In addition, the monthly premium rates to be paid by beneficiaries who are married and lived with their spouse at any time during the taxable year, but file a separate tax return from their spouse, are also announced and listed in the following chart:

Beneficiaries who are married and lived with their spouse at any time during the year, but file a separate tax return from their spouse:	Income-related monthly adjustment amount	Total monthly premium amount
Less than or equal to $85,000	$0.00	$134.00
Greater than $85,000 and less than or equal to $129,000	214.30	348.30
Greater than $129,000	294.60	428.60

The RFA requires agencies to analyze options for regulatory relief of small businesses, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Individuals and states are not included in the definition of a small entity. This notice announces the monthly actuarial rates for aged (age 65 and over) and disabled (under 65) beneficiaries enrolled in Part B of the Medicare SMI program beginning January 1, 2017. Also, this notice announces the monthly premium for aged and disabled beneficiaries as well as the income-related monthly adjustment amounts to be paid by beneficiaries with modified adjusted gross income above certain threshold amounts. As a result, we are not preparing an analysis for the RFA because the Secretary has determined that this notice 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. As we discussed previously, we are not preparing an analysis for section 1102(b) of the Act because the Secretary has determined that this notice will not have a significant effect on a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1-year of $100 million in 1995 dollars, updated annually for inflation. In 2016, that threshold is approximately $146 million. Part B enrollees who are also enrolled in Medicaid have their monthly Part B premiums paid by Medicaid. The 2017 premium increase is estimated to be a cost to each state Medicaid program that is less than the threshold. This notice does not impose mandates that will have a consequential effect of the threshold amount or more on state, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it publishes a proposed rule (and subsequent final rule) that imposes substantial direct compliance costs on state and local governments, preempts state law, or otherwise has Federalism implications. We have determined that this notice does not significantly affect the rights, roles, and responsibilities of states. Accordingly, the requirements of Executive Order 13132 do not apply to this notice.

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

V. Waiver of Proposed Notice

The Medicare statute requires the publication of the monthly actuarial rates and the Part B premium amounts in September. We ordinarily use general notices, rather than notice and comment rulemaking procedures, to make such announcements. In doing so, we note that, under the Administrative Procedure Act, interpretive rules, general statements of policy, and rules of agency organization, procedure, or practice are excepted from the requirements of notice and comment rulemaking.

We considered publishing a proposed notice to provide a period for public comment. However, we may waive that procedure if we find, for good cause, that prior notice and comment are impracticable, unnecessary, or contrary to the public interest. The statute establishes the time period for which the premium rates will apply, and delaying publication of the Part B premium rate such that it would not be published before that time would be contrary to the public interest. Moreover, we find that notice and comment are unnecessary because the formulas used to calculate the Part B premiums are statutorily directed. Therefore, we find good cause to waive publication of a proposed notice and solicitation of public comments.

Dated: November 8, 2016.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: November 8, 2016.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

[FR Doc. 2016–27425 Filed 11–10–16; 4:15 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–8063–N]

RIN 0938–AS71

Medicare Program; CY 2017 Part A Premiums for the Uninsured Aged and for Certain Disabled Individuals Who Have Exhausted Other Entitlement

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

ACTION: Notice.

SUMMARY: This annual notice announces Medicare's Hospital Insurance (Part A) premium for uninsured enrollees in calendar year (CY) 2017. This premium is paid by enrollees age 65 and over who are not otherwise eligible for benefits under Medicare Part A (hereafter known as the ''uninsured aged'') and by certain disabled individuals who have exhausted other entitlement. The monthly Part A premium for the 12 months beginning January 1, 2017, for these individuals will be $413. The premium for certain other individuals as described in this notice will be $227.

DATES: *Effective Date:* This notice is effective on January 1, 2017.

FOR FURTHER INFORMATION CONTACT: Clare McFarland, (410) 786–6390.

