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 BURDEN[1]

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]

BILLING CODE 4160–01–S

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.

[FR Doc. E9–25374 Filed 10–21–09; 8:45 am]

BILLING CODE 4140–01–M

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

Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173), the Part B deductible was set in statute. After setting the 2005 deductible amount at $110.00, section 629 of the MMA (amending section 1833(b) of the Act) requires that the Part B deductible be indexed beginning in 2006. The inflation factor to be used each year is the annual percentage increase in the Part B actuarial rate for enrollees age 65 and over. Specifically, the 2010 Part B deductible is calculated by multiplying the 2009 deductible by the ratio of the 2010 aged actuarial rate over the 2009 aged actuarial rate. The amount determined under this formula is then rounded to the nearest $1.

The monthly Part B premium rate to be paid by aged and disabled enrollees is also announced. (Although the costs to the program per disabled enrollee are different than for the aged, the statute provides that they pay the same premium amount.) Beginning with the passage of section 203 of the Social Security Amendments of 1972 (Pub. L. 92–603), the premium rate, which was determined on a fiscal year basis, was limited to the lesser of the actuarial rate for aged enrollees, or the current monthly premium rate increased by the same percentage as the most recent general increase in monthly Title II Social Security benefits.

However, the passage of section 124 of the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA) (Pub. L. 97–248) suspended this premium determination process. Section 124 of TEFRA changed the premium basis to 50 percent of the monthly actuarial rate for aged enrollees (that is, 25 percent of program costs for aged enrollees). Section 606 of the Social Security Amendments of 1983 (Pub. L. 98–21), section 2302 of the Deficit Reduction Act of 1984 (DEFRA 84) (Pub. L. 98–369), section 9313 of the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA 85) (Pub. L. 99–272), section 4080 of the Omnibus Budget Reconciliation Act of 1987 (OBRA 87) (Pub. L. 100–203), and section 6301 of the Omnibus Budget Reconciliation Act of 1989 (OBRA 89) (Pub. L. 101–239) extended the provision that the premium be based on 50 percent of the monthly actuarial rate for aged enrollees (that is, 25 percent of program costs for aged enrollees). This extension expired at the end of 1990.

The premium rate for 1991 through 1995 was legislated by section 1839(e)(1)(B) of the Act, as added by section 4301 of the Omnibus Budget Reconciliation Act of 1990 (OBRA 90) (Pub. L. 101–508). In January 1996, the premium determination basis would have reverted to the method established by the 1972 Social Security Act Amendments. However, section 13571 of the Omnibus Budget Reconciliation Act of 1993 (OBRA 93) (Pub. L. 103–66) changed the premium basis to 50 percent of the monthly actuarial rate for aged enrollees (that is, 25 percent of program costs for aged enrollees) for 1996 through 1998.

Section 4571 of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33) permanently extended the provision that the premium be based on 50 percent of the monthly actuarial rate for aged enrollees (that is, 25 percent of program costs for aged enrollees).

The BBA included a further provision affecting the calculation of the Part B actuarial rates and premiums for 1998 through 2003. Section 4611 of the BBA modified the home health benefit payable under Part A for individuals enrolled in Part B. Under this section, beginning in 1998, expenditures for home health services not considered ''post-institutional'' are payable under Part B rather than Part A. However, section 4611(e)(1) of the BBA required that there be a transition from 1998 through 2002 for the aggregate amount of the expenditures transferred from Part A to Part B. Section 4611(e)(2) of the BBA also provided a specific yearly proportion for the transferred funds. The proportions were 1/6 for 1998, 1/3 for 1999, 1/2 for 2000, 2/3 for 2001, and 5/6 for 2002. For the purpose of determining the correct amount of financing from general revenues of the Federal Government, it was necessary to include only these transitional amounts in the monthly actuarial rates for both aged and disabled enrollees, rather than the total cost of the home health services being transferred.

Section 4611(e)(3) of the BBA also specified, for the purpose of determining the premium, that the monthly actuarial rate for enrollees age 65 and over be computed as though the transition would occur for 1998 through 2003 and that 1/7 of the cost be transferred in 1998, 2/7 in 1999, 3/7 in 2000, 4/7 in 2001, 5/7 in 2002, and 6/7 in 2003. Therefore, the transition period for incorporating this home health transfer into the premium was 7 years while the transition period for including these services in the actuarial rate was 6 years.

