effective date of this authorization until the timing and process for effective transfer to the State are mutually agreed upon. EPA and Virginia agree to coordinate the administration of permits in order to maintain consistency.

EPA will not issue any more new permits or new portions of permits for the provisions included in this revised authorization after the effective date of this authorization. EPA will continue to implement and issue permits for HSWA requirements for which Virginia is not yet authorized.

J. How Does This Action Affect Indian Country (18 U.S.C. 115) in Virginia?

Virginia is not seeking authorization to operate the program on Indian lands, since there are no Federally-recognized Indian lands in Virginia.

K. What is Codification and Is EPA Codifying Virginia's Hazardous Waste Program as Authorized in This Rule?

Codification is the process of placing the State's statutes and regulations that comprise the State's authorized hazardous waste program into the Code of Federal Regulations. We do this by referencing the authorized State rules in 40 CFR part 272. We reserve the amendment of 40 CFR part 272, subpart VV for this authorization of Virginia's revised program until a later date.

L. Administrative Requirements

The Office of Management and Budget has exempted this action from the requirements of Executive Order 12866 (58 FR 51735, October 4, 1993), and therefore this action is not subject to review by OMB. This action authorizes State requirements for the purpose of RCRA 3006 and imposes no additional requirements beyond those imposed by State law. Accordingly, I certify that this action will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Because this action authorizes pre-existing requirements under State law and does not impose any additional enforceable duty beyond that required by State law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). For the same reason, this action would not significantly or uniquely affect the communities of Tribal governments, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). In any case, Executive Order 13175 does not apply to this rule since there are no Federally recognized tribes in Region 3.

This action will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because it merely authorizes State requirements as part of the State RCRA hazardous waste program without altering the relationship or the distribution of power and responsibilities established by RCRA. This action also is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because it is not economically significant and it does not make decisions based on environmental health or safety risks that may disproportionately affect children. This rule is not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355 (May 22, 2001)) because it is not a significant regulatory action under Executive Order 12866.

Under RCRA 3006(b), EPA grants a State's application for authorization as long as the State meets the criteria required by RCRA. It would thus be inconsistent with applicable law for EPA, when it reviews a State authorization application, to require the use of any particular voluntary consensus standard in place of another standard that otherwise satisfies the requirements of RCRA. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. As required by section 3 of Executive Order 12988 (61 FR 4729, February 7, 1996), in issuing this rule, EPA has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct. EPA has complied with Executive Order 12630 (53 FR 8859, March 15, 1988) by examining the takings implications of the rule in accordance with the Attorney General's Supplemental Guidelines for the Evaluation of Risk and Avoidance of Unanticipated Takings issued under the executive order. This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this document and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. Although this action is not a ''major rule'' as defined by 5 U.S.C. 804(2), this action will be effective June 2, 2008.

List of Subjects in 40 CFR Part 271

Environmental protection, Administrative practice and procedure, Confidential business information, Hazardous waste, Hazardous waste transportation, Indian lands, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements.

Authority: This action is issued under the authority of sections 2002(a), 3006 and 7004(b) of the Solid Waste Disposal Act as amended 42 U.S.C. 6912(a), 6926, 6974(b).

Dated: March 18, 2008.

William T. Wisniewski,

Acting Regional Administrator, EPA Region III.

[FR Doc. E8–6724 Filed 4–2–08; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 422 and 423

[CMS–4133–F]

RIN 0938–AP25

Medicare Program; Modification to the Weighting Methodology Used To Calculate the Low-Income Benchmark Amount

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

ACTION: Final rule.

SUMMARY: This final rule changes the weighting methodology used to calculate the low-income benchmark premium amount (benchmark) for 2009 and thereafter. Under this final rule, the benchmark weighting methodology is adjusted so that the relative weights of the Medicare Advantage Prescription Drug (MA–PD) plan premiums and Prescription Drug Plan (PDP) plan premiums in the low-income benchmark premium amount reflect the

distribution of enrollment of beneficiaries eligible for the low-income subsidy in each plan.

DATES: *Effective Dates:* These regulations are effective on May 31, 2008.

FOR FURTHER INFORMATION CONTACT: Deondra Moseley, (410) 786–4577. Meghan Elrington, (410) 786–8675.

