

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 413

[CMS-1435-IFC]

RIN 0938-AQ94

**Medicare Programs: Changes to the End-Stage Renal Disease
Prospective Payment System Transition Budget-Neutrality
Adjustment.**

AGENCY: Centers for Medicare & Medicaid Services (CMS),
HHS.

ACTION: Interim final rule with comment period

SUMMARY: This interim final rule with comment will revise the end-stage renal disease (ESRD) transition budget-neutrality adjustment finalized in the CY 2011 ESRD Prospective Payment System (PPS) final rule for renal dialysis services provided on April 1, 2011 through December 31, 2011. We are revising the transition budget-neutrality adjustment to reflect the actual election decision to receive payment under the ESRD PPS for renal dialysis services furnished on or after January 1, 2011 made by ESRD facilities, rather than projected elections using the same methodology as described in the ESRD PPS proposed and final rules. This results in a zero percent adjustment

for renal dialysis services furnished April 1, 2011 through December 31, 2011.

DATES: Effective date: April 1, 2011.

Comment date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on [OFR—insert date 60 days after the date of publication at OFR.]

ADDRESSES: In commenting, please refer to file code CMS-1435-IFC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed)

1. Electronically. You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the "Submit a comment" instructions.

2. By regular mail. You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1435-IFC,
P.O. Box 8010,
Baltimore, MD 21244-8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1435-IFC,
Mail Stop C4-26-05,
7500 Security Boulevard,
Baltimore, MD 21244-1850.

4. By hand or courier. If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC--
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Room 445-G, Hubert H. Humphrey Building,
200 Independence Avenue, SW.,
Washington, DC 20201

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy

of the comments being filed.)

b. For delivery in Baltimore, MD--
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
7500 Security Boulevard,
Baltimore, MD 21244-1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786-9994 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the "SUPPLEMENTARY INFORMATION" section.

FOR FURTHER INFORMATION CONTACT:

Terri Deutsch, (410) 786-9462.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as

possible after they have been received:

<http://regulations.gov>. Follow the search instructions on that Web site to view public comments.

Comments received timely will be also available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

I. Background

A. Establishment of the ESRD PPS Transition Budget-Neutrality Adjustment

On August 12, 2010, we published a final rule (75 FR 49030 through 49214) in the **Federal Register**, entitled "Medicare Program; End-Stage Renal Disease Prospective Payment System", hereinafter, referred to as the CY 2011 ESRD PPS final rule. In the CY 2011 ESRD PPS final rule, we implemented a case-mix adjusted bundled prospective payment system (PPS) for Medicare outpatient end-stage renal disease (ESRD) dialysis services furnished beginning January 1, 2011, in accordance with the statutory provisions set forth in section 153(b) of the Medicare Improvements for

Patients and Providers Act of 2008 (MIPPA).

Section 1881(b)(14) of the Social Security Act (the Act) requires a case-mix adjusted bundled ESRD PPS for renal dialysis services furnished by ESRD facilities beginning January 1, 2011, which replaces the basic case-mix adjusted composite payment system. Section 1881(b)(14)(E)(i) of the Act requires the Secretary to provide a "four-year phase-in" of the payments under the ESRD PPS for renal dialysis services furnished on or after January 1, 2011. For the purposes of this interim final rule with comment, the term "transition" will be used to describe the timeframe during which payments are based on the blend of the payment rates under the basic case-mix adjusted composite payment system and the ESRD PPS. Section 1881(b)(14)(E)(ii) of the Act permits an ESRD facility to make a one-time election prior to January 1, 2011, in a form and manner specified by the Secretary of the Department of Health and Human Services (the Secretary), to be excluded from the transition and be paid entirely based on the payment amount under the ESRD PPS.

As specified in regulations at 42 CFR §413.239(b)(1), ESRD facilities were required to notify their fiscal intermediary or Medicare administrative contractor (FI/MAC) of their election choice to either be included or excluded

from the 4-year transition period in a manner established by the FI/MAC no later than November 1, 2010. In addition, §413.239(b)(1) provides that once a decision is made, the election to be excluded from the 4-year transition cannot be rescinded. As required under §413.239(b)(3), ESRD facilities that became certified for Medicare participation and began to furnish dialysis services on November 1, 2010 through December 31, 2010, must have notified their FI/MAC of their election decision at the time of enrollment. For ESRD facilities that failed to make an election by November 1, 2010, §413.239(b)(2) requires that payment be based on the blended payment during the transition. Further, under §413.239(c), ESRD facilities that are certified for Medicare participation and begin furnishing renal or home dialysis services on or after January 1, 2011, are paid under the ESRD PPS.