Section 811 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173), also known as the Medicare Modernization Act, or MMA), which amended section 1839 of the Act, requires that, starting on January 1, 2007, the Part B premium a beneficiary pays each month be based on his or her annual income. Specifically, if a beneficiary's ''modified adjusted gross income'' is greater than the legislated threshold amounts (for 2010, $85,000 for a beneficiary filing an individual income tax return, and $170,000 for a beneficiary filing a joint tax return) the beneficiary is responsible for a larger portion of the estimated total cost of Part B benefit coverage. In addition to the standard 25 percent premium, these beneficiaries have to pay an income-related monthly adjustment amount. The MMA made no change to the actuarial rate calculation, and the standard premium, which will continue to be paid by beneficiaries whose modified adjusted gross income is below the applicable thresholds, still represents approximately 25 percent of the estimated total cost to the program of Part B coverage for an aged enrollee. However, depending on income and tax filing status, a beneficiary could be responsible for 35, 50, 65 or 80 percent of the estimated total cost of Part B coverage, rather than 25 percent. The end result of the higher premium is that the Part B premium subsidy is reduced and less general revenue financing is required for beneficiaries with higher income because they are paying a larger share of the total cost with their premium. That is, the premium subsidy will continue to be approximately 75 percent for beneficiaries with income below the applicable income thresholds, but will be reduced for beneficiaries with income above these thresholds. The MMA specified that there be a 5-year transition to full implementation of this provision. However, section 5111 of the Deficit Reduction Act of 2005 (DRA) (Pub. L. 109–171) modified the transition to a 3-year period. The full reduction in the Part B premium subsidy for beneficiaries with incomes above the applicable thresholds is in effect for calendar years 2009 and later.

Section 4732(c) of the BBA added section 1933(c) of the Act, which required the Secretary to allocate money from the Part B trust fund to the State Medicaid programs for the purpose of providing Medicare Part B premium assistance from 1998 through 2002 for the low-income Medicaid beneficiaries who qualify under section 1933 of the Act. This allocation, while not a benefit expenditure, was an expenditure of the trust fund and was included in calculating the Part B actuarial rates through 2002. For 2003 through 2010, the allocation was temporarily extended.

A further provision affecting the calculation of the Part B premium is

section 1839(f) of the Act, as amended by section 211 of the Medicare Catastrophic Coverage Act of 1988 (MCCA 88) (Pub. L. 100–360). (The Medicare Catastrophic Coverage Repeal Act of 1989 (Pub. L. 101–234) did not repeal the revisions to section 1839(f) made by MCCA 88.) Section 1839(f) of the Act, referred to as the ''hold-harmless'' provision, provides that if an individual is entitled to benefits under section 202 or 223 of the Act (the Old-Age and Survivors Insurance Benefit and the Disability Insurance Benefit, respectively) and has the Part B premiums deducted from these benefit payments, the premium increase will be reduced, if necessary, to avoid causing a decrease in the individual's net monthly payment. This decrease in payment occurs if the increase in the individual's social security benefit due to the cost-of-living adjustment under section 215(i) of the Act is less than the increase in the premium. Specifically, the reduction in the premium amount applies if the individual is entitled to benefits under section 202 or 223 of the Act for November and December of a particular year and the individual's Part B premiums for December and the following January are deducted from the respective month's section 202 or 223 benefits. The ''hold-harmless'' provision does not apply to beneficiaries who are required to pay an income-related monthly adjustment amount.

A check for benefits under section 202 or 223 of the Act is received in the month following the month for which the benefits are due. The Part B premium that is deducted from a particular check is the Part B payment for the month in which the check is received. Therefore, a benefit check for November is not received until December, but has December's Part B premium deducted from it.

Generally, if a beneficiary qualifies for hold-harmless protection, that is, if the beneficiary was in current payment status for November and December of the previous year, the reduced premium for the individual for that January and for each of the succeeding 11 months for which he or she is entitled to benefits, under section 202 or 203 of the Act, is the greater of the following—

- The monthly premium for January reduced as necessary to make the December monthly benefits, after the deduction of the Part B premium for January, at least equal to the preceding November's monthly benefits, after the deduction of the Part B premium for December; or
- The monthly premium for that individual for that December.