SUPPLEMENTARY INFORMATION:

I. Background

The beneficiary premiums for Prescription Drug Plans (PDPs) are based on an annual bidding process. Each year the beneficiary premium for a Part D plan can change as a result of this bidding process. In addition, each year, as required by statute, CMS recalculates the Federal Part D premium low-income subsidy (LIS) available to low-income beneficiaries based on the new premiums for plans in each region. As a result of these premium and subsidy changes, the premium for a Part D plan can be fully covered by the LIS in one year and not the following year.

The amount of the premium subsidy available to LIS-eligible individuals cannot be calculated until after bids are submitted for the calendar year in question, because the subsidy amount is based on the bids that are submitted. Therefore, a PDP sponsor whose premium for LIS-eligible enrollees is currently zero does not know at the time its bid is submitted whether the premium that would result from its bid will be higher or lower than the premium subsidy amount.

LIS-eligible individuals enrolled in a PDP that does not charge them a premium are faced with the possibility that the plan they are enrolled in will impose a premium during the next calendar year that would require them to make monthly payments. Section 1860D–1(b)(1)(C) of the Social Security Act (the Act) mandates the initial enrollment of full-benefit dual eligible individuals not choosing a plan into a PDP where they would not pay a premium. It does not, however, require that individuals be reassigned to a plan that would not charge them a premium, if they would be required to pay a premium in their plan the following calendar year. Using our authority under Section 1860D–1(b)(1)(A) of the Act to, ''establish a process for the enrollment, disenrollment, termination, and change of enrollment of Part D eligible individuals in prescription drug plans,'' we have specified that LIS-eligible individuals facing the above situation may ''elect'' a PDP with no premium (to which they would be randomly assigned) by taking no action. We have referred to this process as our reassignment process. Beneficiaries eligible for the full low-income premium subsidy who have not chosen a plan on their own, including beneficiaries dually eligible for benefits under Titles XVIII and XIX of the Act, are subject to reassignment. Beneficiaries eligible for a partial premium subsidy are not subject to reassignment.

For 2008, the number of beneficiaries reassigned to a different organization under this process varied widely by region, ranging from as few as 17 beneficiaries to approximately 402,322 beneficiaries. The average number of beneficiaries reassigned to an organization other than the one with which they were enrolled was 34,044 per region. Alternatively, LIS beneficiaries can affirmatively elect to stay in their plan and begin paying a premium, or choose another plan with or without a premium.

While the reassignment policy prevents an LIS-eligible individual who did not choose to elect a plan from being charged a premium, it disrupts continuity and stability in coverage. Individuals who are reassigned may have to change their pharmacy, get new copies of their prescription from their doctor, and determine whether they need a change in medications because the formulary might be different.

Currently, under the demonstration project entitled, ''Medicare Demonstration to Transition Enrollment of Low-Income Subsidy Beneficiaries'' (established in 2007 and extended to 2008), if the premium amount for a LIS-eligible individual in the above situation is lower than a specified ''de minimis'' amount, the individual would not be charged this de minimis amount, and could remain in his or her current plan without paying a premium. This demonstration also transitions the calculation of the low-income benchmark premium amount for a region from a method that weights the standardized Part D bids for PDPs equally to the statutory method required under the current regulation, which calculates the benchmarks by weighting the bids for PDPs and Medicare Advantage Prescription Drug (MA–PD) plans in that region based on each plan's share of total Part D enrollment. While the evaluation for this demonstration project is still underway, we believe it has demonstrated the advantages of continuity of care and stability.

In the proposed rule published on January 8, 2008, ''Option for Prescription Drug Plans to Lower their Premiums for Low-income Subsidy Beneficiaries'' (73 FR 1301), we proposed an approach to reducing the disruption caused by the re-assignment process. In that proposed rule, we proposed an approach that focused on the premiums that would be charged to LIS-eligible individuals in cases in which they would be subject to paying a premium if they stayed in the plan they were in. Specifically, we proposed, under certain circumstances, to give PDP Sponsors the option of setting a separate premium amount for such LIS-eligible individuals at the low-income benchmark amount. We expected this policy to reduce the number of beneficiaries who would have to be re-assigned, and would ensure a choice of at least five no-premium plans for full LIS-eligible individuals in each region.