Section 1881(b)(14)(E)(iii) of the Act requires that we make an adjustment to payments for renal dialysis services provided by ESRD facilities during the transition so that the estimated total amount of payments under the ESRD PPS, including payments under the transition, equal the estimated total amount of payments that would otherwise occur under the ESRD PPS without a transition. We refer to this provision as the transition budget-neutrality adjustment.

As described in the CY 2011 ESRD PPS final rule (75 FR 49082), the transition budget-neutrality adjustment is comprised of two parts. The first part created a payment adjustment under the basic case-mix adjusted composite payment system portion of the blended rate during the transition. The second part created a factor that would make the estimated total amount of payments under the ESRD PPS, including payments under the transition, equal the estimated total amount of payments that would otherwise occur without such a transition. In this interim final rule with comment, we are addressing the second part of the transition budget-neutrality adjustment finalized in the CY 2011 ESRD PPS final rule.

B. Transition Budget-Neutrality Adjustment

In the CY 2011 ESRD PPS final rule (75 FR 49082), we explained that section 1881(b)(14)(E)(iii) of the Act requires that we make an adjustment to payments for renal dialysis services furnished by the ESRD facilities during the transition so that the estimated total amount of payments under the ESRD PPS, including payments under the transition, equals the estimated total amount of payments that would otherwise occur under the ESRD PPS without such a transition. In calculating the transition budget-neutrality adjustment, we first determined the estimated increases in

payments under the transition and then determined an offset factor, based on certain assumptions of which facilities would choose to opt out of the transition (74 FR 49946). We explained that using estimates of simulated payments under the basic case-mix adjusted composite payment and under the ESRD PPS by facility, we estimated that 43 percent of the 4,951 ESRD facilities would choose to be excluded from the transition and that 57 percent of those ESRD facilities would choose to be paid the blended rate during the transition. As a result, we estimated that during the first year of the transition, total payments would exceed the estimated payments under the ESRD PPS in the absence of the transition (75 FR 49083).

In order to maintain the 98 percent budget-neutrality requirement in section 1881 (b) (14) (A) (ii) of the Act during the initial year of the transition period, we finalized the reduction of all payments to ESRD facilities in CY 2011 by a factor that is equal to 1 minus the ratio of estimated payments under the ESRD PPS if there were no transition, to the total estimated payments under the transition, or 3.1 percent. This approach resulted in a 3.1 percent reduction in all payments to ESRD facilities (that is, the 3.1 percent adjustment would be applied to both the blended payments made under the transition and payments made 100

percent under the ESRD PPS). We stated that we believed that because the application of the 3.1 percent reduction to all payments would evenly distribute the effect of the transition adjustment, it would not have affected the decision of ESRD facilities when choosing whether or not to opt out of the transition.

In the CY 2011 ESRD PPS final rule (75 FR 49082 through 49083), we acknowledged that the transition budget-neutrality adjustment may not reflect the actual choices made by the ESRD facilities regarding whether or not to opt out of the ESRD PPS transition. We also indicated that we were not able to wait until November 1, 2010, when ESRD facilities were to notify their respective FI/MACs, to establish the transition budget-neutrality adjustment. We explained that we based the final budget-neutrality adjustment on our best projections of how ESRD facilities would fare under the ESRD PPS compared to the basic case-mix adjusted composite payment system. We stated that we believed that ESRD facilities would choose to be excluded from the blended payment if payment under the ESRD PPS provided financial benefits. We also indicated that the transition budget-neutrality adjustment would be updated each year of the transition to reflect the appropriate blend of the PPS and composite rate payments. Finally, we noted

that given that the transition budget-neutrality adjustment applies in each transition year, we would consider whether we would prospectively correct for an over or understatement of the number of facilities that chose to opt out of the transition when we updated the adjustment for CY 2012.

The simulation (resulting in the 3.1 percent reduction) was based on determining which payment approach (that is, blended payments or 100 percent ESRD PPS payments) would financially benefit an ESRD facility. However, based upon analysis of the elections submitted by ESRD facilities, we found that the decision to receive payment under the blend or under the ESRD PPS did not appear to be based solely on which payment approach would be more financially advantageous. Rather than 43 percent of ESRD facilities electing to receive 100 percent payment under the ESRD PPS as was determined by simulating 2007 payments, 87 percent of ESRD facilities elected to opt out of the transition and elected to receive full payment under the ESRD PPS. We received elections from 5,645 ESRD facilities. Of the 5,645 elections received, 5,068 (or 90 percent) opted to receive payment under the ESRD PPS. We matched the 5,645 elections received in 2010 from ESRD facilities to the 4,951 facilities in 2007 that were used in the simulation. Of the 4,951 facilities, we received terminations for three

facilities and therefore, we removed those three facilities from our computation. In addition, we did not receive an election for 210 facilities. As §413.239(b)(2) requires that payment be made under the blend during the transition for facilities that fail to make an election by November 1, 2010, we considered the 210 facilities to have elected the transition. Therefore, after matching the 5,645 elections to the 4,951 facilities in 2007 (including 3 terminations and 210 assumptions), we determined that 4,324 of the 4,951 ESRD facilities in 2007 (or 87 percent) elected to receive payment under the ESRD PPS for CY 2011.

