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), the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

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). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). Although we do not consider this notice to constitute a substantive rule, this notice is economically significant under section 3(f)(1) of Executive Order 12866. As stated in section IV of this notice, we estimate that the total increase in costs to beneficiaries associated with this notice is about $390 million due to: (1) The increase in the deductible and coinsurance amounts; and (2) the increase in the number of deductibles and daily coinsurance amounts paid.

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 website at *http://www.sba.gov/content/small-business-size-standards*). Individuals and states are not included in the definition of a small entity. This annual notice announces the Medicare Part A deductible and coinsurance amounts for CY 2019 and will have an impact on the Medicare beneficiaries. 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 RIA 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. This annual notice announces the Medicare Part A deductible and coinsurance amounts for CY 2019 and will have an impact on the Medicare beneficiaries. As a result, 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 (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 2018, that threshold is approximately $150 million. This notice does not impose mandates that will have a consequential effect of $150 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. This notice will not have a substantial direct effect on state or local governments, preempt state law, or otherwise have Federalism implications.

Executive Order 13771, titled ''Reducing Regulation and Controlling Regulatory Costs,'' was issued on January 30, 2017 (82 FR 9339, February 3, 2017). It has been determined that this notice is a transfer notice that does not impose more than de minimis costs and thus is not a regulatory action for the purposes of E.O. 13771.

Consistent with the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*), this notice has been transmitted to the Congress and the Comptroller General for review.

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

Although this notice does not constitute a substantive rule, we nevertheless prepared this Impact Analysis in the interest of ensuring that the impacts of this notice are fully understood.

Dated: October 3, 2018.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: October 11, 2018.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2018–22526 Filed 10–12–18; 11:15 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–8070–N]

RIN 0938–AT35

Medicare Program; Medicare Part B Monthly Actuarial Rates, Premium Rates, and Annual Deductible Beginning January 1, 2019

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, 2019. In addition, this notice announces the monthly premium for aged and disabled beneficiaries, the deductible for 2019, and 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 2019 are $264.90 for aged enrollees and $315.40 for disabled

enrollees. The standard monthly Part B premium rate for all enrollees for 2019 is $135.50, which is equal to 50 percent of the monthly actuarial rate for aged enrollees (or approximately 25 percent of the expected average total cost of Part B coverage for aged enrollees) plus the $3.00 repayment amount required under current law. (The 2018 standard premium rate was $134.00, which also included the $3.00 repayment amount.) The Part B deductible for 2019 is $185.00 for all Part B beneficiaries. If a beneficiary has to pay an income-related monthly adjustment, he or she will have to pay a total monthly premium of about 35, 50, 65, 80, or 85 percent of the total cost of Part B coverage plus a repayment amount of $4.20, $6.00, $7.80, $9.60, or $10.20, respectively.

DATES: *Effective Date:* January 1, 2019.

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 the following: Physicians' services; outpatient hospital services; certain home health services; services furnished by rural health clinics, ambulatory surgical centers, and 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 to 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 described in 42 CFR part 407, subpart B, and part 408, respectively. The premiums paid by (or on behalf of) all enrollees fund approximately one-fourth of the total incurred costs, and transfers from the general fund of the Treasury pay approximately three-fourths of these costs.

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 amounts, according to actuarial estimates, will equal, respectively, one-half of the expected average monthly cost of Part B for each aged enrollee (age 65 or over) and one-half of the expected average monthly cost of Part B for each disabled enrollee (under age 65).

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, section 629 of the MMA (amending section 1833(b) of the Act) required 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 2019 Part B deductible is calculated by multiplying the 2018 deductible by the ratio of the 2019 aged actuarial rate to the 2018 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 1997) (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 1997 included a further provision affecting the calculation of the Part B actuarial rates and premiums for 1998 through 2003. Section 4611 of the BBA 1997 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 1997 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 1997 also provided a specific yearly proportion for the transferred funds. The proportions were one-sixth for 1998, one-third for 1999, one-half for 2000, two-thirds for 2001, and five-sixths 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 1997 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 one-seventh of the cost be transferred in 1998, two-sevenths in 1999, three-sevenths in 2000, four-sevenths in 2001, five-sevenths in 2002,

