Health and Human Services or members of the Board who are designated to conduct a hearing.

■ 16. Section 498.56 is amended by—

■ A. Revising paragraph (a)(2).

■ B. Adding a new paragraph (e).

The revision and addition read as follows:

§ 498.56 Hearing on new issues.

* * * * *

(a) * * *

(2) Except for provider or supplier enrollment appeals which are addressed in § 498.56(e), the ALJ may consider new issues even if CMS or the OIG has not made initial or reconsidered determinations on them, and even if they arose after the request for hearing was filed or after the prehearing conference.

* * * * *

(e) *Provider and supplier enrollment appeals: Good cause requirement.* (1) *Examination of any new documentary evidence.* After a hearing is requested but before it is held, the ALJ will examine any new documentary evidence submitted to the ALJ by a provider or supplier to determine whether the provider or supplier has good cause for submitting the evidence for the first time at the ALJ level.

(2) *Determining if good cause exists.*

(i) *If good cause exists.* If the ALJ finds that there is good cause for submitting new documentary evidence for the first time at the ALJ level, the ALJ must include evidence and may consider it in reaching a decision.

(ii) *If good cause does not exist.* If the ALJ determines that there was not good cause for submitting the evidence for the first time at the ALJ level, the ALJ must exclude the evidence from the proceeding and may not consider it in reaching a decision.

(2) *Notification to all parties.* As soon as possible, but no later than the start of the hearing, the ALJ must notify all parties of any evidence that is excluded from the hearing.

■ 17. Section 498.78 is amended by revising paragraph (a) to read as follows:

§ 498.78 Remand by the Administrative Law Judge.

(a) If CMS requests a remand, the ALJ may remand any case properly before him or her to CMS.

* * * * *

■ 18. A new § 498.79 is added to subpart D to read as follows:

§ 498.79 Timeframes for deciding an enrollment appeal before an ALJ.

When a request for an ALJ hearing is filed after CMS or a FFS contractor has denied an enrollment application, the ALJ must issue a decision, dismissal order or remand to CMS, as appropriate, no later than the end of the 180-day period beginning from the date the appeal was filed with an ALJ.

Subpart E—Departmental Appeals Board Review

■ 19. Section 498.86 is amended by revising paragraph (a) to read as follows:

§ 498.86 Evidence admissible on review.

(a) Except for provider or supplier enrollment appeals, the Board may admit evidence into the record in addition to the evidence introduced at the ALJ hearing (or the documents considered by the ALJ if the hearing was waived) if the Board considers that the additional evidence is relevant and material to an issue before it.

* * * * *

■ 20. Section 498.88 is amended by adding a new paragraph (g) to read as follows:

§ 498.88 Decision or remand by the Departmental Appeals Board.

* * * * *

(g) When a request for Board review of a denial of an enrollment application is filed after an ALJ has issued a decision or dismissal order, the Board must issue a decision, dismissal order or remand to the ALJ, as appropriate, no later than 180 days after the appeal was received by the Board.

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

Dated: November 16, 2007.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: *March 17, 2008.*

Michael O. Leavitt,

Secretary.

Editorial Note: This document was received in the Office of the Federal Register on June 20, 2008.

[FR Doc. E8–14440 Filed 6–26–08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 406, 407, and 408

[CMS–4129–F]

RIN 0938–AO77

Medicare Program; Special Enrollment Period and Medicare Premium Changes

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

ACTION: Final rule.

SUMMARY: This final rule provides a special enrollment period (SEP) for Medicare Part B and premium Part A for certain individuals who are sponsored by prescribed organizations as volunteers outside of the United States and who have health insurance that covers them while outside the United States. Under the SEP provision, qualifying volunteers can delay enrollment in Part B and premium Part A, or terminate such coverage, for the period of service outside of the United States and reenroll without incurring a premium surcharge for late enrollment or reenrollment.

This final rule also codifies provisions that require certain beneficiaries to pay an income-related monthly adjustment amount (IRMAA) in addition to the standard Medicare Part B premium, plus any applicable increase for late enrollment or reenrollment. The income-related monthly adjustment amount is to be paid by beneficiaries who have a modified adjusted gross income that exceeds certain threshold amounts. It also represents the amount of decreases in the Medicare Part B premium subsidy, that is, the amount of the Federal government's contribution to the Federal Supplementary Medicare Insurance (SMI) Trust Fund.