Requirements for Issuance of Regulations

Section 902 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) amended section 1871(a) of the Act and requires the Secretary, in consultation with the Director of the Office of Management and Budget, to establish and publish timelines for the publication of Medicare final regulations based on the previous publication of a Medicare proposed or interim final regulation. Section 902 of the MMA also states that the timelines for these regulations may vary but shall not exceed 3 years after publication of the preceding proposed or interim final regulation except under exceptional circumstances.

This final rule responds to comments we received on provisions set forth in the January 8, 2008 proposed rule. In addition, this final rule has been published within the 3-year time limit imposed by section 902 of the MMA. Therefore, we believe that the final rule is in accordance with the Congress' intent to ensure timely publication of final regulations.

II. Analysis of the Proposed Rule and Responses to Public Comments

We received 32 timely items of correspondence in response to the January 8, 2008 proposed rule. We received comments from a broad spectrum of commenters, including consumer groups, health plans and industry trade associations, and States. Approximately 13 comments were from consumer groups, 9 comments were from health plans and industry associations, 5 comments were from States, 3 comments were from pharmacists/providers, and 2 comments were from students. With a few exceptions, the commenters were

concerned that the proposed rule would not adequately address the reassignment issue, and suggested alternative approaches. Virtually all of these commenters recommended that, rather than adopting the proposed approach, we consider alternative methods for calculating the low-income benchmark premium amounts. The following is a summary of the public comments and our responses.

Comment: Two commenters proposed that the low-income benchmark premium amounts be calculated by weighting each plan's premium by its share of total LIS enrollment, rather than its share of total Part D enrollment.

Response: Because section 1860D–14(b)(2) of the Act requires only that the premium calculation be ''weighted'', we believe that the statute could reasonably be interpreted to permit this proposed weighting methodology, and in response to these comments we have determined that this approach more effectively addresses the LIS reassignment issue that the proposed rule was intended to address. Therefore, we are adopting this approach in our final rule instead of our originally proposed option for PDPs to reduce their premiums for full-subsidy eligible beneficiaries.

Specifically, the benchmark amounts for each Part D region will be calculated as a weighted average of the Part D premium amounts for basic Part D coverage with the weight for each PDP and MA–PD plan equal to a percentage in which the numerator is equal to the number of LIS eligible beneficiaries enrolled in the Part D plan in the reference month and the denominator is equal to the total number of LIS eligible beneficiaries enrolled in PDP and MA–PD plans (not including PACE, private fee-for-services plans or 1876 cost plans) in the reference month.

Currently, CMS calculates the weighted portion of the low-income benchmark premium amount using a weighted average of the MA and PDP premiums that is based on total Part D enrollment. MA–PD sponsors can lower their Part D premiums through the application of Part C rebates. As a result, the Part D premiums for MA–PD plans tend to be lower than PDP premiums. In addition, the benchmark amounts tend to be significantly lower in regions with high MA–PD penetration than in other Part D regions.

The lower benchmarks have contributed to large-scale reassignments of LIS beneficiaries in many of these regions. This is because the relatively low benchmarks result in many PDPs having a basic Part D premium that is not fully covered by the Federal premium subsidy. As noted above, CMS has reassigned full-subsidy beneficiaries in these PDPs to different, lower-premium PDPs in order to avoid a financial hardship for these beneficiaries.

The conclusion of the ''Medicare Demonstration to Transition Enrollment of Low-Income Subsidy Beneficiaries,'' will put increased downward pressure on the benchmarks in these regions with high MA–PD enrollment and upward pressure on the number of reassignments. Calculating the benchmark amounts using a weighted average based on LIS enrollment, however, will help stabilize the benchmarks in these regions. As noted above, Part D beneficiary premiums for PDPs tend to be higher than for MA–PDs. In addition, PDPs tend to have a greater share of LIS enrollment because of auto and facilitated enrollment. As a result, weighting Part D plan premiums by total LIS enrollment gives greater weight to PDP premiums and tends to increase the benchmarks. As compared to the current regulatory formula, we estimate that this change in the methodology for calculating the benchmarks would have reduced the number of 2008 reassignments by approximately 850,000 LIS beneficiaries. This is significantly greater than the 200,000 reassignment reduction estimated for the policy proposed in the proposed rule.