and six-sevenths 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 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 2019, $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 now 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 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 can now be responsible for 35, 50, 65, 80, or 85 percent of the estimated total cost of Part B coverage, rather than 25 percent. Section 402 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10) modified the income thresholds beginning with 2018, and section 53114 of the Bipartisan Budget Act of 2018 (BBA of 2018) (Pub. L. 115–123) further modified the income thresholds beginning with 2019. For years beginning with 2019, the BBA of 2018 established a new income threshold. If a beneficiary's modified adjusted gross income is greater than or equal to $500,000 for a beneficiary filing an individual income tax return and $750,000 for a beneficiary filing a joint tax return, the beneficiary is responsible for 85 percent of the estimated total cost of Part B coverage. The BBA of 2018 specified that these new income threshold levels will be inflation-adjusted beginning in 2028. 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 continues to be approximately 75 percent for beneficiaries with income below the applicable income thresholds, but it will be reduced for beneficiaries with income above these thresholds. The MMA specified that there be a 5-year transition period to reach 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.

Section 4732(c) of the BBA 1997 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 2015, the expenditure was made from the trust fund because the allocation was temporarily extended. However, because the extension occurred after the financing was determined, the allocation was not included in the calculation of the financing rates for these years. Section 211 of MACRA permanently extended this expenditure, which is included in the calculation of the Part B actuarial rates for 2016 and subsequent years.

Another 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) of the Act 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 premium 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 December's Part B premium has been deducted from it.

Generally, if a beneficiary qualifies for hold-harmless protection, the reduced premium for the individual for that January and for each of the succeeding 11 months is the greater of either—

- 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.

Section 1839 of the Act, as amended by section 601(a) of the Bipartisan Budget Act of 2015 (Pub. L. 114–74), specified that the 2016 actuarial rate for enrollees age 65 and older be determined as if the hold-harmless provision did not apply. The premium revenue that was lost by using the resulting lower premium (excluding the forgone income-related premium revenue) was replaced by a transfer of general revenue from the Treasury,

which will be repaid over time to the general fund.

Starting in 2016, in order to repay the balance due (which includes the transfer amount and the forgone income-related premium revenue), the Part B premium otherwise determined will be increased by $3.00. These repayment amounts will be added to the Part B premium otherwise determined each year and paid back to the general fund of the Treasury and will continue until the balance due is paid back.

High-income enrollees pay the $3.00 plus an additional $1.20, $3.00, $4.80, $6.60, or $7.20 in repayment as part of the income-related monthly adjustment amount (IRMAA) premium dollars, which reduce (dollar for dollar) the amount of general revenue received by Part B from the general fund of the Treasury. Because of this general revenue offset, the repayment IRMAA premium dollars are not included in the direct repayments made to the general fund of the Treasury from Part B in order to avoid a double repayment. (Only the $3.00 monthly repayment amounts are included in the direct repayments).

These repayment amounts will continue until the total amount collected is equal to the beginning balance due. (In the final year of the repayment, the additional amounts may be modified to avoid an overpayment.) The repayment amounts (excluding the repayment amounts for high-income enrollees) are subject to the hold-harmless provision. The beginning balance due was $9,066,409,000, consisting of $1,625,761,000 in forgone income-related premium revenue plus a transfer amount of $7,440,648,000. An estimated $2,628,512,000 will have been collected for repayment to the general fund by the end of 2018.

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 2019 are $264.90 for enrollees age 65 and over and $315.40 for disabled enrollees under age 65. In section II.B. of this notice, we present the actuarial assumptions and bases from which these rates are derived. The Part B standard monthly premium rate for all enrollees for 2019 is $135.50.

The following are the 2019 Part B monthly premium rates to be paid by (or on behalf of) beneficiaries who file either individual tax returns (and are single individuals, heads of households, qualifying widows or widowers with dependent children, or married individuals filing separately who lived apart from their spouses for the entire taxable year), or joint tax returns.