DATES: *Effective Date:* These regulations are effective on August 26, 2008.

FOR FURTHER INFORMATION CONTACT: Denise Cox, (410) 786–3195.

SUPPLEMENTARY INFORMATION:

I. Background

A. General

Medicare is a Federal health insurance program that helps millions of Americans pay for health care. Beneficiaries include eligible individuals age 65 or older and certain people younger than age 65 who also qualify to receive Medicare. These individuals include those who have

disabilities and those who have permanent kidney failure (end-stage renal disease).

Medicare Parts A and B are the subject of this final rule. Hospital insurance (Part A) helps to pay for inpatient care in hospitals, skilled nursing facilities, as well as home health care and hospice care. Part B or supplementary medical insurance (SMI) helps to pay for physicians' services, outpatient hospital services, durable medical equipment, and a number of other medical services and supplies that are not covered under Part A.

Part A is financed primarily through compulsory payroll taxes under the Federal Insurance Contributions Act (FICA). Individuals age 65 or over who are entitled to receive Social Security or railroad retirement benefits, or who are eligible for Social Security benefits and have filed an application for hospital insurance, are entitled to receive Part A benefits without paying a monthly premium. However, individuals who do not qualify for premium-free Part A, may voluntarily enroll in Part A but are required to pay a monthly premium. These individuals generally include those who have not worked 10 years in Medicare-covered employment or are not the spouse, divorced spouse or widow(er) of an individual who has worked 10 years in Medicare-covered employment. In addition, they must meet the following requirements: (1) Be at least age 65; (2) a resident of the United States; (3) a United States citizen or an alien who has been lawfully admitted for permanent residence and who has resided continuously in the United States for the 5-year period immediately preceding the month of enrollment; (4) not otherwise eligible to receive Part A benefits without having to pay a premium; and (5) entitled to Part B or are eligible and have enrolled.

Enrollment in Part B is open to all persons who are entitled to Part A benefits, as well as to persons who are not entitled to Part A benefits, provided certain requirements are satisfied. Part B is financed primarily through premiums paid by or on behalf of beneficiaries, along with transfers made from the General Fund of the Treasury. Section 1839(a) of the Social Security Act (the Act) requires the Secretary of Health and Human Services to determine the Medicare Part B standard monthly premium amount annually. Currently, the standard monthly premium represents approximately 25 percent of the estimated total Part B program cost for aged enrollees. The remaining 75 percent of the total estimated cost is subsidized by the Federal government through transfers to the Federal SMI Trust Fund from the General Fund of the Treasury.

Individuals who do not enroll in Part B or premium Part A when first eligible or who enroll and later terminate their coverage may only enroll during the general enrollment period, which is January through March of each year, unless an exception applies. The coverage will be effective the following July 1. Under section 1839(b) of the Act, individuals who delay enrolling in premium Part A or Part B for 12 or more months must pay a premium surcharge.

B. General Enrollment Period Exceptions

1. Special Enrollment Period (SEP)

Currently, section 1837(i) of the Act provides a special enrollment period (SEP) for individuals age 65 or over who are working or who are the spouses of working individuals who are covered under a group health plan (GHP). For disabled individuals, who are under age 65, the SEP applies if the individual is covered by a GHP by reason of the current employment status of the individual or the individual's spouse, or if the individual is covered by a large group health plan (LGHP) by reason of the current employment status of the individual or a member of the individual's family. In this type of situation, enrollment in Part B can take place anytime the individual is covered under the GHP or LGHP based on current employment status or during the 8-month period that begins the first full month after the GHP or LGHP coverage ends. Because section 1818(c) of the Act provides that the enrollment provisions in section 1837 (except subsection (f) thereof) apply to persons authorized to enroll in premium Part A, we have extended this SEP to premium Part A enrollments.

2. Transfer Enrollment Period (TEP)

Another exception is the transfer enrollment period (TEP) for enrollment in premium Part A. The TEP is for individuals age 65 or older who are otherwise eligible to enroll in premium Part A; are enrolled in a plan with an organization listed in section 1876 of the Act; and whose coverage under the plan is terminated for any reason. Here, an individual may enroll in premium Part A beginning any month that the individual is enrolled in the plan, and ending with the last day of the 8-month period following the last month in which the individual is no longer enrolled in the plan.