II. Provisions of the Interim Final Rule with Comment

In this interim final rule with comment, we are revising the ESRD transition budget-neutrality adjustment finalized in the CY 2011 ESRD PPS final rule (75 FR 49030 through 49214). We believe that this updated adjustment better reflects the actual elections made by ESRD facilities with regard to the transition because there is a significant difference between the projected and the actual number of ESRD facilities that elected to receive full payment under the ESRD PPS.

Subsequent to the publication of the CY 2011 ESRD PPS final rule, we received numerous comments from stakeholders including ESRD facilities and major ESRD associations

requesting that we not defer reconciling any discrepancies between the estimated simulated election decisions with the actual decisions made by ESRD facilities. These stakeholders cited many negative outcomes that would result from a 3.1 percent transition budget-neutrality adjustment reduction, including limiting or reducing renal dialysis services which would result in individuals with ESRD experiencing difficulties in accessing vital and life-sustaining dialysis services. Additionally, these stakeholders cited that as a result of the 3.1 percent transition budget-neutrality adjustment reduction, they would have difficulty recruiting and retaining staff, staff to patient ratios would decrease, and renal dialysis services could be limited.

We find these requests compelling specifically because the number of ESRD facilities electing to receive full payment under the ESRD PPS is substantially greater than the the number of facilities that we estimated would elect to receive full payment under the ESRD PPS and therefore, the assumption used in the simulation to calculate the transition budget-neutrality adjustment was understated. We believe that rather than provide for a prospective adjustment in CY 2012, it is important to revise the

transition budget-neutrality adjustment at this time for services furnished on April 1, 2011 through December 31, 2011.

As discussed in detail below, in this interim final rule with comment, we are revising the transition budget-neutrality adjustment by using the actual number of ESRD facilities that elected to receive 100 percent payment under the ESRD PPS. We believe that revising the transition budget-neutrality adjustment and eliminating the 3.1 percent reduction to payments in CY 2011, as discussed below, will mitigate difficulties cited above in patient access to renal dialysis services that could result from ESRD facilities limiting renal dialysis services due to the reduction in payments.

We are revising the transition budget-neutrality adjustment by re-calculating the transition budget-neutrality adjustment based on the actual elections received by the FI/MACs using the same methodology as described in the CY 2011 ESRD PPS proposed and final rules. This results in a zero percent adjustment. The zero percent adjustment is equal to 1 minus the ratio of the estimated payments under the ESRD PPS were there no transition (that is, 98 percent of total estimated payments that would have been made under the basic case-mix adjusted composite payment) to

the total estimated payments under the transition.

Therefore, in this interim final rule with comment, the revised transition budget-neutrality adjustment of zero percent will apply prospectively to renal dialysis services furnished April 1, 2011 through December 31, 2011. As discussed earlier, we are not changing the application of the transition budget-neutrality adjustment factor. We are applying the zero percent transition budget-neutrality adjustment to both the blended payments under the transition and payments under the ESRD PPS.

We note that in the analysis of the 2010 ESRD facility elections and in our computation of the revised transition budget-neutrality adjustment using actual facility elections that we are finalizing in this interim final rule with comment, we did not change the methodology that was described in the CY 2011 ESRD PPS proposed rule (75 FR 49944 through 49947) published on September 29, 2009, and finalized in the CY 2011 ESRD PPS final rule (75 FR 49030 through 49214) for determining the revision to the transition budget-neutrality adjustment that will apply to renal dialysis services furnished on April 1, 2011 through December 31, 2011; rather, we are merely changing the number of ESRD facilities that elected to opt out of the transition that was used in the transition budget-neutrality

calculation to reflect the actual rather than projected elections. All other provisions finalized in the CY 2011 ESRD PPS final rule remain unchanged.

III. Waiver of Notice of Proposed Rulemaking and the 30-Day Delay in the Effective Date

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** in accordance with 5 U.S.C. section 553(b) of the Administrative Procedure Act (APA) and invite public comment on the proposed rule. The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed, and the terms and substances of the proposed rule or a description of the subjects and issues involved. This procedure can be waived, however, if an agency finds good cause that a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued.

In addition, we ordinarily provide a 30-day delay in the effective date of the provisions of an interim final rule with comment. Section 553(d) of the APA (5 U.S.C. section 553(d)) ordinarily requires a 30-day delay in the effective date of final rules after the date of their publication in the **Federal Register**. This 30-day delay in effective date can be waived, however, if an agency finds

for good cause that the delay is impracticable, unnecessary, or contrary to the public interest, and the agency incorporates a statement of the finding and its reasons in the rule issued. In addition, similar notice-and-comment procedures and a 30-day delay in effective date are required, but can be waived under section 1871 of the Act.