Beneficiaries who file individual tax returns with income:	Beneficiaries who file joint tax returns 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	$135.50
Greater than $85,000 and less than or equal to $107,000.	Greater than $170,000 and less than or equal to $214,000.	54.10	189.60
Greater than $107,000 and less than or equal to $133,500.	Greater than $214,000 and less than or equal to $267,000.	135.40	270.90
Greater than $133,500 and less than or equal to $160,000.	Greater than $267,000 and less than or equal to $320,000.	216.70	352.20
Greater than $160,000 and less than $500,000	Greater than $320,000 and less than $750,000	297.90	433.40
Greater than or equal to $500,000	Greater than or equal to $750,000	325.00	460.50

In addition, the monthly premium rates to be paid by (or on behalf of) beneficiaries who are married and lived with their spouses at any time during the taxable year, but who file separate tax returns from their spouses, are as follows:

Beneficiaries who are married and lived with their spouses at any time during the year, but who file separate tax returns from their spouses:	Income-related monthly adjustment amount	Total monthly premium amount
Less than or equal to $85,000	$0.00	$135.50
Greater than $85,000 and less than $415,000	297.90	433.40
Greater than or equal to $415,000	325.00	460.50

The Part B annual deductible for 2019 is $185.00 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 2019

The actuarial assumptions and bases used to determine the monthly actuarial rates and the monthly premium rates for Part B are established by the Centers for Medicare & Medicaid Services Office of the Actuary. The estimates underlying these determinations are prepared by actuaries meeting the qualification standards and following the actuarial standards of practice established by the Actuarial Standards Board.

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

Under section 1839 of the Act, 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 2017 and 2018.

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 ($ in millions)	Liabilities ($ in millions)	Assets less liabilities ($ in millions)
December 31, 2017	79,882	30,008	49,873
December 31, 2018	96,940	34,298	62,641

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 2019 is determined by first establishing per enrollee costs by type of service from program data through 2017 and then projecting these costs for subsequent years. The projection factors used for financing periods from January 1, 2016 through December 31, 2019 are shown in Table 2.

As indicated in Table 3, the projected per enrollee amount required to pay for one-half of the total of benefits and administrative costs for enrollees age 65 and over for 2019 is $263.47. Based on current estimates, the assets associated with the aged Medicare beneficiaries at the end of 2018 are not large enough to provide a fully sufficient 2019 contingency reserve, which is necessary 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. The monthly actuarial rate of $264.90 provides an adjustment of $3.74 for a contingency margin and −$2.31 for interest earnings.

Starting in 2011, manufacturers and importers of brand-name prescription drugs pay a fee that is allocated to the Part B account of the SMI trust fund. For 2019, the total amount of these brand-name drug fees is estimated to be $2.8 billion. The contingency margin has been reduced to account for this additional revenue.

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. To accomplish this goal, a 17-percent reserve ratio, which is a fully adequate contingency reserve level, has been the normal target used to calculate the Part B premium. Assets associated with the aged Medicare beneficiaries at the end of 2018 are expected to be below the fully adequate level. The financing rates for 2019 are set to restore the assets in the Part B account to a fully adequate level by the end of 2019 under current law. The actuarial rate of $264.90 per month for aged beneficiaries, as announced in this notice for 2019, reflects the combined effect of the factors previously described and the projected 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 manner 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 per enrollee amount required to pay for one-half of the total of benefits and administrative costs for disabled enrollees for 2019 is $325.15. The monthly actuarial rate of $315.40 also provides an adjustment of −$2.90 for interest earnings and −$6.85 for a contingency margin, reflecting the same factors described previously for the aged actuarial rate at magnitudes appropriate to the disabled rate determination. Based on current estimates, the assets associated with the disabled Medicare beneficiaries at the end of 2019 are sufficient to cover the amount of incurred, but unpaid, expenses and to provide for a significant degree of variation between actual and projected costs. A negative contingency margin is needed to maintain assets at an appropriate level.