In determining the premium limitations under section 1839(f) of the Act, the monthly benefits to which an individual is entitled under section 202 or 223 of the Act do not include retroactive adjustments or payments and deductions on account of work. Also, once the monthly premium amount is established under section 1839(f) of the Act, it will not be changed during the year even if there are retroactive adjustments or payments and deductions on account of work that apply to the individual's monthly benefits.

Individuals who have enrolled in Part B late or who have re-enrolled after the termination of a coverage period are subject to an increased premium under section 1839(b) of the Act. The increase is a percentage of the premium and is based on the new premium rate before any reductions under section 1839(f) of the Act are made.

II. Provisions of the Notice

A. Notice of Medicare Part B Monthly Actuarial Rates, Monthly Premium Rates, and Annual Deductible

The Medicare Part B monthly actuarial rates applicable for 2010 are $221.00 for enrollees age 65 and over and $270.40 for disabled enrollees under age 65. Section II.B. of this notice below, presents the actuarial assumptions and bases from which these rates are derived. The Part B standard monthly premium rate for 2010 is $110.50. The Part B annual deductible for 2010 is $155.00. Listed below are the 2010 Part B monthly premium rates to be paid by beneficiaries who file an individual tax return (including those who are single, head of household, qualifying widow(er) with dependent child, or married filing separately who lived apart from their spouse for the entire taxable year), or a joint tax return. (The income thresholds are indexed to the Consumer Price Index and rounded to the nearest $1,000.)

Beneficiaries who file an individual tax return with income:	Beneficiaries who file a joint tax return with income:	Income-related monthly adjustment amount	Total monthly premium amount
Less than or equal to $85,000	Less than or equal to $170,000	$0.00	$110.50
Greater than $85,000 and less than or equal to $107,000.	Greater than $170,000 and less than or equal to $214,000.	44.20	154.70
Greater than $107,000 and less than or equal to $160,000.	Greater than $214,000 and less than or equal to $320,000.	110.50	221.00
Greater than $160,000 and less than or equal to $214,000.	Greater than $320,000 and less than or equal to $428,000.	176.80	287.30
Greater than $214,000	Greater than $428,000	243.10	353.60

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 listed below.

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	$110.50
Greater than $85,000 and less than or equal to $129,000	176.80	287.30
Greater than $129,000	243.10	353.60

The Part B annual deductible for 2010 is $155.00 for all beneficiaries.

B. Statement of Actuarial Assumptions and Bases Employed in Determining the Monthly Actuarial Rates and the Monthly Premium Rate for Part B Beginning January 2010

1. Actuarial Status of the Part B Account in the Supplementary Medical Insurance Trust Fund

Under the statute, the starting point for determining the standard monthly premium is the amount that would be necessary to finance Part B on an incurred basis. This is the amount of income that would be sufficient to pay for services furnished during that year (including associated administrative costs) even though payment for some of these services will not be made until after the close of the year. The portion of income required to cover benefits not paid until after the close of the year is added to the trust fund and used when needed.

The premium rates are established prospectively and are, therefore, subject to projection error. Additionally, legislation enacted after the financing was established, but effective for the period in which the financing is set, may affect program costs. As a result, the income to the program may not equal incurred costs. Therefore, trust fund assets must be maintained at a level that is adequate to cover an appropriate degree of variation between actual and projected costs, and the amount of incurred, but unpaid, expenses. Numerous factors determine what level of assets is appropriate to cover variation between actual and projected costs. The three most important of these factors are: (1) The difference from prior years between the actual performance of the program and estimates made at the time financing was established; (2) the likelihood and potential magnitude of expenditure changes resulting from enactment of legislation affecting Part B costs in a year subsequent to the establishment of financing for that year, and (3) the expected relationship between incurred and cash expenditures. These factors are analyzed on an ongoing basis, as the trends can vary over time.

Table 1 summarizes the estimated actuarial status of the trust fund as of the end of the financing period for 2008 and 2009.

TABLE 1—ESTIMATED ACTUARIAL STATUS OF THE PART B ACCOUNT IN THE SUPPLEMENTARY MEDICAL INSURANCE TRUST FUND AS OF THE END OF THE FINANCING PERIOD

Financing period ending	Assets (millions)	Liabilities (millions)	Assets less liabilities (millions)
December 31, 2008	$59,382	$12,490	$46,892
December 31, 2009	59,876	13,999	45,876

2. Monthly Actuarial Rate for Enrollees Age 65 and Older

The monthly actuarial rate for enrollees age 65 and older is one-half of the sum of monthly amounts for: (1) The projected cost of benefits; and (2) administrative expenses for each enrollee age 65 and older, after adjustments to this sum to allow for interest earnings on assets in the trust fund and an adequate contingency margin. The contingency margin is an amount appropriate to provide for possible variation between actual and projected costs and to amortize any surplus assets or unfunded liabilities.

