the demonstration to Medicare was $50 million.

Both approaches to assessing BN have strengths and limitations. The ‘‘All NMS Analysis’’ provides the broadest view of the Medicare population that would have been eligible for the demonstration's expanded coverage of chiropractic services. Its inclusion of all beneficiaries with neuromusculoskeletal conditions guards against validity threats of selection. However, this approach creates a large heterogeneous group which may only include a small proportion of chiropractic service users. Basing estimates of BN on such a large heterogeneous group increases the potential for changes in the use of services seldom affected by chiropractors to be falsely attributed to the demonstration, which could result in the costs of the demonstration to appear larger than actual.

Consistent with the CY 2010 PFS proposed rule (74 FR 33520, 33639 through 33640), for this final rule with comment period, we continue to believe

that the BN estimate should be based on the ''Chiropractic User Analysis'' because of its focus on users of chiropractic services rather than all Medicare beneficiaries with neuromusculoskeletal conditions, including those who did not use chiropractic services and who would not have become users of chiropractic services even with expanded coverage for them. Users of chiropractic services are most likely to have been affected by the expanded coverage provided by this demonstration. Cost increases and offsets, such as reductions in hospitalizations or other types of ambulatory care, are more likely to be observed in this group. Therefore, as proposed, we are adjusting the Medicare PFS for all chiropractors using the estimate provided in the ''Chiropractic User Analysis.''

The CMS Office of the Actuary (OACT) estimates chiropractic expenditures in CY 2010 to be approximately $487 million based on actual Medicare spending for chiropractic services for the most recent available year. Because the costs of this demonstration were higher than expected and we did not anticipate a reduction to the PFS of greater than 2 percent per year, we are finalizing our proposal (74 FR 33639 through 33640) to recoup the $50 million in expenditures from this demonstration over a 5-year period rather than over a 2-year period. As proposed, we are recouping $10 million each year through adjustments to the PFS for chiropractic codes in calendar years 2010 through 2014. This approach reflects a change from our BN discussion in the CY 2006, 2007, and 2008 PFS rules, which was described previously in this section. In those rules, we had proposed that if the adjustment for BN was greater than 2 percent of spending for the chiropractor fee schedule codes, the adjustment would be implemented over a 2-year period. Under this final rule, we are recouping costs by reducing payment under the PFS for chiropractic fee codes by $10 million each year starting CY 2010 through CY 2014. We note that in the proposed rule, we proposed a 2 percent reduction in the chiropractic fee codes in order to achieve the $10 million yearly recoupment. We note that 2 percent was an approximation. Because of rounding, the $10 million recoupment in each of CYs 2010 through 2014 will amount to approximately a 2 percent reduction since the reduction in the chiropractic fee codes may be slightly higher or lower than 2 percent, depending on OACT's estimate of chiropractic expenditures for that calendar year. In order to reflect this fact, we are refining the language in this final rule to indicate that the chiropractic fee codes will be reduced by approximately 2 percent for CYs 2010 through 2014. Additionally, we believe that spreading this adjustment over a longer period of time will minimize its potential negative impact on chiropractic practices.

3. Payment Adjustment

To implement the required BN adjustment, as was proposed (74 FR 33640), we are reducing the payment amount under the PFS for the chiropractic CPT codes (that is, CPT codes 98940, 98941, and 98942). As explained previously, we are finalizing our plans to recoup $10 million each year through adjustments to chiropractic CPT codes for calendar years 2010 through 2014. In order to achieve the $10 million recoupment during such years, payment under the PFS for these codes will be reduced by approximately 2 percent. As stated in prior PFS rules, application of the BN adjustment would be specific to these three codes which represent the ''chiropractic fee schedule'' because they are the only chiropractic codes recognized under the PFS. This methodology also appropriately impacts the chiropractic profession that is directly affected by the demonstration. Consistent with the proposed rule, for this final rule with comment period, we are reflecting this reduction only in the payment files used by the Medicare contractors to process Medicare claims rather than through adjusting the RVUs. Avoiding an adjustment to the RVUs would preserve the integrity of the PFS, particularly since many private payers also base payment on the RVUs. The RVUs published in Addendum B and posted on our Web site will not show this reduction but will be annotated to state that the reduction resulting from the chiropractic demonstration is not reflected in the RVUs.