3. Statutory Changes

Section 5115(a)(2) of the Deficit Reduction Act of 2005 (DRA) (Pub. L. 109–171) amended section 1837 of the Act to add a new subsection (k), which provides a SEP for certain international volunteers. Beginning January 1, 2007, a SEP for Part B is provided to qualifying international volunteers who are eligible to enroll in Part B because they meet the requirements in section 1836(1) or (2) of the Act, but who do not enroll in Part B during the initial enrollment period or who terminate enrollment during a month in which they qualify as an international volunteer. Enrollment can take place during the 6-month period beginning on the first day of the month which includes the date the individual no longer qualifies under this provision. Coverage for an individual who enrolls during a SEP in accordance with this provision begins on the first day of the month following the month in which the individual enrolls.

Under new section 1837(k)(3) of the Act, an individual qualifies as an international volunteer if he or she is serving in a program outside of the United States that covers at least a 12-month period, and that is sponsored by an organization described in section 501(c)(3) of the Internal Revenue Code of 1986 (the Code) and exempt from taxation under section 501(a) of the same Code. The individual must also have health insurance coverage to cover medical services while serving overseas in the program. Specifically, qualifying organizations under section 501(c)(3) of the Code that are exempt from taxation under section 501(a) of the Code are ''corporations, and any community chest, fund, or foundation, organized and operated exclusively for religious, charitable, scientific, testing for public safety, literary, or educational purposes, or to foster national or international amateur sports competition (but only if no part of its activities involve the provision of athletic facilities or equipment), or for the prevention of cruelty to children or animals. * * *'' Furthermore, to qualify for this exemption, no part of the net earnings of the organization can inure to the benefit of any private shareholder or individual and no substantial part of the activities can be used for propaganda, or otherwise attempt to influence legislation (except as otherwise provided in section 510(h) of the Code) or participate or intervene (including the publishing or distributing of statements) in political campaigns on behalf of (or in opposition to) any candidate for public office.

C. Income-Related Monthly Adjustment Amount Under Medicare Part B

Section 811 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) amends section 1839 of the Act and establishes a Medicare Part B premium subsidy reduction referred to as the ''Income-Related Monthly Adjustment Amount'' (IRMAA). Section 1839(i) of the Act requires that an income-related monthly adjustment amount be added to a beneficiary's Part B premium if his or her modified adjusted gross income exceeds the established threshold amounts. The IRMAA reduces the amount that the beneficiary's premium is subsidized by the Federal government. All beneficiaries will continue to receive some subsidy of their premium.

Section 1839(i) of the Act establishes a sliding scale that will be used to establish four income-related monthly adjustment amounts that will increase a beneficiary's Medicare Part B premium by specific percentages. If a beneficiary's modified adjusted gross income is greater than the statutory threshold amounts, the beneficiary will pay a larger portion of the estimated total cost of Part B coverage. The 2007 income ranges, as set forth in section 1839(i)(3)(C)(i) of the Act, started at $80,000 for a beneficiary filing an individual tax return, and $160,000 for a beneficiary filing a joint income tax return, and are listed in the following table:

Individual tax filers with income:	Joint tax filers with income:	Premium percentage
Greater than $80,000 and less than or equal to $100,000	Greater than $160,000 and less than or equal to $200,000	35
Greater than $100,000 and less than or equal to $150,000	Greater than $200,000 and less than or equal to $300,000	50
Greater than $150,000 and less than or equal to $200,000	Greater than $300,000 and less than or equal to $400,000	65
Greater than $200,000	Greater than $400,000	80

In calendar year (CY) 2007, individual tax filers with income less than or equal to $80,000 and joint tax filers with income less than or equal to $160,000 will continue to pay the standard premium which represents roughly 25 percent of the estimated total Part B program costs. As specified in section 1839(i)(5) of the Act, each dollar amount in this table would be adjusted annually based on the Consumer Price Index.

Section 811 of the MMA also provided for a 5-year phase-in of the Medicare Part B premium subsidy reduction. However, section 1839(i) was subsequently amended by section 5111 of the DRA to provide for a 3-year phase-in period. Therefore, the percentages presented in this table reflect the Part B premium percentages that certain beneficiaries will pay once IRMAA is fully phased-in.