The monthly actuarial rate for enrollees age 65 and older for 2010 is determined by first establishing per-enrollee cost by type of service from program data through 2008 and then projecting these costs for subsequent years. The projection factors used for financing periods from January 1, 2007 through December 31, 2010 are shown in Table 2.

As indicated in Table 3, the projected monthly rate required to pay for one-half of the total of benefits and administrative costs for enrollees age 65 and over for 2010 is $189.84. Based on current estimates, the assets are not sufficient to cover the amount of incurred, but unpaid, expenses and to provide for a significant degree of variation between actual and projected costs. Thus, a positive contingency margin is needed to increase assets to a more appropriate level. The monthly actuarial rate of $221.00 provides an adjustment of $34.32 for a contingency margin and –$3.16 for interest earnings.

The size of the contingency margin for 2010 is affected by several factors. The first and largest factor involves current law formula for physician fees, which will result in a reduction in physician fees of approximately 21 percent in 2010 and is projected to cause additional reductions in subsequent years. Smaller scheduled reductions in physician payments have been legislatively avoided in every year since 2002. In recognition of the strong possibility of substantial increases in Part B expenditures that would result from similar legislation to override the decreases in physician fees in 2010 or later years, it is appropriate to maintain a significantly larger Part B contingency reserve than would otherwise be necessary. The asset level projected for the end of 2009 is not adequate to accommodate this contingency.

A second, much smaller factor underlying the need for an adequate contingency reserve, is the possibility for increased Part B costs in 2010 as a result of a serious flu season.

The third factor has a large impact on the level of the contingency reserve. As noted previously, for most Part B beneficiaries the hold-harmless provision prevents their benefits under section 202 or 223 of the Act from decreasing as a result of an increase in the Part B premium. The increase in the benefits under section 202 and 223 of the Act is nearly certain to be 0 percent for 2010 and possibly for 2011. As a result, the increase in the Part B premium for 2010 (the $14.10 increase from the 2009 standard monthly premium of $96.40 to the 2010 standard monthly premium of $110.50) will be paid by only a small percentage of Part B enrollees. (Approximately 27 percent of beneficiaries are not subject to the hold-harmless provision because they are subject to the income-related additional premium amount (5 percent), they are new enrollees during the year (3 percent), or they do not have their Part B premiums withheld from social security benefit payments (19 percent), including those who qualify for both Medicare and Medicaid and have their Part B premiums paid on their behalf by Medicaid (17 percent).) In order for Part B to be adequately funded in 2010, the 2010 contingency margin has been increased to account for this situation. However, the result is a larger-than-usual premium paid by or on behalf of a minority of Part B enrollees.

The traditional goal for the Part B reserve has been that assets minus liabilities at the end of a year should

represent between 15 and 20 percent of the following year's total incurred expenditures. Within this range, 17 percent has been the normal target. In view of the high probability that premiums and matching general revenues in 2010 will be inadequate, due to the hold-harmless provision, and the strong likelihood of actual expenditures exceeding estimated levels, due to the enactment of legislation after the financing has been set for a given year, a contingency reserve ratio in excess of 20 percent of the following year's expenditures would better ensure that the assets of the Part B account can adequately cover the cost of incurred-but-not-reported benefits together with variations between actual and estimated cost levels.

The actuarial rate of $221.00 per month for aged beneficiaries, as announced in this notice for 2010, reflects the combined net effect of the factors described above and the projection assumptions listed in Table 2.

3. Monthly Actuarial Rate for Disabled Enrollees

Disabled enrollees are those persons under age 65 who are enrolled in Part B because of entitlement to Social Security disability benefits for more than 24 months or because of entitlement to Medicare under the end-stage renal disease (ESRD) program. Projected monthly costs for disabled enrollees (other than those with ESRD) are prepared in a fashion parallel to the projection for the aged using appropriate actuarial assumptions (see Table 2). Costs for the ESRD program are projected differently because of the different nature of services offered by the program.