We received the following comments regarding the methodology used to evaluate BN in the chiropractic services demonstration.

Comment: Instead of the application of an adjustment to the national chiropractor fee schedule, the commenter believes the Congressional intent was for CMS to make an adjustment to the totality of services payable under the Part B Trust Fund because of the language in section 651(f)(A) of the MMA, which directs the Secretary to ''provide for the transfer from the Federal Supplementary Insurance Trust Fund * * * of such funds as are necessary for the costs of carrying out the demonstration projects under this section.''

Response: We disagree that the intent of section 651 of the MMA requires the application of a BN adjustment to the totality of services payable under the Part B Trust Fund. Specifically, section 651(f)(1)(B) of the MMA requires the Secretary to ''ensure that the aggregate payments made by the Secretary under the medicare program do not exceed the amount which the Secretary would have paid under the medicare program if the demonstration projects under this section were not implemented.'' This statutory provision does not specify a particular methodology for ensuring BN, but leaves that decision to the Secretary. Additionally, section 651(f)(1)(A) of the MMA, in pertinent part, provides that ''the Secretary shall provide for the transfer from the Federal Supplementary Insurance Trust Fund * * * of such funds as are necessary for the costs of carrying out the demonstration projects under this section.'' This provision merely indicates that payment for the demonstration is to be made from Part B Trust Fund dollars. Section 651(f)(1)(A) of the MMA does not specify in any manner the methodology by which the Secretary is to ensure BN. Consequently, we do not believe it is a mandate requiring the application of an adjustment to the totality of services payable under the Part B Trust Fund.

Comment: The commenter states that more information is necessary to fully understand the findings provided by the evaluator, Brandeis University. The commenter noted that the increase in costs from the demonstration was completely due to the Illinois site, and not the other sites, and that it is ''premature to use demonstration findings to estimate the cost of a national roll out * * * without further investigation of why the Chicago area is such an outlier.'' The commenter also asks how the increase in costs for all neuromusculoskeletal conditions could be causally related to the demonstration project.

Response: Regardless of the differences in the demonstration areas, the evaluation conducted by Brandeis University found that expanding coverage for chiropractic services under the demonstration resulted in increased Medicare expenditures, and the Secretary must recoup these costs in order to meet the BN requirement of the law. The decision to recoup funds is related to the results of the demonstration and the requirement in the law and not to the discussion in the

evaluation report of the costs of a national expansion of coverage.

With respect to the comment questioning how the increase in costs for all NMS conditions could be causally related to the demonstration, we are unsure of what the commenter is asking. If the commenter is asking if Medicare costs associated with all neuromusculoskeletal conditions were used in the evaluation, the response is no, only costs for specific NMS diagnoses that can be treated by chiropractors were included in the evaluation. If the commenter is asking for the rationale for the ''All NMS'' analysis, the response is that this analysis provides a broader view of all of the beneficiaries who would have been eligible for the expanded coverage under the demonstration. This analysis includes beneficiaries with the appropriate neuromusculoskeletal conditions who could have been treated by either a chiropractic physician or other medical physician. The intent-to-treat approach of the ''All NMS'' analysis guards against selection threats to validity. As mentioned previously in this section, we did not base the BN estimate on the ''All NMS'' analysis because it included Medicare beneficiaries who did not use chiropractic services and who would not have become users of chiropractic services even with expanded coverage for them.

K. Comprehensive Outpatient Rehabilitation Facilities (CORF) and Rehabilitation Agency Issues

A Comprehensive Outpatient Rehabilitation Facility (CORF) is a Medicare provider that furnishes respiratory therapy services among other services. In § 485.70, we set forth the personnel qualifications that must be satisfied by a CORF as a condition of participation under § 485.58 and as a condition of coverage of CORF services, including personnel qualifications for respiratory therapists providing CORF respiratory therapy services.

In the CY 2009 PFS proposed rule (73 FR 38502) and subsequent final rule with comment period (73 FR 69942), we revised the definition of a respiratory therapist under § 485.70(j). The change in the definition of respiratory therapist was intended to ensure accuracy in reference to persons who are qualified to perform respiratory therapy and to ensure that language regarding these professionals is consistent with current industry requirements for education, training, and practice.