The ''hold-harmless'' provision in section 1839(f) of the Act provides for a reduction to the Part B premium for beneficiaries whose Social Security or Railroad Board (RRB) annuity cost of living adjustments (COLAs) are not sufficient to cover the Part B premium increase. If in a given year, the increase in the Part B premium would cause an individual's Social Security or RRB check to be less than it was the year before, the premium is reduced to ensure that the amount of the individual's Social Security benefit (or RRB annuity) stays the same. To be held harmless, a beneficiary must have had the Part B premium deducted from both the December check of the prior year and the January check of the next year. Under section 1839(f) of the Act, the ''hold-harmless'' provision does not apply to beneficiaries who are required to pay an IRMAA based on their modified adjusted gross income. These beneficiaries must pay the full Medicare Part B standard monthly premium, plus any applicable penalty for late enrollment or reenrollment, plus the income-related monthly adjustment amount.

Section 702(a)(5) of the Act allows SSA to make the rules and regulations necessary or appropriate to carry out the functions of SSA. Other provisions in section 811 of the MMA provide SSA with additional specific authorization to make rules and regulations to determine which beneficiaries are required to pay the different income-related monthly adjustment amounts.

In the October 27, 2006 **Federal Register** (71 FR 62923), SSA issued a final rule establishing regulations governing the determination of income-related monthly adjustment amounts. This final rule explains: (1) The statutory requirement to implement an income-related adjustment to the Part B premium subsidy; (2) the information that would be used to determine whether a beneficiary must pay an income-related monthly adjusted amount and the amount of any adjustment; (3) when SSA will consider a major life-changing event that results in a significant reduction in a beneficiary's modified adjusted gross income; and (4) how a beneficiary can appeal SSA's determination about the beneficiary's income-related monthly adjustment amount. For a more detailed discussion see SSA's October 27, 2006 final rule (71 FR 62923).

II. Provisions of the Proposed Regulation and Analysis of and Responses to Public Comments

We received four timely public comments in response to the Special Enrollment Period and Medicare Premium Changes proposed rule published in the September 28, 2007 **Federal Register**. In this section of the final rule, we address all comments received regarding the provisions of our proposed rule.

We proposed to add a new § 406.25, which would allow certain individuals who are sponsored by prescribed organizations as volunteers outside of the United States and have health care insurance to qualify for a SEP for premium hospital insurance (Part A). We recognize that section 5115 of the DRA, in amending section 1839(b) of the Act, explicitly provides only for a SEP for Part B, which we have provided for in new § 407.21. However, since section 1818(c) of the Act applies all of the provisions of section 1837 of the Act (except subsection (f) thereof) to persons authorized to enroll under section 1818 of the Act, we believe that the SEP provided in section 5115 of the DRA also applies to enrollment in premium Part A.

Comment: Three commenters expressed concern that although § 406.25 of the September 2007 proposed rule tracks the language of section 5115 of the DRA, § 407.21 is not worded exactly the same as § 406.25 and could be interpreted as imposing different standards. Specifically, they believe that the requirements of § 406.25 (''an individual [that] is serving as a volunteer outside the United States through a program that covers at least a 12-month period'') and the requirement of § 407.21 (''if while serving as a volunteer outside of the United States the individual is in a program that covers a 12-month period of service outside of the United States'') are two different standards.

The commenters also note that there is a slight difference between the wordings in the preamble for these two sections. They believe that § 406.25 and § 407.21 should be substantively identical.

Response: To ensure that the SEP standards are interpreted consistently, we are revising the regulation text of § 406.25 and § 407.21.

In § 406.33(a)(3), we proposed to make a technical correction by removing an incorrect phrase ''the 7-month special enrollment period under § 406.21(e)'' and replacing it with the phrase ''the special enrollment period under § 406.24.'' We did not receive any public comment on this proposal and are adopting the provision with only a technical change, as discussed further in this section.

In § 406.33(a)(5) and (6), we proposed to exclude from the calculation of the premium surcharge those months the individual qualifies for the SEP described in § 406.25(a). We did not receive any public comment on this proposal and are adopting the provision with technical changes, as discussed further in this section.