As shown in Table 4, the projected monthly rate required to pay for one-half of the total of benefits and administrative costs for disabled enrollees for 2010 is $222.93. The monthly actuarial rate of $270.40 also provides an adjustment of –$3.64 for interest earnings and $51.11 for a contingency margin, reflecting the same factors described above for the aged actuarial rate. Based on current estimates, the assets associated with the disabled Medicare beneficiaries are not sufficient to cover the amount of incurred, but unpaid, expenses and to provide for a significant degree of variation between actual and projected costs. Thus, a large contingency margin is needed to increase assets to an appropriate level.

The actuarial rate of $270.40 per month for disabled beneficiaries, as announced in this notice for 2010, reflects the combined net effect of the factors described above for aged beneficiaries and the projection assumptions listed in Table 2.

4. Sensitivity Testing

Several factors contribute to uncertainty about future trends in medical care costs. It is appropriate to test the adequacy of the rates using alternative assumptions. The results of those assumptions are shown in Table 5. One set represents increases that are lower and, therefore, more optimistic than the current estimate. The other set represents increases that are higher and, therefore, more pessimistic than the current estimate. The values for the alternative assumptions were determined from a statistical analysis of the historical variation in the respective increase factors.

As indicated in Table 5, the monthly actuarial rates would result in an excess of assets over liabilities of $66,192 million by the end of December 2010 under the assumptions used in preparing this report. This amounts to 31 percent of the estimated total incurred expenditures for the following year.

Assumptions that are somewhat more pessimistic (and that therefore test the adequacy of the assets to accommodate projection errors) produce a surplus of $42,525 million by the end of December 2010, which amounts to 18 percent of the estimated total incurred expenditures for the following year. Under fairly optimistic assumptions, the monthly actuarial rates would result in a surplus of $89,783 million by the end of December 2010, or 47 percent of the estimated total incurred expenditures for the following year.

The above analysis indicates that the premium and general revenue financing established for 2010, together with existing Part B account assets would be adequate to cover estimated Part B costs for 2010 under current law, even if actual costs prove to be somewhat greater than expected.

5. Premium Rates and Deductible

As determined in accordance with section 1839 of the Act, listed below are the 2010 Part B monthly premium rates to be paid by beneficiaries who file an individual tax return (including those who are single, head of household, qualifying widow(er) with dependent child, or married filing separately who lived apart from their spouse for the entire taxable year), or a joint tax return.

Beneficiaries who file an individual tax return with income:	Beneficiaries who file a joint tax return with income:	Income-related monthly adjustment amount	Total monthly premium amount
Less than or equal to $85,000	Less than or equal to $170,000	$0.00	$110.50
Greater than $85,000 and less than or equal to $107,000.	Greater than $170,000 and less than or equal to $214,000.	44.20	154.70
Greater than $107,000 and less than or equal to $160,000.	Greater than $214,000 and less than or equal to $320,000.	110.50	221.00
Greater than $160,000 and less than or equal to $214,000.	Greater than $320,000 and less than or equal to $428,000.	176.80	287.30
Greater than $214,000	Greater than $428,000	243.10	353.60

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 listed below.

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	$110.50
Greater than $85,000 and less than or equal to $129,000	176.80	287.30

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
Greater than $129,000	243.10	353.60

TABLE 2—PROJECTION FACTORS[1] 12-MONTH PERIODS ENDING DECEMBER 31 OF 2007–2010

[In percent]

Calendar year	Physicians' services		Durable medical equipment	Carrier LAB[4]	Other carrier services[5]	Outpatient hospital	Home health agency	Hospital LAB[6]	Other intermediary services[7]	Managed care
	Fees[2]	Residual[3]								
Aged:										
2007	−1.4	3.5	2.9	9.8	4.7	8.5	18.8	3.2	8.4	3.6
2008	0.4	3.8	7.6	7.9	4.7	4.9	11.6	3.9	5.0	5.1
2009	1.7	4.0	−2.1	11.1	7.4	8.9	13.4	9.3	8.9	2.0
2010	−21.7	8.1	2.9	3.7	4.4	5.1	1.4	−1.7	5.1	−1.9
Disabled:										
2007	−1.4	3.4	3.6	13.1	6.7	8.8	20.7	6.1	8.8	4.5
2008	0.4	4.1	7.8	12.4	9.1	6.8	9.8	5.7	6.9	4.8
2009	1.7	5.5	1.3	15.6	10.0	9.6	14.2	10.4	9.6	1.9
2010	−21.7	8.1	3.2	3.6	3.6	5.1	1.8	−1.7	5.1	−2.1