The actuarial rate of $315.40 per month for disabled beneficiaries, as announced in this notice for 2019, reflects the combined net effect of the factors described previously 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 cost growth rate assumptions. The results of those assumptions are shown in Table 5. One set represents increases that are higher and, therefore, more pessimistic than the current estimate. The other set

represents increases that are lower and, therefore, more optimistic 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 $69,255 million by the end of December 2019 under the cost growth rate assumptions shown in Table 2 and assuming that the provisions of current law are fully implemented. This result amounts to 17.6 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 $17,717 million by the end of December 2019 under current law, which amounts to 4.0 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 $122,576 million by the end of December 2019, or 35.7 percent of the estimated total incurred expenditures for the following year.

The sensitivity analysis indicates that the premium and general revenue financing established for 2019, together with existing Part B account assets, would be adequate to cover estimated Part B costs for 2019 under current law should actual costs prove to be somewhat greater than expected.

5. Premium Rates and Deductible

As determined in accordance with section 1839 of the Act, the following are the 2019 Part B monthly premium rates to be paid by beneficiaries who file either individual tax returns (and are single individuals, heads of households, qualifying widows or widowers with dependent children, or married individuals filing separately who lived apart from their spouses for the entire taxable year), or joint tax returns.

Beneficiaries who file individual tax returns with income:	Beneficiaries who file joint tax returns 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	$135.50
Greater than $85,000 and less than or equal to $107,000.	Greater than $170,000 and less than or equal to $214,000.	54.10	189.60
Greater than $107,000 and less than or equal to $133,500.	Greater than $214,000 and less than or equal to $267,000.	135.40	270.90
Greater than $133,500 and less than or equal to $160,000.	Greater than $267,000 and less than or equal to $320,000.	216.70	352.20
Greater than $160,000 and less than $500,000	Greater than $320,000 and less than $750,000	297.90	433.40
Greater than or equal to $500,000	Greater than or equal to $750,000	325.00	460.50

In addition, the monthly premium rates to be paid by beneficiaries who are married and lived with their spouses at any time during the taxable year, but who file separate tax returns from their spouses, are as follows:

Beneficiaries who are married and lived with their spouses at any time during the year, but who file separate tax returns from their spouses:	Income-related monthly adjustment amount	Total monthly premium amount
Less than or equal to $85,000	$0.00	$135.50
Greater than $85,000 and less than $415,000	297.90	433.40
Greater than or equal to $415,000	325.00	460.50

TABLE 2—PROJECTION FACTORS [1]
12-MONTH PERIODS ENDING DECEMBER 31 OF 2016–2019

Calendar year	Physicians' services	Durable medical equipment	Carrier lab [2]	Other carrier services [3]	Outpatient hospital	Home health agency	Hospital lab [4]	Other inter-mediary services [5]	Managed care
Aged:									
2016	−1.3%	−7.2%	−2.2%	6.8%	5.3%	−0.9%	3.1%	2.7%	3.3%
2017	0.3	−5.7	3.4	6.2	7.1	0.5	0.5	4.0	2.9
2018	1.7	11.3	4.9	6.0	7.8	3.1	2.0	7.4	6.8
2019	3.7	6.6	−3.7	5.4	7.5	4.6	−5.5	4.9	5.3
Disabled:									
2016	−1.8	−6.0	−14.8	5.7	4.5	−3.0	3.1	6.9	5.7
2017	0.5	0.5	−0.2	8.0	6.4	0.0	−0.2	7.9	3.4
2018	3.3	14.4	6.1	9.3	9.6	7.7	4.3	10.6	6.8
2019	3.6	6.5	−3.8	5.9	7.2	4.4	−5.6	5.0	5.4

[1] All values for services other than managed care are per fee-for-service enrollee. Managed care values are per managed care enrollee.
[2] Includes services paid under the lab fee schedule furnished in the physician's office or an independent lab.
[3] Includes physician-administered drugs, ambulatory surgical center facility costs, ambulance services, parenteral and enteral drug costs, supplies, etc.
[4] Includes services paid under the lab fee schedule furnished in the outpatient department of a hospital.
[5] 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, 2016 THROUGH DECEMBER 31, 2019