SUPPLEMENTARY INFORMATION:

I. Background

Section 1818 of the Social Security Act (the Act) provides for voluntary enrollment in the Medicare Hospital Insurance Program (Medicare Part A), subject to payment of a monthly premium, of certain persons aged 65 and older who are uninsured under the Old-Age, Survivors, and Disability Insurance (OASDI) program or the Railroad Retirement Act and do not otherwise meet the requirements for entitlement to Medicare Part A. These ''uninsured aged'' individuals are uninsured under the OASDI program or the Railroad Retirement Act, because they do not have 40 quarters of coverage under Title II of the Act (or are/were not married to someone who did). (Persons insured under the OASDI program or the Railroad Retirement Act and certain others do not have to pay premiums for Medicare Part A.)

Section 1818A of the Act provides for voluntary enrollment in Medicare Part A, subject to payment of a monthly premium for certain disabled individuals who have exhausted other entitlement. These are individuals who were entitled to coverage due to a disabling impairment under section 226(b) of the Act, but who are no longer entitled to disability benefits and free Medicare Part A coverage because they have gone back to work and their earnings exceed the statutorily defined ''substantial gainful activity'' amount (section 223(d)(4) of the Act).

Section 1818A(d)(2) of the Act specifies that the provisions relating to premiums under section 1818(d) through section 1818(f) of the Act for the aged will also apply to certain disabled individuals as described above.

Section 1818(d)(1) of the Act requires us to estimate, on an average per capita basis, the amount to be paid from the Federal Hospital Insurance Trust Fund for services incurred in the upcoming calendar year (CY) (including the associated administrative costs) on behalf of individuals aged 65 and over who will be entitled to benefits under Medicare Part A. We must then determine the monthly actuarial rate for the following year (the per capita amount estimated above divided by 12) and publish the dollar amount for the monthly premium in the succeeding CY. If the premium is not a multiple of $1, the premium is rounded to the nearest multiple of $1 (or, if it is a multiple of 50 cents but not of $1, it is rounded to the next highest $1).

Section 13508 of the Omnibus Budget Reconciliation Act of 1993 (Pub. L. 103–66) amended section 1818(d) of the Act to provide for a reduction in the premium amount for certain voluntary enrollees (section 1818 and section 1818A of the Act). The reduction applies to an individual who is eligible to buy into the Medicare Part A program and who, as of the last day of the previous month:

- Had at least 30 quarters of coverage under Title II of the Act;
- Was married, and had been married for the previous 1-year period, to a person who had at least 30 quarters of coverage;
- Had been married to a person for at least 1 year at the time of the person's death if, at the time of death, the person had at least 30 quarters of coverage; or
- Is divorced from a person and had been married to the person for at least 10 years at the time of the divorce if, at the time of the divorce, the person had at least 30 quarters of coverage.

Section 1818(d)(4)(A) of the Act specifies that the premium that these individuals will pay for CY 2017 will be equal to the premium for uninsured aged enrollees reduced by 45 percent.

II. Monthly Premium Amount for CY 2017

The monthly premium for the uninsured aged and certain disabled individuals who have exhausted other entitlement for the 12 months beginning January 1, 2017, is $413.

The monthly premium for the individuals eligible under section 1818(d)(4)(B) of the Act, and therefore, subject to the 45 percent reduction in the monthly premium, is $227.

III. Monthly Premium Rate Calculation

As discussed in section I of this notice, the monthly Medicare Part A premium is equal to the estimated monthly actuarial rate for CY 2017 rounded to the nearest multiple of $1 and equals one-twelfth of the average per capita amount, which is determined by projecting the number of Medicare Part A enrollees aged 65 years and over as well as the benefits and administrative costs that will be incurred on their behalf.

The steps involved in projecting these future costs to the Federal Hospital Insurance Trust Fund are:

- Establishing the present cost of services furnished to beneficiaries, by type of service, to serve as a projection base;
- Projecting increases in payment amounts for each of the service types; and
- Projecting increases in administrative costs.

We base our projections for CY 2017 on—(1) current historical data; and (2) projection assumptions derived from current law and the Mid-Session Review of the President's Fiscal Year 2017 Budget.

We estimate that in CY 2017, 48,634,512 people aged 65 years and over will be entitled to (enrolled in) benefits (without premium payment) and that they will incur about $240.891 billion in benefits and related administrative costs. Thus, the estimated monthly average per capita amount is $412.76 and the monthly premium is $413. Subsequently, the full monthly premium reduced by 45 percent is $227.