Comment: Many commenters expressed concerns about various features of the proposed policy and suggested clarifications or changes. Commenters asked CMS to describe the methodology for selecting participating sponsors and any contingencies. Commenters asked CMS to make the checkbox in the bid pricing tool (BPT) where PDP Sponsors were to indicate whether the plan will participate in the second premium visible and unambiguous. Commenters also asked whether certification and attestation requirements should be amended. In addition, commenters suggested changes including limiting plans' financial losses by placing a cap on the amount by which the premium could be reduced for LIS beneficiaries and commented on the complexity of explaining the rule to beneficiaries.

Response: We agree that the various features of the proposed rule would have needed clarification in the final rule. This final rule does not incorporate the option for PDP Sponsors to offer a reduced premium to full subsidy eligible individuals. The final rule takes a different approach and changes the weighting methodology used to calculate the low-income benchmark premium amount. This approach is relatively simple and transparent and does not raise the complexities of the dual premium policy in the proposed rule about which these commenters are concerned.

Comment: Many commenters suggested that we continue with our de minimis policy, rather than adopt the policy in the proposed rule.

Response: We believe that the methodology established in this final rule is a better approach to reducing reassignments than continuing with the de minimis policy as it directly addresses the benchmark disparities across regions. As stated in the proposed rule, we were concerned about an approach that permanently would employ a fixed dollar figure, and decided that a methodology under which the number is not known in advance would better preserve incentives for plans to submit a low bid.

Comment: Many commenters suggested calculating the benchmark before applying Part C rebates to MA–PD premiums. CMS currently calculates the low-income benchmark premium amount using MA–PD premiums after Part C rebates have been applied. Calculating the benchmarks using MA–PD premiums before the application of rebates would increase the benchmark amounts in areas with high MA–PD penetration and in turn decrease the number of reassignments in these Part D regions, compared to the current regulation. Commenters argued that this is a better representation of the true drug cost for MA–PDs. Commenters believed that such an approach is permissible under the statute.

Response: Section 1860D–14(b)(2) of the Act describes the calculation of the benchmark. The statute provides that for an MA–PD plan, CMS must use the weighted averages of the ''portion of the MA monthly prescription drug beneficiary premium that is attributable to basic prescription drug benefits'' to calculate the benchmark for each region. The Act states that the term ''MA monthly prescription drug beneficiary premium'' means, ''the base beneficiary premium * * * as adjusted * * *, less the amount of rebate credited toward such amount * * *'' CMS interprets the phrase ''portion of the MA monthly prescription drug beneficiary premium that is attributable to basic prescription drug benefits'' for an MA–PD plan to mean the base beneficiary premium adjusted for the difference between the bid and benchmark less the rebates. Therefore, we do not believe it is permissible under the statute to calculate the benchmarks with MA–PD premiums before the application of rebates. However, this regulation will

have a comparable effect on LIS reassignments to calculating the benchmarks using the MA–PD premiums that have not been reduced by rebates, and hence produces the outcome recommended by the commenters.

Comment: Some commenters supported our alternative of allowing PDPs to waive the difference between the premium and the benchmark for full subsidy eligible beneficiaries. Commenters believed that CMS overestimated the impact this would have on bids as plans would be motivated to keep bids low in order to receive new auto-assignments.

Response: We continue to believe that this option would have a negative impact on bid competition and bid integrity. As stated in the proposed rule, we did not choose this approach for two reasons. First, if the difference between the two amounts were too great, this would produce a significant disparity between the revenue needs assumed in the bid, and the revenue that would be received under the reduced premium, and undermine the integrity of the bid process. More importantly, if a PDP sponsor knew that it could be assured of reducing its premium for LIS-eligible individuals to the LIS amount no matter how much the premium produced by its bid exceeded this amount, this would greatly reduce existing incentives to bid as low as possible. In response to the commenters' argument, we do not believe new auto-assignees would be enough incentive to keep bids low.

Comment: Many commenters did not support the alternative in which CMS would change the current reassignment process so that beneficiaries would be informed of plans that offer a zero premium for full-subsidy eligible beneficiaries but would have to take action to change to such a plan. Commenters believed that based on their experience, placing the burden on beneficiaries to make the change would result in beneficiaries remaining in plans they cannot afford and would increase premium collection problems. Two commenters believed that CMS should implement this alternative, because it would be easier to address non-payment of premium issues than the issues with continuity of care that come with reassignment.