We proposed to add a new § 407.21, which implements section 5115 of the DRA by allowing certain individuals who are sponsored by prescribed organizations as volunteers outside of the United States and have health care insurance that covers medical services while serving overseas to qualify for a Medicare Part B SEP.

Comment: Two commenters noted that section 5115 of the DRA requires that volunteers serve in a program that covers at least a 12-month period, as opposed to requiring that their actual service outside the country last for at least 12 months. These commenters stated that, under rare, unforeseeable circumstances, a volunteer in a program that covers at least a 12-month period may be required to return to the United States in less than 12 months. They believe that these volunteers should qualify for the SEP provided by section 5115 of the DRA.

Response: We agree and have revised § 407.21 to clarify that the volunteer has to serve in a program that covers at least a 12-month period.

In § 408.20 (e)(3)(iii), we proposed to implement section 811(b)(1)(C) of the MMA by excluding from the ''hold harmless'' provision (known as the ''nonstandard premium'') individuals who are required to pay the income-related monthly adjustment amount (IRMAA). Such beneficiaries must pay the full Medicare Part B standard monthly premium plus any applicable premium surcharge for late enrollment or re-enrollment, plus the income-related monthly adjustment amount. We did not receive any public comment on this proposal and are adopting the provision as proposed.

In § 408.24(a)(10), we proposed to implement section 5115(a) of the DRA by excluding from the calculation of the premium surcharge those months the individual meets the requirements of proposed § 407.21. We also proposed to make a conforming change in § 408.24 (b)(2)(i) of this section by revising the cross-reference to include the new paragraph § 408.24(a)(10). We did not receive any public comment on these proposals and are adopting the provisions as proposed.

Finally, we proposed to add a new § 408.28 to specify that, beginning January 1, 2007, Medicare beneficiaries will be informed that they may be required to pay an income-related monthly adjustment amount in addition to the standard Part B premium, plus any applicable increase for late enrollment or reenrollment, if their modified adjusted gross income exceeds the threshold limits specified in 20 CFR 418.1115. We did not receive any public comment on this proposal and are adopting the provision as proposed.

After review and analysis of public comment, we are also making the following technical changes in this final rule:

- In § 406.33(a)(3), the cross-reference ''§ 406.24 of this part'' is revised to read ''§ 406.24 of this subpart''.
- In § 406.33(a)(5), the cross-reference ''§ 406.25 of this subpart'' is revised to read ''for a SEP under 406.25(a) of this subpart''.
- In § 406.33(a)(6), the cross-reference ''§ 406.25(b) of this part'' is revised to read ''§ 406.25(b) of this subpart''.
- In § 407.21(b), the cross-reference ''paragraph (b) of this section'' is revised to read ''paragraph (a) of this section''.

Lastly, we are making a technical change to the section heading for § 406.24 to clarify that the special enrollment period relates to coverage under group health plans.

III. Collection of Information Requirements

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

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

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs).

A. ICRs Related to Special Enrollment Period for Volunteers Outside the United States (§ 406.25)

Section 406.25 outlines the requirements that an individual volunteer must meet to qualify for a SEP. A qualifying individual can enroll or reenroll without incurring a surcharge for a late enrollment or reenrollment. Specifically, § 406.25(a)(1) and (2) state that an individual volunteer must demonstrate that his or her volunteer service is through a program that covers at least a 12-month period and is sponsored by an organization described in section 501(c)(3) of the Internal Revenue Code of 1986 and exempt from taxation under section 501(a) of the Internal Revenue Code.

The burden associated with this requirement is the time and effort associated with verifying that the volunteer was in a 12-month program and demonstrating the tax-exempt status of the organization sponsoring the individual. The estimated burden associated with this requirement is 15 minutes per individual. We estimate that 1,500 individuals will be subject to this requirement on a yearly basis for a total annual burden of 375 burden hours.

In addition, § 406.25(a)(3) requires that an individual demonstrate that he or she has health insurance that covers medical services received outside of the United States during his or her period of service. The burden associated with this requirement is the time and effort associated with demonstrating possession of health insurance coverage that covers the medical services received outside of the United States. We estimate the burden for verifying coverage to be 15 minutes per individual; we also estimate that 1,500 individuals will be subject to this requirement on a yearly basis. The total

estimated burden is 375 annual burden hours.