	CY 2016	CY 2017	CY 2018	CY 2019
Covered services (at level recognized):				
Physician fee schedule	$73.60	$72.32	$71.42	$73.51
Durable medical equipment	5.76	5.30	5.73	6.06
Carrier lab [1]	4.19	4.22	4.31	4.11
Other carrier services [2]	23.76	24.62	25.40	26.54
Outpatient hospital	45.07	47.05	49.36	52.60
Home health	9.43	9.24	9.27	9.61
Hospital lab [3]	2.30	2.25	2.23	2.09
Other intermediary services [4]	17.53	17.78	18.58	19.33
Managed care	83.23	89.43	99.69	106.33
Total services	264.86	272.20	285.99	300.17
Cost sharing:				
Deductible	−6.35	−7.00	−7.00	−7.08
Coinsurance	−27.72	−27.24	−27.75	−28.80
Sequestration of benefits	−4.61	−4.75	−5.02	−5.28
Health information technology payment incentives	−0.56	−0.13	0.12	0.00
Total benefits	225.61	233.08	246.34	259.01
Administrative expenses	3.37	4.48	4.66	4.46
Incurred expenditures	228.98	237.56	251.00	263.47
Value of interest	−1.50	−1.61	−1.85	−2.31
Contingency margin for projection error and to amortize the surplus or deficit	10.12	25.95	12.75	3.74
Monthly actuarial rate	237.60	261.90	261.90	264.90

[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 4—DERIVATION OF MONTHLY ACTUARIAL RATE FOR DISABLED ENROLLEES FOR FINANCING PERIODS ENDING DECEMBER 31, 2016 THROUGH DECEMBER 31, 2019

	CY 2016	CY 2017	CY 2018	CY 2019
Covered services (at level recognized):				
Physician fee schedule	$77.83	$76.10	$74.44	$75.61
Durable medical equipment	11.32	11.03	11.90	12.40
Carrier lab [1]	6.03	5.85	5.89	5.54
Other carrier services [2]	25.96	27.14	28.09	29.05
Outpatient hospital	62.94	65.21	67.69	71.01
Home health	7.50	7.25	7.35	7.49
Hospital lab [3]	2.82	2.74	2.71	2.51
Other intermediary services [4]	46.40	47.33	51.80	52.98
Managed care	81.47	90.48	107.84	117.87
Total services	322.27	333.12	357.72	374.46
Cost sharing:				
Deductible	−5.97	−6.57	−6.58	−6.66
Coinsurance	−41.86	−41.34	−42.37	−43.30
Sequestration of benefits	−5.49	−5.69	−6.17	−6.48
Health information technology payment incentives	−0.58	−0.14	0.12	0.00
Total benefits	268.37	279.38	302.73	318.02
Administrative expenses	3.99	5.38	7.27	7.14
Incurred expenditures	272.36	284.75	310.00	325.15
Value of interest	−2.55	−3.01	−3.14	−2.90
Contingency margin for projection error and to amortize the surplus or deficit	12.79	−27.54	−11.86	−6.85
Monthly actuarial rate	282.60	254.20	295.00	315.40

[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, 2019

	As of December 31		
	2017	2018	2019
Actuarial status (in millions):			
Assets	$79,882	$96,940	$105,203
Liabilities	$30,008	$34,298	$35,948
Assets less liabilities	$49,873	$62,641	$69,255
Ratio [1]	14.6%	17.1%	17.6%
Low-cost projection:			
Actuarial status (in millions):			
Assets	$79,882	$115,004	$157,034
Liabilities	$30,008	$32,291	$34,458
Assets less liabilities	$49,873	$82,713	$122,576
Ratio [1]	15.6%	24.9%	35.7%
High-cost projection:			
Actuarial status (in millions):			
Assets	$79,882	$79,849	$55,445
Liabilities	$30,008	$36,197	$37,728
Assets less liabilities	$49,873	$43,651	$17,717
Ratio [1]	13.9%	10.8%	4.0%

[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. 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.*).

IV. Regulatory Impact Analysis

A. Statement of Need

Section 1839 of the Act requires us to annually announce (that is, by September 30th of each year) the Part B monthly actuarial rates for aged and disabled beneficiaries as well as the monthly Part B premium. We also announce the Part B annual deductible because its determination is directly linked to the aged actuarial rate.

B. Overall Impact

We have examined the impacts of this notice in accordance with 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. 804(2)).