Response: We agree with the commenters who opposed the alternative for the reasons stated in our proposed rule. We are concerned about charging beneficiaries a premium without them electing to pay it and the potential financial hardship for individual beneficiaries.

Comment: Several commenters suggested changes to the reassignment process, such as reassigning on other than a random basis, extending reassignment to people who have elected a plan with no premium and improvements to the premium information provided to choosers. One commenter asked CMS to review formularies to ensure they do not discourage access for vulnerable beneficiaries.

Response: We do not believe these changes would be appropriate. Congress has favored random assignment by specifying it in the case of initial assignment. We believe that it is appropriate to extend this to re-assignment. It is not clear what the commenter means by reassigning people who have elected a plan with no premium, since they would have made an affirmative choice that we believe should be respected. We also believe that the information currently provided to beneficiaries on their choices is appropriate. Finally, we believe that beneficiaries are in the best position to make plan choices based on plan formularies.

Comment: One commenter was concerned that the regulation would not come out in time for plans to use the information to model their bids.

Response: We agree that Part D sponsors need to know how the LIS benchmarks will be calculated in order to prepare their Part D bids. Therefore, we are releasing this final rule before April 7, 2008, which is the beginning of the formal bid preparation period for 2009. On April 7, 2008, CMS will release all other final Part D payment policy information for 2009 as part of the Announcement of CY 2009 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies. This document is released annually by statute on the first Monday in April. With the release of the Rate Announcement and the publication of this final rule, Part D sponsors will have all the information on Part D payment policies that is needed from CMS to prepare their 2009 bids.

III. Provisions of the Final Regulations

As noted above, we believe that the statute can reasonably be interpreted to permit us to weight the premiums used for the benchmark calculation by total LIS enrollment for each plan. The calculation of the benchmarks is described in section 1860–14(b)(2) of the Act. The statute provides that we must take the ''weighted average'' of the premium amounts described to calculate the benchmarks. The term ''weighted average,'' however, is not definitively defined. The statutory language reads as follows:

(2) LOW-INCOME BENCHMARK PREMIUM AMOUNT DEFINED.—

(A) IN GENERAL.—For purposes of this subsection, the term ''low-income benchmark premium amount'' means, with respect to a PDP region in which—

(i) All prescription drug plans are offered by the same PDP sponsor, the weighted average of the amounts described in (B)(i) for such plans; or

(ii) There are prescription drug plans offered by more than one PDP sponsor, the weighted average of amounts described in subparagraph (B) for prescription drug plans and MA–PD plans described in section 1851(a)(2)(A)(i) offered in such region.

(B) PREMIUM AMOUNTS DESCRIBED.—The premium amounts described in this subparagraph are, in the case of—

(i) A prescription drug plan that is a basic prescription drug plan, the monthly beneficiary premium for such plan;

(ii) A prescription drug plan that provides alternative prescription drug coverage the actuarial value of which is greater than that of standard prescription drug coverage, the portion of the monthly beneficiary premium that is attributable to basic prescription drug coverage; and

(iii) An MA–PD plan, the portion of the MA monthly prescription drug beneficiary premium that is attributable to basic prescription drug benefits (described in section 1854(b)(2)(B)) * * *

We historically have interpreted ''weighted average'' to mean an average based on the plan's share of total Part D enrollment. We believe that ''weighted average'' could also reasonably be interpreted to mean weighted based on the plan's share of LIS enrollment, particularly given that the benchmarks are applicable to LIS beneficiaries only.

The revised interpretation requires a change in the regulation. Therefore, we are revising § 423.780(b)(2) to provide for the low-income benchmark premium amount for a PDP region to be a weighted average of the premium amounts described in § 423.780(b)(2)(ii). The weight for each PDP and MA–PD plan will be equal to a percentage. The numerator will be the number of Part D LIS eligible individuals enrolled in the plan in a reference month (as defined in § 422.258(c)(1)). The denominator will be equal to the total number of Part D LIS eligible individuals enrolled in all PDP and MA–PD plans (but not including PACE, private fee-for-service plans, or 1876 cost plans) in a PDP region in the reference month. We will include both partial and full-subsidy individuals in the weighting calculation.