[1] All values for services other than managed care are per fee-for-service enrollee. Managed care values are per managed care enrollee.
[2] As recognized for payment under the program.
[3] Increase in the number of services received per enrollee and greater relative use of more expensive services.
[4] Includes services paid under the lab fee schedule furnished in the physician's office or an independent lab.
[5] Includes physician-administered drugs, ambulatory surgical center facility costs, ambulance services, parenteral and enteral drug costs, supplies, etc.
[6] Includes services paid under the lab fee schedule furnished in the outpatient department of a hospital.
[7] Includes services furnished in dialysis facilities, rural health clinics, Federally qualified health centers, rehabilitation and psychiatric hospitals, etc.

TABLE 3—DERIVATION OF MONTHLY ACTUARIAL RATE FOR ENROLLEES AGE 65 AND OVER FOR FINANCING PERIODS ENDING DECEMBER 31, 2007 THROUGH DECEMBER 31, 2010

	Financing periods			
	CY 2007	CY 2008	CY 2009	CY 2010
Covered services (at level recognized):				
Physician fee schedule	78.46	78.70	81.13	68.34
Durable medical equipment	9.65	9.99	9.53	9.75
Carrier lab[1]	3.96	4.11	4.45	4.59
Other carrier services[2]	19.74	19.88	20.81	21.60
Outpatient hospital	29.87	30.18	32.03	33.48
Home health	9.84	10.57	11.67	11.76
Hospital lab[3]	2.80	2.79	2.98	2.91
Other intermediary services[4]	13.26	13.53	14.54	13.93
Managed care	41.93	49.89	54.74	54.51
Total services	209.51	219.65	231.87	220.87
Cost sharing:				
Deductible	−5.33	−5.49	−5.50	−6.32
Coinsurance	−30.74	−30.31	−31.42	−28.29
Total benefits	173.44	183.84	194.95	186.26
Administrative expenses	5.68	2.95	3.41	3.58
Incurred expenditures	179.12	186.79	198.36	189.84
Value of interest	−1.98	−3.35	−2.83	−3.16
Contingency margin for projection error and to amortize the surplus or deficit	9.86	9.26	−2.83	34.32
Monthly actuarial rate	187.00	192.70	192.70	221.00

[1] Includes services paid under the lab fee schedule furnished in the physician's office or an independent lab.
[2] Includes physician-administered drugs, ambulatory surgical center facility costs, ambulance services, parenteral and enteral drug costs, supplies, etc.
[3] Includes services paid under the lab fee schedule furnished in the outpatient department of a hospital.
[4] Includes services furnished in dialysis facilities, rural health clinics, Federally qualified health centers, and rehabilitation and psychiatric hospitals, etc.

TABLE 4—DERIVATION OF MONTHLY ACTUARIAL RATE FOR DISABLED ENROLLEES FOR FINANCING PERIODS ENDING DECEMBER 31, 2007 THROUGH DECEMBER 31, 2010

	Financing periods			
	CY 2007	CY 2008	CY 2009	CY 2010
Covered services (at level recognized):				
Physician fee schedule	78.44	79.83	84.46	71.37
Durable medical equipment	16.95	17.76	17.76	18.29
Carrier lab [1]	5.00	5.41	6.10	6.31
Other carrier services [2]	23.11	24.47	26.57	27.45
Outpatient hospital	40.10	41.44	44.75	46.92
Home health	8.24	8.79	9.89	10.05
Hospital lab [3]	4.37	4.47	4.85	4.75
Other intermediary services [4]	40.76	41.29	43.26	43.48
Managed care	29.87	36.50	39.83	39.49
Total services	246.85	259.96	277.47	268.11
Cost sharing:				
Deductible	−5.00	−5.11	−5.15	−5.92
Coinsurance	−43.83	−44.25	−46.42	−43.08
Total benefits	198.03	210.60	225.90	219.11
Administrative expenses	3.85	3.37	3.66	3.82
Incurred expenditures	201.88	213.97	229.56	222.93
Value of interest	−3.37	−4.32	−3.29	−3.64
Contingency margin for projection error and to amortize the surplus or deficit	−1.21	0.05	−2.07	51.11
Monthly actuarial rate	197.30	209.70	224.20	270.40

[1] Includes services paid under the lab fee schedule furnished in the physician's office or an independent lab.
[2] Includes physician-administered drugs, ambulatory surgical center facility costs, ambulance services, parenteral and enteral drug costs, supplies, etc.
[3] Includes services paid under the lab fee schedule furnished in the outpatient department of a hospital.
[4] Includes services furnished in dialysis facilities, rural health clinics, Federally qualified health centers, rehabilitation and psychiatric hospitals, etc.