IV. Costs to Beneficiaries

The CY 2017 premium of $413 is approximately 0.5 percent higher than the CY 2016 premium of $411. We estimate that approximately 654,000 enrollees will voluntarily enroll in Medicare Part A, by paying the full premium. Note that states pay Part A premiums for persons who are enrolled in the Qualified Medicare Beneficiary Program (a Medicaid program which helps certain low-income individuals with Medicare premium and cost-sharing liability). Furthermore, the CY 2017 reduced premium of $227 is approximately 0.5 percent higher than the CY 2016 premium of $226. We estimate an additional 67,000 enrollees will pay the reduced premium. Therefore, we estimate that the total aggregate cost to enrollees paying these premiums in CY 2017, compared to the amount that they paid in CY 2016, will be about $17 million.

V. Waiver of Proposed Notice and Comment Period

We use general notices, rather than notice and comment rulemaking procedures, to make announcements such as this premium notice. In doing so, we acknowledge that, under the Administrative Procedure Act (APA), interpretive rules, general statements of policy, and rules of agency organization, procedure, or practice are excepted from the requirements of notice and comment rulemaking. The agency may also waive notice and comment if there is ''good cause,'' as defined by the statute. We considered publishing a proposed notice to provide a period for public comment. However, under the APA, we may waive that procedure if we find good cause that prior notice and comment are impracticable, unnecessary, or contrary to the public interest.

We are not using notice and comment rulemaking in this notification of Medicare Part A premiums for CY 2017 as that procedure is unnecessary because of the lack of discretion in the statutory formula that is used to calculate the premium and the solely ministerial function that this notice serves. The APA permits agencies to waive notice and comment rulemaking when notice and public comment thereon are unnecessary. On this basis, we waive publication of a proposed notice and a solicitation of public comments.

VI. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

VII. Regulatory Impact Analysis

A. Statement of Need

Section 1818(d) of the Act requires the Secretary of the Department of Health and Human Services (the Secretary) during September of each year to determine and publish the amount to be paid, on an average per capita basis, from the Federal Hospital Insurance Trust Fund for services incurred in the impending CY (including the associated administrative costs) on behalf of individuals aged 65 and over who will be entitled to benefits under Medicare Part A.

B. Overall Impact

We have examined the impact of this notice as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. Part I, Ch. 8).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major notices with economically significant effects ($100 million or more in any 1 year). As stated in section IV of this notice, we estimate that the overall effect of the changes in the Part A premium will be a cost to voluntary enrollees (section 1818 and section 1818A of the Act) of about $17 million. As a result, this notice is non-economically significant under section 3(f)(1) of Executive Order 12866 and is not a major action under the Congressional Review Act. In accordance with the provisions of Executive Order 12866, this notice was reviewed by the Office of Management and Budget.

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than $7.5 million to $38.5 million in any 1 year (for details, see the Small Business Administration's Web site at *http://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf*).

Individuals and states are not included in the definition of a small entity. As discussed above, this annual notice announces Medicare's Hospital Insurance (Part A) premium for uninsured enrollees in CY 2017. As a result, we are not preparing an analysis for the RFA because the Secretary has determined that this notice will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Social Security 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. As discussed above, we are not preparing an analysis for section 1102(b) of the Act, because the Secretary has determined that this notice will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2016, that threshold is approximately $146 million. This notice does not impose mandates that will have a consequential effect of $146 million or more on state, local, or tribal governments or on the private sector.

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

Dated: September 23, 2016.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: November 8, 2016.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

[FR Doc. 2016–27388 Filed 11–10–16; 4:15 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–1311]

Paul S. Singh: Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The U.S. Food and Drug Administration (FDA or Agency) is issuing an order under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) permanently debarring Paul S. Singh from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Dr. Singh was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act. Dr. Singh was given notice of the proposed permanent debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. Dr. Singh failed to request a hearing. Dr. Singh's failure to request a hearing constitutes a waiver of his right to a hearing concerning this action.