We find good cause that it is unnecessary to undertake notice-and-comment rulemaking to revise the ESRD transition budget-neutrality adjustment by updating estimated figures with actual figures, because we are not changing our underlying methodology for computing or applying the transition budget-neutrality adjustment. The numbers we are updating pertain to elections made by ESRD facilities with regard to participation in the transition. Because we are not attempting to further project how ESRD facilities would behave and are instead using the actual number of the facilities that opted out of the transition, we find notice and the opportunity for public comment unnecessary.

In addition, we also find good cause to waive these procedures with regard to revising the transition budget-neutrality adjustment because it would be contrary to the public interest to maintain the adjustment finalized in the CY 2011 ESRD PPS final rule for the remainder of CY 2011. In particular, we believe that delaying the revision of the

transition budget-neutrality adjustment until the CY 2012 rulemaking in order to allow ESRD facilities an opportunity to comment on the revised adjustment that converts a 3.1 percent payment reduction to zero percent payment adjustment, could further decrease renal dialysis services to a vulnerable population that relies on these services to maintain their lives. For example, stakeholders have informed us that as a result of the 3.1 percent transition budget-neutrality adjustment reduction based on CMS' estimation of the ESRD facilities that would elect to receive full payment under the ESRD PPS, they will have difficulty recruiting and retaining staff, staff to patient ratios could decrease, and services could decrease due to decreases in staff and supplies. Therefore, we believe that delaying this revision could result in difficulties in access of care. We believe that revising the transition budget-neutrality adjustment in the way we discussed above and applying it without delay will mitigate these concerns and difficulties, and therefore, we find good cause to waive notice and comment rulemaking.

Also, for the reasons above, we believe that it is unnecessary and it is contrary to the public interest to delay the application of the revised transition budget-neutrality adjustment factor in order to provide for the

required 30-day delay in the effective date of this interim final rule with comment. Delaying the effective date for an additional 30 days would further delay revising the adjustment (and therefore, the underestimation of how ESRD facilities would elect to receive payment under the ESRD PPS) and would continue to place a financial burden on ESRD facilities.

Therefore, for the reasons stated above, we believe there is good cause to waive not only notice-and-comment procedures but also the 30-day delay in the effective date for this interim final rule with comment.

IV. Collection of Information Requirements

This interim final rule with comment does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

V. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the "DATES" section of this preamble, and, when

we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VI. Regulatory Impact Statement

We have examined the impact of this interim final rule with comment period as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year).

This is not a significant rule and we have determined that this interim final rule with comment does not have a significant economic impact. Therefore, we have not prepared an RIA.

With regards to the ESRD transition budget-neutrality adjustment, we believe that with a zero percent adjustment we are budget-neutral for payments made for renal dialysis services furnished on April 1, 2011 through December 31, 2011. The zero percent transition budget-neutrality adjustment applied to payments made to ESRD facilities for renal dialysis services furnished on April 1, 2011 through December 31, 2011 will increase payments to providers as compared to payments they would receive with a 3.1 percent transition budget-neutrality adjustment reduction. This will benefit all providers.

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of \$7.0 million to \$34.5 million in any 1 year. Individuals and States are not

included in the definition of a small entity. All ESRD facilities will receive a zero percent budget-neutrality adjustment to their payment for renal dialysis services furnished April 1, 2011 through December 31, 2011, instead of a 3.1 percent reduction, including small dialysis facilities. We are not preparing an analysis for the RFA because the Secretary has determined that this interim final rule with comment will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Social Security Act (the Act) requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because the Secretary has determined this rule does not have a substantial impact on small rural hospitals. Most dialysis facilities are free standing and we have determined that that this interim final rule with comment will not have a

significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2011, that threshold is approximately \$136 million. This rule will have no consequential effect on State, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Since this regulation does not impose any costs on State or local governments, the requirements of Executive Order 13132 are not applicable.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services are revising the 3.1 percent transition budget-neutrality adjustment reduction to a zero percent transition budget-neutrality adjustment for renal dialysis services furnished on April 1, 2011 through December 31, 2011.

CMS-1435-IFC

(Catalog of Federal Domestic Assistance Program No. 93.773,
Medicare--Hospital Insurance; and Program No. 93.774,
Medicare--Supplementary Medical Insurance Program)

Dated: March 18, 2011

Donald M. Berwick,

Administrator,

Centers for Medicare & Medicaid

Services.

Approved: March 29, 2011

Kathleen Sebelius,

Secretary.

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