TABLE 5—ACTUARIAL STATUS OF THE PART B ACCOUNT IN THE SMI TRUST FUND UNDER THREE SETS OF ASSUMPTIONS FOR FINANCING PERIODS THROUGH DECEMBER 31, 2010

As of December 31,	2008	2009	2010
This projection:			
Actuarial status (in millions):			
Assets	59,382	59,876	79,611
Liabilities	12,490	13,999	13,419
Assets less liabilities	46,892	45,876	66,192
Ratio (in percent) [1]	22.6	22.7	31.4
Low cost projection:			
Actuarial status (in millions):			
Assets	59,382	67,931	102,532
Liabilities	12,490	13,188	12,748
Assets less liabilities	46,892	54,744	89,783
Ratio (in percent) [1]	23.6	29.2	47.4
High cost projection:			
Actuarial status (in millions):			
Assets	59,382	52,148	56,681
Liabilities	12,490	14,778	14,156
Assets less liabilities	46,892	37,370	42,525
Ratio (in percent)[1]	21.8	17.2	18.2

[1] Ratio of assets less liabilities at the end of the year to the total incurred expenditures during the following year, expressed as a percent.

III. Regulatory Impact Analysis

We have examined the impacts of this notice 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 one year).

We have examined the impact of this notice as required by Executive Order 12866 (September 1993, Regulatory Planning and Review) and the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354). 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).

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. 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. Therefore, 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. 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 analyses for either the RFA or section 1102(b) of the Act.

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 2008, that threshold is approximately $133 million. This notice does not contain mandates that will impose spending costs on State, local or tribal governments in the aggregate, or by the private sector in any one year of $133 million or more.

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.

This notice announces that the monthly actuarial rates applicable for 2010 are $221.00 for enrollees age 65 and over and $270.40 for disabled enrollees under age 65. The Part B deductible for calendar year 2010 is $155.00. The notice also announces the 2010 monthly Part B premium rates to be paid by beneficiaries who file an individual tax return (including those who are single, head of household, qualifying widow(er) with a dependent child, or married filing separately who lived apart from their spouse for the entire taxable year), or a joint tax return.

Beneficiaries who file an individual tax return with income:	Beneficiaries who file a joint tax return with income:	Income-related monthly adjustment amount	Total monthly premium amount
Less than or equal to $85,000	Less than or equal to $170,000	$0.00	$110.50
Greater than $85,000 and less than or equal to $107,000.	Greater than $170,000 and less than or equal to $214,000.	44.20	154.70
Greater than $107,000 and less than or equal to $160,000.	Greater than $214,000 and less than or equal to $320,000.	110.50	221.00
Greater than $160,000 and less than or equal to $214,000.	Greater than $320,000 and less than or equal to $428,000.	176.80	287.30
Greater than $214,000	Greater than $428,000	243.10	353.60

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 below.

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	$110.50
Greater than $85,000 and less than or equal to $129,000	176.80	287.30
Greater than $129,000	243.10	353.60

The standard Part B premium rate of $110.50 is $14.10 higher than the premium for 2009, so there will be about $2 billion of additional costs in 2010 to the approximately 12 million Part B enrollees who pay the increase in the Part B premium. Therefore, this notice is a major rule as defined in 5 U.S.C. 804(2) and is an economically significant rule under Executive Order 12866.

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

IV. Waiver of Proposed Notice

The statute requires publication of the monthly actuarial rates and the Part B premium amounts. 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. We find that the procedure for notice and comment is unnecessary because the formulas used to calculate the Part B premiums are statutorily directed, and we can exercise no discretion in applying those formulas. Moreover, 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. Therefore, we find good cause to waive publication of a proposed notice and solicitation of public comments.

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

Dated: October 14, 2009.

Charlene Frizzera,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: October 16, 2009.