VI. Collection of Information Requirements

This document 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.

V. Regulatory Impact Statement

A. Overall Impact

We have examined the impact of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), Executive Order 13132 on Federalism, and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Order 12866 directs 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). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This rule allows CMS to calculate the low-income premium benchmark amounts by weighting the premium amounts by total LIS enrollment for each plan in order to reduce the number of reassignments compared to the current regulatory framework. We believe this final rule will lead to additional Federal costs of approximately $90 million for calendar year (CY) 2009. The CY 2009 cost of $90 million represents our best estimate of the cost of the final rule. Generally, our best estimates reflect an equal likelihood of being too high or too low. The estimated cost over the next 10 fiscal years (2009 through 2018) is $1.68 billion. The year-by-year impacts in millions of dollars are shown in Table 1 below. The $90 million estimate above is for CY 2009. The table below summarizes the fiscal year (FY) costs. Yearly growth is due to an estimated increase in the number of enrollees in future years and increasing drug trends that cause higher estimated bids in future years.

TABLE 1.—FEDERAL COSTS FOR FY 2009 THROUGH FY 2018

	Fiscal Year										
	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2009–2018
Estimated Costs (in millions)	$60	$100	$120	$140	$150	$170	$190	$220	$250	$280	$1,680

This rule does reach the economic threshold of $100 million in the out-years and thus is considered a major rule, as outlined by Executive Order 12866.

This cost is due to increased Federal premium subsidy payments, which are the result of generally increasing the low-income benchmarks. The higher benchmarks allow a greater number of low-income beneficiaries to remain in their current plan, rather than reassigning them to a lower cost plan.

In each region, the low-income benchmark essentially functions as a ceiling for the Federal premium subsidy for low-income beneficiaries. That is, the Federal premium subsidy covers the full cost of the plan's basic Part D premium for a full-subsidy beneficiary, up to the low-income benchmark amount.

Weighting based on each plan's share of LIS enrollment generally is expected to increase the low-income benchmarks. We estimated that, in 2008, if the low-income benchmarks had been calculated based on LIS enrollment weighting (rather than based on total Part D enrollment weighting), the benchmarks would have been higher in 27 of the 34 PDP regions. Generally, the higher the low-income benchmarks, the lower the number of LIS reassignments. This is because, under the higher benchmarks, more PDPs are likely to have premiums that are equal to or less than the low-income benchmark and, as a result, will be fully covered by the premium subsidy. Low-income subsidy beneficiaries are able to remain in these PDPs and are not reassigned to other lower-premium PDPs.

We expect this rule will reduce the administrative costs for plan sponsors associated with the reassignment of LIS beneficiaries. These costs include the production of new member informational materials by the new plan, increased staffing of call centers to field beneficiary questions, and costs associated with implementing transition benefits for new enrollees.

Although there is no quantifiable monetary value to CMS to reducing reassignments, we feel this benefit is important, as it will increase program stability and continuity of care. The rule supports pharmacy and formulary consistency for the beneficiary. Particularly in regions with high MA–PD penetration, this rule will reduce the year-to-year volatility in reassignments of LIS beneficiaries and will help avoid the disruption that is inherent anytime a beneficiary is switched from one plan to another.

Based on the most recent bid results, we estimated that if the 2008 benchmarks had been calculated using LIS enrollment weighting, there would have been approximately 850,000 fewer reassignments than if the benchmarks had been calculated using total Part D enrollment weighting. Then we determined the impact of the revised benchmarks and reassignments on program payments throughout the projection period. We do not explicitly project reassignments in future years. The expectation is that the net effect of future reassignments will result in projected cost levels comparable to the results of the reassignments modeled on the most recent bid results.

The cost estimate assumes full enrollment weighting based on LIS enrollment for the calculations of the low-income benchmark premium amounts. The estimate was developed by applying this rule against the 2008 bids and this impact was projected throughout the forecast period. The estimate does not anticipate any change in bidding strategies or outcomes but does include the effect on the level of administrative costs plan sponsors will include in their bids to account for their expected number of LIS beneficiary reassignments.