Prior to its modification by the CY 2009 PFS final rule with comment period, § 485.70(j) reflected the qualifications for Certified Respiratory Therapists (CRTs)'' and ''Registered Respiratory Therapists (RRTs)'' as terms commonly used by the professional industry to identify persons furnishing respiratory therapy services.

Since publication of the CY 2009 PFS final rule with comment, we have been informed by the industry that the changes made in the definition of respiratory therapist exclude a category of professional that has completed the requirements of a CRT, has completed a nationally accredited educational program that confers eligibility for the National Board for Respiratory Care (NBRC) registry exam for respiratory therapists (RTs), and is eligible to sit for the national registry examination administered by the NBRC, but has not yet passed the examination. These persons are referred to in the industry as CRTs.

Because it is our policy that Medicare payment is available for respiratory services provided to Medicare beneficiaries in a CORF only if provided by a respiratory therapist meeting the qualifications set forth in § 485.70(j), payment is not available for respiratory services provided by CRTs in the CORF setting. We note that personnel qualifications for respiratory therapists previously set forth at § 485.70(j) prior to its modification by the CY 2009 PFS final rule with comment period did not exclude this category of personnel from the definition of respiratory therapist. We have also heard from CRTs and from CORFs that this change has limited the availability of respiratory therapy services to Medicare beneficiaries in certified CORFs, as many of these services are provided by CRTs. Thus, in modifying the definition of respiratory therapist in the CY 2009 PFS final rule with comment period, we may have inadvertently impacted access to respiratory therapy services for some Medicare beneficiaries.

Thus, we proposed to modify the definition of respiratory therapist and to clarify the terms that are used to identify those persons who furnish respiratory services in CORFs in § 485.70(j) to include CRTs, that is those individuals who have completed a nationally accredited educational program for respiratory therapists and are eligible to sit for the national registry examination administered by the National Board for Respiratory Care (NBRC), but who have not yet passed the examination. The change in the definition we proposed would permit CRTs to furnish respiratory therapy services to Medicare beneficiaries in the CORF setting.

As proposed, our intent was to assure that persons who were qualified to furnish respiratory therapy services to patients in CORFs prior to the finalization of CY 2009 PFS final rule with comment period (73 FR 69942), will continue to qualify to furnish RT services to CORF patients under this proposed rule.

We solicited public comment on the proposed change to § 485.70(j). We also solicited comments from the industry regarding the difference in services furnished by the different levels of professionals who provide RT services in CORFs.

The following is summary of the comments we received regarding the discussion of the proposed changes to § 485.70(j).

Comment: Commenters expressed strong support for the regulatory changes that we proposed, specifically the clarification of the professional qualifications for respiratory therapists (RTs) in the CORFs setting.

Response: We appreciate support for this regulatory change as we believe it is in the best interest of Medicare and Medicaid beneficiaries. As a result of the comments, we are finalizing these regulatory requirements as proposed.

L. Ambulance Fee Schedule: Technical Correction to the Rural Adjustment Factor Regulations (§ 414.610)

Section 1834(l)(9) of the Act provides that for ''ground ambulance services furnished on or after July 1, 2001, and before January 1, 2004, for which transportation originates in a rural area * * * or in a rural census tract of a metropolitan statistical area * * * the fee schedule established under this subsection shall provide that, with respect to the payment rate for mileage for a trip above 17 miles, and up to 50 miles, the rate otherwise established shall be increased by not less than ½ of the additional payment per mile established for the first 17 miles of such a trip originating in a rural area.'' Thus, the statute authorized a rural mileage bonus for miles 18 through 50 for ground ambulance services furnished on or after July 1, 2001 and prior to January 1, 2004. This provision was implemented in § 414.610(c)(5)(i), but the regulation text does not currently specify the statutory time period during which this rural mileage bonus was effective. In the ''Medicare Program; Coverage and Payment of Ambulance Services; Inflation Update for CY 2004'' final rule with comment period (68 FR 67960, 67961), we acknowledged that we inadvertently omitted from the regulation text the time period during which this statutory adjustment was