B. ICRs Related to Special Enrollment Period for Volunteers Outside the United States (§ 407.21)

Section 407.21 addresses the provision of a SEP for an individual who elects not to enroll or to be deemed enrolled in SMI when first eligible and an individual who terminates SMI enrollment. To be eligible for the SEP, the individual must meet the criteria outlined in the regulations text. As stated in § 407.21(a), the individual must: (1) Serve as a volunteer in a program that covers at least a 12-month period of service; (2) be a volunteer in a program sponsored by an organization described in section 501(c)(3) of the Internal Revenue Code of 1986 and exempt from taxation under 501(a) of such Code; and (3) be able to demonstrate that he or she had health insurance coverage that covers medical services received outside of the United States during his or her period of service.

The burden associated with the requirements in § 407.21(a)(1) and (2) is the time and effort associated with verifying that the volunteer was in a 12-month program, and demonstrating the tax-exempt status of the organization sponsoring the individual, and submitting the information to CMS. The burden associated with these requirements is discussed in detail in the explanation of the burden for § 406.25.

The burden associated with the § 407.21(a)(3) is the time and effort associated with an individual demonstrating that he or she has health insurance that covers medical services received outside of the United States during his or her period of service. The burden associated with this requirement is discussed in detail in the explanation of the burden for § 406.25.

TABLE A.—ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDEN

Regulation section(s)	OMB Control No.	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)
§ 406.25(a)(1 and 2) and § 407.21(a)(1 and 2).	0938–New	1500	1500	.25	375
§ 406.25(a)(3) and § 407.21(a)(3)	0938–New	1500	1500	.25	375
Total					750

We have submitted a copy of this final rule to OMB for its review of the information collection requirements contained in this section. In addition, we are seeking OMB approval for the aforementioned information collection requirements under a separate notice and comment process. These requirements are not final until they are approved by OMB.

IV. Regulatory Impact Statement

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), and Executive Order 13132.

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). We do not anticipate that there will be more than 1,500 beneficiaries (international volunteers) at any one time who will qualify for a SEP. To qualify under this SEP, the Medicare beneficiary must have elected not to enroll in Part B or premium Part A during the initial enrollment period, or terminated enrollment, because the individual was serving as a volunteer outside the United States. In addition, the individual must have served as a volunteer outside of the United States in a program that covers at least a 12-month period, and that is sponsored by an organization described in section 501(c)(3) of the Internal Revenue Code of 1986 and exempt from taxation under section 501(a) of that Code, and must have health care insurance coverage that covers medical services while serving overseas in the program. It is for this reason that we anticipate that the overall expenditure for this provision of the Medicare program projected over a 5-year period would be negligible. In addition, this rule only codifies the income-related monthly adjustment amount provision of MMA. It is for these reasons that this rule does not reach the economic threshold and thus is not considered a major rule.

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 million to $29 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 that this rule 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 and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act, because we have determined that this final rule 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 $120 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 (and subsequent final rule)

that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. We have determined that this final rule does not impose any costs on State or local governments, therefore the requirements of E.O. 13132 are not applicable.

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

List of Subjects

42 CFR Part 406

Health facilities, Kidney diseases, Medicare.

42 CFR Part 407

Medicare.

42 CFR Part 408

Medicare.

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

PART 406—HOSPITAL INSURANCE ELIGIBILITY AND ENTITLEMENT

■ 1. The authority citation for part 406 continues to read as follows:

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

Subpart C—Premium Hospital Insurance

■ 2. Section 406.24 is amended by revising the section heading to read as follows:

§ 406.24 Special enrollment period related to coverage under group health plans.

* * * * *

■ 3. Section 406.25 is added to read as follows:

§ 406.25 Special enrollment period for volunteers outside the United States.

(a) *General rule.* A SEP, as defined in § 406.24(a)(4) of this subchapter, is provided for an individual that meets the following requirements:

(1) The individual is serving as a volunteer outside of the United States in a program that covers at least a 12-month period.

(2) The individual is in a program that is sponsored by an organization described in section 501(c)(3) of the Internal Revenue Code of 1986 and is exempt from taxation under section 501(a) of Internal Revenue Code of 1986.

(3) The individual can demonstrate that he or she has health insurance that covers medical services that the individual receives outside the United States while serving in the program.