The proposed rule estimated Federal savings of approximately $20 million per calendar year. However, the final rule estimates an additional $90 million in Federal costs for CY 2009. There are two reasons that the cost estimate has changed. First, the budget baseline has been updated since the issuance of the proposed rule. The Mid-Session Review baseline assumed the continuation of the $1 de minimis policy; the President's 2009 Budget baseline does not. Because of the change in assumptions about the de minimis

policy, even if we had stayed with the five zero-premium organization policy in the proposed rule, the cost of the final rule would have changed from savings of approximately $20 million per year to costs of approximately $10 million per year. Second, this final rule changes the weighting methodology used to calculate the low-income benchmark premium amount. As discussed in the rationale, CMS has changed the method for calculating the Federal premium subsidy for LIS beneficiaries so that the subsidy amount better reflects the premiums of plans in which LIS beneficiaries are enrolled. The final rule uses each plan's share of LIS enrollment, rather than each plan's share of total Part D enrollment, to weight each plan's premium. This change results in fewer reassignments than the proposed rule (approximately 670,000) and greater low-income premium subsidy costs. The relationship between reassignments and the premium subsidy is described above.

The RFA requires agencies to analyze options for regulatory relief of small businesses. 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 $6.5 million to $31.5 million in any 1 year. Individuals and States are not included in the definition of a small entity. We are not preparing an analysis for the RFA because we have determined, and the Secretary certifies, that this regulation will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of 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 we have determined, and the Secretary certifies, that this regulation 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. That threshold level is currently approximately $130 million. This rule will have no consequential effect on State, local, or tribal governments in the aggregate, or by 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 E.O. 13132 are not applicable.

B. Anticipated Effects

We have estimated the effect this regulation will have on the number of reassignments, the number of zero-premium plans available to full-subsidy eligible individuals in each region, and bid incentives.

This rule will reduce the number of reassignments compared to the current regulatory framework. In 2008, under the provisions of the ''Medicare Demonstration to Transition Enrollment of Low-Income Subsidy Beneficiaries'', approximately 1.19 million LIS beneficiaries were reassigned to new Part D organizations. We estimated that if the 2008 benchmarks had been calculated under the current regulation (that is, full enrollment weighted using all enrollees), the number of LIS reassignments would have been 2.18 million. Under the policy in the proposed rule, the number of reassignments would have declined by approximately 200,000 (compared to the current regulation) to 2.0 million. We estimate that, if the 2008 benchmarks had been calculated using the LIS weighting methodology in this final rule, the benchmarks would have been higher in 27 of the 34 regions and the number of reassignments would have been 1.33 million—approximately 850,000 lower than under the current regulation.

We estimate that this final rule, if implemented in 2008, would have reduced the benchmarks slightly in seven regions as compared to the current regulation. These regions tend to have low MA–PD penetration and a concentration of LIS beneficiaries in PDPs with relatively low premiums. The amount of the benchmark reduction was typically less than $0.50. In 2008, these benchmark reductions would have increased reassignments in total by less than 50,000. The 1.33 million estimate noted above is net of these increased reassignments.

We estimate that this final rule, if implemented in 2008, would have increased the number of zero premium organizations available to beneficiaries in 20 of the 34 PDP regions. This is somewhat lower than the number of regions where the benchmarks would have been higher (27), because some regions did not have any new plans that landed under the benchmark with the new calculation. In addition, in 2008, this regulation would have resulted in at least five zero-premium organizations in every Part D region with the exception of one region, which would have had four zero-premium organizations.

This approach maintains a strong incentive to bid low to keep and possibly add LIS beneficiaries. Absent the rule, there may be a ''winner take all'' outcome in certain regions with one organization acquiring all of the LIS beneficiaries in the region. It is difficult to predict what will happen in the absence of this rule, but we expect some organizations will be induced to bid even lower while other organizations will give up on this population and bid higher.

C. Alternatives Considered

As stated in the ''Background'' section of this final rule, we considered allowing PDP Sponsors to reduce their premium to the subsidy amount after it was established for LIS-eligible individuals without regard to the amount of their premium. We also considered allowing plans with premiums under a fixed dollar amount to reduce their low-income premiums to the premium subsidy amount (de minimis). We determined, however, that these options would undermine the integrity and competitiveness of the bidding process.