Kathleen Sebelius,

Secretary.

[FR Doc. E9–25370 Filed 10–16–09; 4:15 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–8037–N]

RIN 0938–AP42

Medicare Program; Inpatient Hospital Deductible and Hospital and Extended Care Services Coinsurance Amounts for Calendar Year 2010

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

ACTION: Notice.

SUMMARY: This notice announces the inpatient hospital deductible and the hospital and extended care services coinsurance amounts for services furnished in calendar year (CY) 2010 under Medicare's Hospital Insurance Program (Medicare Part A). The Medicare statute specifies the formulae used to determine these amounts. For CY 2010, the inpatient hospital deductible will be $1,100. The daily coinsurance amounts for CY 2010 will be—(a) $275 for the 61st through 90th day of hospitalization in a benefit period; (b) $550 for lifetime reserve days; and (c) $137.50 for the 21st through 100th day of extended care services in a skilled nursing facility in a benefit period.

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

FOR FURTHER INFORMATION CONTACT: Clare McFarland, (410) 786–6390 for general information. Gregory J. Savord, (410) 786–1521 for case-mix analysis.

SUPPLEMENTARY INFORMATION:

I. Background

Section 1813 of the Social Security Act (the Act) provides for an inpatient hospital deductible to be subtracted from the amount payable by Medicare for inpatient hospital services furnished to a beneficiary. It also provides for certain coinsurance amounts to be subtracted from the amounts payable by Medicare for inpatient hospital and extended care services. Section 1813(b)(2) of the Act requires us to determine and publish each year the amount of the inpatient hospital deductible and the hospital and extended care services coinsurance amounts applicable for services furnished in the following CY.

II. Computing the Inpatient Hospital Deductible for CY 2010

Section 1813(b) of the Act prescribes the method for computing the amount of the inpatient hospital deductible. The inpatient hospital deductible is an amount equal to the inpatient hospital deductible for the preceding CY, adjusted by our best estimate of the payment-weighted average of the applicable percentage increases (as defined in section 1886(b)(3)(B) of the Act) used for updating the payment rates to hospitals for discharges in the fiscal year (FY) that begins on October 1 of the same preceding CY, and adjusted to reflect changes in real case-mix. The adjustment to reflect real case-mix is determined on the basis of the most recent case-mix data available. The amount determined under this formula is rounded to the nearest multiple of $4 (or, if midway between two multiples of $4, to the next higher multiple of $4).

Under section 1886(b)(3)(B)(i)(XX) of the Act, the percentage increase used to update the payment rates for FY 2010 for hospitals paid under the inpatient prospective payment system is the market basket percentage increase, otherwise known as the market basket update. Under section 1886(b)(3)(B)(viii) of the Act, hospitals will receive the full market basket update only if they submit quality data as specified by the Secretary. The market basket update for hospitals that do not submit this data is reduced by 2.0 percentage points. We are estimating that after accounting for those hospitals receiving the lower market basket update in the payment-weighted average update, the calculated deductible will remain the same.

Under section 1886(b)(3)(B)(ii)(VIII) of the Act, the percentage increase used to update the payment rates for FY 2010 for hospitals excluded from the prospective payment system is the market basket percentage increase, defined according to section 1886(b)(3)(B)(iii) of the Act.

The market basket percentage increase for 2010 is 2.1 percent, as announced in the final rule with comment period published in the **Federal Register** on August 27, 2009 entitled, ''Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and Fiscal Year 2010 Rates; and Changes to the Long-Term Care Hospital Prospective Payment System and Rate Years 2010 and 2009 Rates (IPPS/RY 2010 LTCH PPS) (74 FR 43754).'' Therefore, the percentage increase for hospitals paid under the prospective payment system is 2.1 percent. The average payment percentage increase for hospitals excluded from the prospective payment system is 2.5 percent. Weighting these percentages in accordance with payment volume, our best estimate of the payment-weighted average of the increases in the payment rates for FY 2010 is 2.15 percent.

To develop the adjustment to reflect changes in real case-mix, we first calculated for each hospital an average case-mix that reflects the relative costliness of that hospital's mix of cases compared to those of other hospitals. We then computed the change in average case-mix for hospitals paid under the Medicare prospective payment system in FY 2009 compared to FY 2008. (We excluded from this calculation hospitals whose payments are not based on the Acute care prospective payment system because their payments are based on alternate