(4) The individual—

(i) At the time he or she first met the requirements of § 406.10 through 406.15 or § 406.20(b), elected not to enroll in premium hospital insurance during the individual's initial enrollment period; or

(ii) Terminated enrollment in premium hospital insurance during a month in which the individual met the requirements of this section for a SEP.

(b) *Duration of SEP.* The SEP is the 6-month period beginning on the first day of the month that includes the date that the individual no longer meets the requirements of paragraph (a) of this section.

(c) *Effective date of coverage.* Coverage under a SEP authorized by this section begins on the first day of the month following the month in which the individual enrolls.

■ 4. Section 406.33 is amended by—

■ A. Revising paragraph (a)(3).

■ B. Adding paragraphs (a)(5) and (a)(6).

The revision and additions read as follows:

§ 406.33 Determination of months to be counted for premium increase: Enrollment.

(a) * * *

(3) Any months during the SEP under § 406.24 of this subpart, during which premium hospital insurance coverage is in effect.

* * * * *

(5) For premiums due for months after December 2006, any months during which the individual met the requirements for a SEP under § 406.25(a) of this subpart.

(6) Any months during the 6-month SEP described in § 406.25(b) of this subpart during which premium hospital insurance coverage is in effect.

* * * * *

PART 407—SUPPLEMENTARY MEDICAL INSURANCE (SMI) ENROLLMENT AND ENTITLEMENT

■ 5. The authority citation for part 407 continues to read as follows:

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

Subpart B—Individual Enrollment and Entitlement for SMI

■ 6. Section 407.21 is added to read as follows:

§ 407.21 Special enrollment period for volunteers outside the United States.

(a) *General rule.* A SEP, as defined in § 406.24(a)(4) of this subchapter, is provided for an individual who does not elect to enroll or to be deemed enrolled in SMI when first eligible, or who terminates SMI enrollment, if the individual meets the following requirements:

(1) The individual is serving as a volunteer outside of the United States in a program that covers at least a 12-month period.

(2) The individual is in a program that is sponsored by an organization described in section 501(c)(3) of the Internal Revenue Code of 1986 and is exempt from taxation under section 501(a) of the Internal Revenue Code of 1986.

(3) The individual demonstrates that he or she has health insurance that covers medical services that the individual receives outside of the United States while serving in the program.

(b) *Duration of SEP.* The SEP is the 6-month period beginning on the first day of the month that includes the date that the individual no longer satisfies the provisions of paragraph (a) of this section.

(c) *Effective date of coverage.* Coverage under a SEP authorized by this section, begins on the first day of the month following the month in which the individual enrolls.

PART 408—PREMIUMS FOR SUPPLEMENTARY MEDICAL INSURANCE

■ 7. The authority citation for part 408 continues to read as follows:

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

Subpart B—Amount of Monthly Premiums

■ 8. Section 408.20 is amended by adding paragraph (e)(3)(iii) to read as follows:

§ 408.20 Monthly premiums.

* * * * *

(e) * * *

(3) * * *

(iii) Beginning with CY 2007, a nonstandard premium may not be applied to individuals who are required to pay an income-related monthly adjustment amount described in § 408.28 of this part.

* * * * *

■ 9. Section 408.24 is amended by—

■ A. Adding paragraph (a)(10).

■ B. Revising paragraph (b)(2)(i).

The addition and revision read as follows:

§ 408.24 Individuals who enrolled or reenrolled before April 1, 1981 or after September 30, 1981.

(a) * * *

(10) For premiums due for months beginning with January 1, 2007, the following:

(i) Any months after December 2006 during which the individual met the conditions under § 407.21(a) of this chapter.

(ii) Any months of Part B (SMI) coverage for which the individual enrolled during a special enrollment period as provided in § 407.21(b) of this chapter.

(b) * * *

(2) * * *

(i) Any of the periods specified in paragraph (a) of this section; and

* * * * *

■ 10. Section 408.28 is added to read as follows:

§ 408.28 Increased premiums due to the income-related monthly adjustment amount (IRMAA).

Beginning January 1, 2007, Medicare beneficiaries must pay an income-related monthly adjustment amount in addition to the Part B (SMI) standard monthly premium, plus any applicable increase for late enrollment or reenrollment, if the beneficiary's modified adjusted gross income exceeds the threshold amounts specified in 20 CFR 418.1115.