We also considered changing our approach to reassignment to an approach that would allow LIS-eligible individuals to be informed of zero-premium PDP options for full-subsidy eligibles, but would remain in their current plan, regardless of the premium, if they take no action. Beneficiary advocacy groups were concerned about beneficiaries being charged a premium without electing to pay it.

We also considered changing the regulation to calculate the benchmarks using MA–PD premiums before they have been reduced by Part C rebates. That approach, however, is not permitted under the statute.

Finally, we considered the policy in the proposed rule itself, which was an option for PDP Sponsors in regions with less than five zero-premium PDPs to

offer a separate prescription drug premium amount for full subsidy eligible individuals subject to certain conditions. In response to comments received on the proposed rule, we determined that this approach did not address the reassignment issue as effectively as the LIS benchmark weighting approach recommended by commenters.

D. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf*), in Table 2 below, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this final rule. This table provides our best estimate of the cost associated due to increased Federal low-income premium subsidy payments, which are primarily the result of allowing a greater number of low-income beneficiaries to remain in their current plan, rather than reassigning them to a lower cost plan. All expenditures are classified as costs to the Federal Government.

TABLE 2.—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES FOR THE MODIFICATION TO THE WEIGHTING METHODOLOGY USED TO CALCULATE THE LOW-INCOME BENCHMARK AMOUNT, FINAL RULE

[$ Millions]

Category: Monetized costs	Costs
Single Year CY 2009	$90
Annualized Monetized Costs Using 7% Discount Rate FY 2009–FY 2018	155.6
Annualized Monetized Costs Using 3% Discount Rate FY 2009–FY 2018	162.6
Undiscounted Cumulative Costs—FY 2009–FY 2018	1,680

Costs reflect transfers from the Federal Government to Health Plans.

E. Conclusion

This rule is estimated to result in an increased Federal cost of $90 million in CY 2009 and $1.68 billion over the next 10 fiscal years (2009 through 2018). As explained above, these costs are primarily due to an increase in low-income premium subsidy payments. This rule will not have a significant economic impact on a substantial number of small entities, so we are not preparing an analysis for the RFA. In addition, the regulation will not have a significant impact on the operations of a substantial number of small rural hospitals, so we are not preparing an analysis for section 1102(b) of the Act. The analysis above, together with the preamble, provides a Regulatory Impact Analysis as it qualifies as a major rule under Executive Order 12866.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 423

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, Reporting and recordkeeping.

■ For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

■ 1. The authority citation for part 423 continues to read as follows:

Authority: Secs. 1102, 1860D–1 through 1860D–42, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395w–101 through 1395w–152, and 1395hh).

Subpart P—Premium and Cost-Sharing Subsidies for Low-Income Individuals

■ 2. Amend § 423.780 by revising paragraph (b)(2)(i) to read as follows:

§ 423.780 Premium subsidy.

* * * * *

(b) * * *

(2) * * *

(i) The low-income benchmark premium amount for a PDP region is a weighted average of the premium amounts described in paragraph (b)(2)(ii) of this section, with the weight for each PDP and MA–PD plan equal to a percentage, the numerator being equal to the number of Part D low-income subsidy eligible individuals enrolled in the plan in the reference month (as defined in § 422.258(c)(1) of this chapter) and the denominator equal to the total number of Part D low-income subsidy eligible individuals enrolled in all PDP and MA–PD plans (but not including PACE, private fee-for-service plans or 1876 cost plans) in a PDP region in the reference month.

* * * * *

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

Dated: March 20, 2008.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

March 27, 2008.

Michael O. Leavitt,

Secretary.

[FR Doc. 08–1088 Filed 3–31–08; 4 pm]

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DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 62

[Docket ID FEMA–2008–0001]

RIN 1660–AA58

National Flood Insurance Program (NFIP); Assistance to Private Sector Property Insurers; Write-Your-Own Arrangement

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Interim Rule.

SUMMARY: This rule amends portions of the Federal Emergency Management Agency (FEMA), Federal Insurance Administration, Financial Assistance/Subsidy Arrangement (Arrangement) between Write-Your-Own Companies (WYO Companies) and FEMA. The rule makes technical changes intended to assist WYO Companies by recognizing each party's duties under the Arrangement and amends the way FEMA communicates changes to the Unallocated Loss Adjustment Expenses