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 rules with economically significant effects ($100 million or more in any one year). The 2019 standard Part B premium rate of $135.50 is $1.50 higher than the 2018 premium of $134.00. We estimate that this premium increase, for the approximately 56 million Part B enrollees in 2019, will have an annual effect on the economy of $100 million or more. Although we do not consider this notice to constitute a substantive rule, this notice is economically significant under section 3(f)(1) of Executive Order 12866.

As discussed earlier, this notice announces that the monthly actuarial rates applicable for 2019 are $264.90 for enrollees age 65 and over and $315.40 for disabled enrollees under age 65. It also announces the 2019 monthly Part B premium rates to be paid by beneficiaries who file either individual tax returns (and are single individuals, heads of households, qualifying widows or widowers with dependent children, or married individuals filing separately who lived apart from their spouses for the entire taxable year), or joint tax returns.

Beneficiaries who file individual tax returns with income:	Beneficiaries who file joint tax returns 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	$135.50
Greater than $85,000 and less than or equal to $107,000.	Greater than $170,000 and less than or equal to $214,000.	54.10	189.60
Greater than $107,000 and less than or equal to $133,500.	Greater than $214,000 and less than or equal to $267,000.	135.40	270.90
Greater than $133,500 and less than or equal to $160,000.	Greater than $267,000 and less than or equal to $320,000.	216.70	352.20
Greater than $160,000 and less than $500,000	Greater than $320,000 and less than $750,000	297.90	433.40

Beneficiaries who file individual tax returns with income:	Beneficiaries who file joint tax returns with income:	Income-related monthly adjustment amount	Total monthly premium amount
Greater than or equal to $500,000	Greater than or equal to $750,000	325.00	460.50

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

Beneficiaries who are married and lived with their spouses at any time during the year, but who file separate tax returns from their spouses:	Income-related monthly adjustment amount	Total monthly premium amount
Less than or equal to $85,000	$0.00	$135.50
Greater than $85,000 and less than $415,000	297.90	433.40
Greater than or equal to $415,000	325.00	460.50

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, 2019. 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 one year of $100 million in 1995 dollars, updated annually for inflation. In 2018, that threshold is approximately $150 million. Part B enrollees who are also enrolled in Medicaid have their monthly Part B premiums paid by Medicaid. The cost to each state Medicaid program from the 2019 premium increase is estimated to be 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.

Executive Order 13771, titled ''Reducing Regulation and Controlling Regulatory Costs,'' was issued on January 30, 2017 (82 FR 9339, February 3, 2017). It has been determined that this notice is a transfer notice that does not impose more than de minimis costs and thus is not a regulatory action for the purposes of E.O. 13771.

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 and Comment Period

Section 553(b) of the Administrative Procedure Act (APA) and section 1871 of the Act require a notice of proposed rulemaking prior to a rule taking effect. However, we believe that the policies published in this document do not constitute agency rulemaking. Rather, the Act specifies the formulas used to calculate the Part B premiums, and we are notifying the public of the changes to the Medicare Part B premiums for CY 2019 in accordance with the statutorily directed formulas. To the extent that any of the policies articulated in this document constitute interpretations of the statute's requirements or procedures that will be used to implement the statute's directive, they are interpretive rules, general statements of policy, and rules of agency organization, procedure, or practice, which are not subject to notice and comment rulemaking under the APA.

To the extent that notice and comment rulemaking would otherwise apply, we find good cause to waive this requirement. Under the APA, we may waive notice and public 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 notice and comment procedures, if such procedures are required at all.

Dated: October 3, 2018.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: October 11, 2018.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2018–22530 Filed 10–12–18; 11:15 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2017–E–6371 and FDA–2017–E–6372]

Determination of Regulatory Review Period for Purposes of Patent Extension; TREMFYA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for TREMFYA and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human biological product.

DATES: Anyone with knowledge that any of the dates as published (see the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by December 17, 2018. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by April 15, 2019. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before December 17, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 17, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket Nos. FDA–2017–E–6371 and FDA–2017–E–6372 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; TREMFYA.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with § 10.20 (21 CFR 10.20) and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.