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

Dated: January 31, 2008.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: April 7, 2008.

Michael O. Leavitt,

Secretary.

[FR Doc. E8–14040 Filed 6–26–08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 482

[CMS–3014–F]

RIN 0938–AJ29

Medicare and Medicaid Programs; Hospital Conditions of Participation: Laboratory Services

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

ACTION: Final rule.

SUMMARY: This final rule finalizes the hospital conditions of participation requirements for hospitals that transfuse blood and blood components. It requires hospitals to: Prepare and follow written procedures for appropriate action when it is determined that blood and blood components the hospitals received and transfused are at increased risk for transmitting hepatitis C virus (HCV); quarantine prior collections from a donor who is at increased risk for transmitting HCV infection; notify transfusion recipients, as appropriate, of the need for HCV testing and counseling; and extend the records retention period for transfusion-related data to 10 years. The intent is to aid in the prevention of HCV infection and to create opportunities for disease prevention that, in most cases, can occur many years after recipient exposure to a donor.

DATES: *Effective Date:* The interim final rule amending 42 CFR part 482 published August 24, 2007 at 72 FR 48562 and effective on February 20, 2008, is adopted as final June 27, 2008.

FOR FURTHER INFORMATION CONTACT: Mary Collins, (410) 786–3189. Marcia Newton, (410) 786–5265.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 1861(e) of the Social Security Act (the Act), hospitals must meet certain conditions in order to participate in the Medicare program. These conditions are intended to protect patient health and safety and ensure that high-quality care is provided. Hospitals receiving payment under Medicaid must meet the Medicare conditions of participation (CoPs).

The CoPs for hospital laboratory services currently specifies the steps hospitals must take when they become aware they have administered potentially human immunodeficiency virus infectious blood or blood components to a patient. All laboratories must be CLIA-certified to participate in Medicare and Medicaid. The Centers for Medicare & Medicaid Services (CMS) and Federal agencies that comprise the Public Health Services, including the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), and the National Institutes of Health (NIH), are responsible for ensuring the safety of blood and blood components.

Hepatitis C virus (HCV) was first discovered and established as a causative agent of transfusion-associated hepatitis in the late 1980s. In October 1989, FDA's Blood Products Advisory Committee (BPAC) first discussed steps to identify and quarantine potentially HCV infectious blood and blood components remaining in storage and notify recipients that they may possibly have received infectious blood or blood products. These steps are known as a ''lookback.'' BPAC advised that there was insufficient information available concerning HCV infection to propose either product quarantine or notification of recipients transfused with blood and blood components prepared from prior collections from donors later determined to be at increased risk for transmitting HCV.

On November 16, 2000, we published in the **Federal Register** a proposed rule (65 FR 69416). In that proposed rule, we discussed in detail the steps that had been taken since the late 1980's to avoid the transmission of HCV infection and to create opportunities for disease prevention that, in most cases, can occur many years after recipient exposure to a donor.

On August 24, 2007, we published an interim final rule with comment period in the **Federal Register** (72 FR 48562). The interim final rule with comment period incorporated the provisions of the November 16, 2000 proposed rule, responses to public comments, and changes to further conform our regulation to FDA's final rule that was also published on August 24, 2007. For a detailed discussion of this information, we refer the reader to the August 24, 2007 interim final rule (72 FR 48562 through 48565).

II. Provisions of the Interim Final Rule With Comment Period

In order to have consistent industry standards for potentially infectious blood and blood components, on August 24, 2007, we published in the **Federal Register** an interim final rule with comment period (72 FR 48562) entitled, ''Medicare and Medicaid Programs; Hospital Conditions of Participation: Laboratory Services''. The provisions of the interim final rule were effective on February 20, 2008. The interim final rule with comment period addressed the comments CMS received regarding the proposed rule that was published on November 16, 2000 (65 FR 69416). Since our proposed rule was published in conjunction with the FDA's rule, we coordinated our responses with the FDA's responses in its ''lookback'' rule (72 FR 48766) entitled, ''Current Good Manufacturing Practice for Blood and Blood Components; Notification of Consignees and Transfusion Recipients Receiving Blood and Blood Components at Increased Risk of Transmitting HCV