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). As stated in section IV of this notice, we estimate that the total increase in costs to beneficiaries associated with this notice is about $730 million due to—(1) The increase in the deductible and coinsurance amounts; and (2) the change in the number of deductibles and daily coinsurance amounts paid. Therefore, this notice is a major rule as defined in Title 5, United States Code, section 804(2), and is an economically significant rule under Executive Order 12866.

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 government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $7.0 million to $34.5 million in any 1 year. Individuals and States are not included in the definition of a small entity. We have determined that this notice will not have a significant economic impact on a substantial number of small entities. Therefore, we are not preparing an analysis under the RFA.

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. The Secretary has determined that this notice will not have a significant impact on the operations of a substantial number of small rural hospitals. Therefore, we are not preparing an analysis under section 1102(b) of the Act.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) 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 2009, that threshold is approximately $133 million. This notice has no consequential effect on State, local, or Tribal governments or on the private sector. However, States may be required to pay the deductibles and coinsurance for dually-eligible beneficiaries.

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. This notice will not have a substantial effect on State or local governments.

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

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance)

Dated: September 1, 2009.

Charlene Frizzera,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: September 17, 2009.

Kathleen Sebelius,

Secretary.

[FR Doc. E9–25372 Filed 10–16–09; 4:15 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–8038–N]

RIN 0938–AP43

Medicare Program; Part A Premium for Calendar Year 2010 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) 2010. 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, 2010 for these individuals will be $461. The reduced premium for certain other individuals as described in this notice will be $254.

DATES: *Effective Date:* This notice is effective on January 1, 2010.

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. (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 of 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 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) 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 following 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, during September of each year, 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 2010 will be equal to the premium for uninsured aged enrollees reduced by 45 percent.

II. Monthly Premium Amount for CY 2010

The monthly premium for the uninsured aged and certain disabled individuals who have exhausted other entitlement for the 12 months beginning January 1, 2010, is $461.

The monthly premium for those individuals subject to the 45 percent reduction in the monthly premium is $254.

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 2010 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 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 2010 on—(1) current historical data; and (2) projection assumptions derived from current law and the Mid-Session Review of the President's Fiscal Year 2010 Budget.

We estimate that in CY 2010, 38,086,139 people aged 65 years and over will be entitled to benefits (without premium payment) and that they will incur about $210.795 billion in benefits and related administrative costs. Thus, the estimated monthly average per capita amount is $461.22 and the monthly premium is $461. The full monthly premium reduced by 45 percent is $254.

IV. Costs to Beneficiaries

The CY 2010 premium of $461 is approximately 4 percent higher than the CY 2009 premium of $443.

We estimate that approximately 558,000 enrollees will voluntarily enroll in Medicare Part A by paying the full premium. We estimate an additional 40,000 enrollees will pay the reduced premium. We estimate that the aggregate cost to enrollees paying these premiums will be about $125 million in CY 2010 more than the amount that they paid in CY 2009.

V. Waiver of Proposed Notice and Comment Period

We are not using notice and comment rulemaking in this notification of Medicare Part A premiums for CY 2010, 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 Administrative Procedure Act (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. Regulatory Impact Statement

We have examined the impacts of this final rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), 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 (Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), 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). As stated in section IV of this notice, we estimate that the overall effect of these changes in the Part A premium will be an increased cost to voluntary enrollees (section 1818 and section 1818A of the Act) of about $125 million. Therefore, this notice is a major rule as defined in Title 5, United States Code, section 804(2) and is an economically significant rule under Executive Order 12866.

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 government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $7 million to $34.5 million in any 1 year. Individuals and States are not included in the definition of a small entity. We have determined that this notice will not have a significant economic impact on a substantial number of small entities. Therefore, we are not preparing an analysis under the RFA.

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. The Secretary has determined that this notice will not have a significant impact on the operations of a substantial number of small rural hospitals. Therefore, we are not preparing an analysis under section 1102(b) of the Act.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) 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 2009, that threshold is approximately $133 million. This notice has no consequential effect on State, local, or tribal governments or on the private sector. However, States are required to

pay the premiums for dually-eligible beneficiaries.

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. This notice will not have a substantial effect on State or local governments.

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

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance)

Dated: September 1, 2009.

Charlene Frizzera,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: September 17, 2009.

Kathleen Sebelius,

Secretary.

[FR Doc. E9–25371 Filed 10–16–09; 4:15 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0664]

Radiological Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Radiological Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on November 17 and 18, 2009, from 8 a.m. to 5:30 p.m.

Location: Holiday Inn, Ballroom, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Toby Lowe, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–6512, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512526. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On November 17, 2009, the committee will discuss and make recommendations regarding the agency's regulatory strategy for Full Field Digital Mammography (FFDM) Devices. The committee will discuss the public comments received in response to the publication of the draft guidance document entitled ''Class II Special Controls Guidance Document: Full Field Digital Mammography System.'' This guidance document can be found on the FDA Web site at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm107552.htm*.

On November 18, 2009, the committee will discuss and make recommendations regarding the agency's regulatory strategy for computer-assisted detection (CADe) devices for radiological devices. CADe devices are devices intended to identify, mark, highlight or in any other manner direct attention to potential abnormalities revealed in radiological data of the human body or imaging device data during interpretation of patient images or patient imaging data by a physician or other health care professional. The committee will discuss two draft guidance documents entitled ''Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data—Premarket Notification [510(k)] Submissions'' and ''Clinical Performance Assessment: Considerations for Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data—Premarket Approval (PMA) and Premarket Notification [510(k)] Submissions.'' These guidance documents can be found on the FDA Web site at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments.* Type in the title of the guidance document included in this notice. The guidance documents will also be available as background materials.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm*. Scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before November 12, 2009. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on both days. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before November 6, 2009. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by November 9, 2009.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact AnnMarie Williams, Conference Management Staff, 301–796–5966, at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: October 16, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–25406 Filed 10–21–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Scientific Management Review Board.

The NIH Reform Act of 2006 (Pub. L.109–482) provides organizational authorities to HHS and NIH officials to: (1) Establish or abolish national research institutes; (2) reorganize the offices within the Office of the Director, NIH including adding, removing, or transferring the functions of such offices or establishing or terminating such offices; and (3) reorganize, divisions, centers, or other administrative units within an NIH national research