

FDA has a guidance document that provides information for those interested in participating in this program. The guidance is entitled

“Implementation of the Inspection by Accredited Persons Program Under the Medical Device User Fee and

Modernization Act of 2002; Accreditation Criteria.”

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

FD&C Act Section:	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
704(g)	3	1	3	80	240

¹ There are no capital costs or operating and maintenance costs associated with this collection of information

FDA based these estimates on conversations with industry, trade association representatives, and internal FDA estimates. Once an organization is accredited, it will not be required to reapply.

Dated: October 7, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–25395 Filed 10–21–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice of Establishment

Pursuant to the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), the Director, National Institutes of Health (NIH), announces the establishment of the Interdisciplinary Molecular Sciences and Training Integrated Review Group, (IRG).

The IRG shall advise the Director, National Institutes of Health (NIH), and the Director, Center for Scientific Review (CSR), on the scientific and technical merit of applications for grants-in-aid for research, research training or research-related grants and cooperative agreements, or contract proposals relating to scientific areas relevant to biological chemistry, biophysics and cell biology, drug discovery and development, devices and detection systems, biomaterials, delivery systems and nanotechnology, computational biology, imaging and data mining, genes, genomes and genetics, environmental monitoring, and basic translational oncology.

Duration of this committee will be continuing with no specified end date.

Dated: October 9, 2009.

Francis S. Collins,

Director, National Institutes of Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–8039–N]

RIN 0938–AP48

Medicare Program; Medicare Part B Monthly Actuarial Rates, Premium Rate, and Annual Deductible Beginning January 1, 2010

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

ACTION: Notice.

SUMMARY: This notice announces the monthly actuarial rates for aged (age 65 and over) and disabled (under age 65) beneficiaries enrolled in Part B of the Medicare Supplementary Medical Insurance (SMI) program beginning January 1, 2010. In addition, 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. The monthly actuarial rates for 2010 are \$221.00 for aged enrollees and \$270.40 for disabled enrollees. The standard monthly Part B premium rate for 2010 is \$110.50, which is equal to 50 percent of the monthly actuarial rate for aged enrollees or roughly 25 percent of the expected average total cost of Part B coverage for aged enrollees. (The 2009 standard premium rate was \$96.40.) The Part B deductible for 2010 is \$155.00 for all Part B beneficiaries. A beneficiary who has to pay an income-related monthly adjustment may have to pay a total monthly premium of roughly 35, 50, 65 or 80 percent of the total cost of Part B coverage.

DATES: *Effective Date:* January 1, 2010.

FOR FURTHER INFORMATION CONTACT: M. Kent Clemens, (410) 786–6391.

SUPPLEMENTARY INFORMATION:

I. Background

Part B is the voluntary portion of the Medicare program that pays all or part

of the costs for physicians' services, outpatient hospital services, certain home health services, services furnished by rural health clinics, ambulatory surgical centers, comprehensive outpatient rehabilitation facilities, and certain other medical and health services not covered by Medicare Part A, Hospital Insurance. Medicare Part B is available to individuals who are entitled to Medicare Part A, as well as to U.S. residents who have attained age 65 and are citizens, and aliens who were lawfully admitted for permanent residence and have resided in the United States for 5 consecutive years. Part B requires enrollment and payment of monthly premiums, as provided for in 42 CFR part 407, subpart B, and part 408, respectively. Part B costs are met by payments from the Part B account of the Supplementary Medical Insurance Trust Fund, which is funded by the premiums paid by all enrollees and general revenues of the Federal Government.

The Secretary of the Department of Health and Human Services (the Secretary) is required by section 1839 of the Social Security Act (the Act) to announce the Part B monthly actuarial rates for aged and disabled beneficiaries as well as the monthly Part B premium. The Part B annual deductible is included because its determination is directly linked to the aged actuarial rate.

The monthly actuarial rates for aged and disabled enrollees are used to determine the correct amount of general revenue financing per beneficiary each month. These rates, according to actuarial estimates, will initially equal, respectively, one-half the expected average monthly cost of Part B for each aged enrollee (age 65 or over) and one-half the expected average monthly cost of Part B for each disabled enrollee (under age 65). The actuarial rates are then adjusted to include any margin necessary to maintain an adequate contingency reserve in the Part B account of the Supplementary Medical Insurance Trust Fund.

The Part B deductible to be paid by enrollees is also announced. Prior to the