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

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2017, that threshold is approximately $148 million. This notice does not impose mandates that will have a consequential effect of $148 million or more on state, local, or tribal governments or on the private sector.

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.

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.

Although this notice merely announces the Medicare Part A deductible and coinsurance amounts for CY 2018 and 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 27, 2017.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: November 1, 2017.

Eric D. Hargan,

Acting Secretary, Department of Health and Human Services.

[FR Doc. 2017–24913 Filed 11–17–17; 4:15 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–8067–N]

RIN 0938–AS72

Medicare Program; Medicare Part B Monthly Actuarial Rates, Premium Rates, and Annual Deductible Beginning January 1, 2018

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, 2018. In addition, this notice announces the monthly premium for aged and disabled beneficiaries, the deductible for 2018, 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 2018 are $261.90 for aged enrollees and $295.00 for disabled enrollees. The standard monthly Part B premium rate for all enrollees for 2018 is $134.00, 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 $3.00. (The 2017 standard premium rate was $134.00, which included the $3.00 repayment amount.) The Part B deductible for 2018 is $183.00 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, or 80 percent of the total cost of Part B coverage plus $4.20, $6.00, $7.80, or $9.60.

DATES: *Effective Date:* January 1, 2018.

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, 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 2018 Part B deductible is calculated by multiplying the 2017 deductible by the ratio of the 2018 aged actuarial rate to the 2017 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 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 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 2018, $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, or 80 percent of the estimated total cost of Part B coverage, rather than 25 percent. (For 2018 and subsequent years, the income thresholds are lower for the two highest income ranges because of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10).) 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 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 foregone 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 foregone 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 repayment amount plus an additional $1.20, $3.00, $4.80, or $6.60 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 foregone income-related premium revenue plus a transfer amount of $7,440,648,000. It is estimated that $1,404,616,000 will have been collected for repayment to the general fund by the end of 2017.

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 2018 are $261.90 for enrollees age 65 and over and $295.00 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 2018 is $134.00.

The following are the 2018 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	$134.00
Greater than $85,000 and less than or equal to $107,000.	Greater than $170,000 and less than or equal to $214,000.	53.50	187.50
Greater than $107,000 and less than or equal to $133,500.	Greater than $214,000 and less than or equal to $267,000.	133.90	267.90
Greater than $133,500 and less than or equal to $160,000.	Greater than $267,000 and less than or equal to $320,000.	214.30	348.30
Greater than $160,000	Greater than $320,000	294.60	428.60

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	$134.00
Greater than $85,000	294.60	428.60

The Part B annual deductible for 2018 is $183.00 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 2018

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 2016 and 2017.

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, 2016	$87,983	$28,494	$59,489
December 31, 2017	79,236	30,559	48,677

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 2018 is determined by first establishing per enrollee costs by type of service from program data through 2016 and then projecting these costs for subsequent years. The projection factors used for financing periods from January 1, 2015 through December 31, 2018 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 2018 is $247.91. Based on current estimates, the assets associated with the aged Medicare beneficiaries at the end of 2017 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. The monthly actuarial rate of $261.90 provides an adjustment of $15.88 for a contingency margin and −$1.89 for interest earnings.

The contingency margin for 2018 is affected by several factors. 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. For 2018, the total of these brand-name drug fees is estimated to be $4.1 billion. The contingency margin has been reduced to account for this additional revenue.

Another factor affecting the contingency margin is attributable to the requirement that certain payment incentives, to encourage the development and use of health information technology (HIT) by Medicare physicians, are to be excluded from the premium determination. HIT positive incentive payments or penalties

will be directly offset through transfers with the general fund of the Treasury. The monthly actuarial rate includes an adjustment of $0.17 for HIT incentives in 2018.

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 at the end of 2017 are expected to be below the fully adequate level. The financing rates for 2018 are set to restore the asset level in the Part B account to the fully adequate level by the end of 2018 under current law. The actuarial rate of $261.90 per month for aged beneficiaries, as announced in this notice for 2018, reflects that 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 2018 is $303.70. The monthly actuarial rate of $295.00 also provides an adjustment of −$2.73 for interest earnings and −$5.97 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 2017 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 $295.00 per month for disabled beneficiaries, as announced in this notice for 2018, 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 $65,598 million by the end of December 2018 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 17.8 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 $16,355 million by the end of December 2018 under current law, which amounts to 3.9 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 $114,191 million by the end of December 2018, or 35.6 percent of the estimated total incurred expenditures for the following year.

The sensitivity analysis indicates that the premium and general revenue financing established for 2018, together with existing Part B account assets, would be adequate to cover estimated Part B costs for 2018 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 2018 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	$134.00
Greater than $85,000 and less than or equal to $107,000.	Greater than $170,000 and less than or equal to $214,000.	53.50	187.50
Greater than $107,000 and less than or equal to $133,500.	Greater than $214,000 and less than or equal to $267,000.	133.90	267.90
Greater than $133,500 and less than or equal to $160,000.	Greater than $267,000 and less than or equal to $320,000.	214.30	348.30
Greater than $160,000	Greater than $320,000	294.60	428.60

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	$134.00
Greater than $85,000	294.60	428.60

TABLE 2—PROJECTION FACTORS [1] 12-MONTH PERIODS ENDING DECEMBER 31 OF 2015–2018

[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:										
2015	−0.5	0.7	5.8	1.6	4.4	7.3	1.4	2.4	5.0	2.9
2016	−0.3	−1.2	−10.4	−2.5	6.4	4.9	−0.6	2.9	2.1	3.4
2017	0.4	1.0	−3.1	4.8	5.8	8.1	2.5	4.0	5.4	2.6
2018	−0.2	2.0	5.1	0.0	4.3	7.8	3.0	−1.9	−4.6	6.4
Disabled:										
2015	−0.5	0.3	6.2	5.8	5.2	7.1	−1.1	0.4	10.1	3.1
2016	−0.3	−0.5	−7.2	−14.0	6.9	5.5	0.0	5.2	7.2	4.9
2017	0.4	1.1	0.2	3.3	7.3	7.5	3.1	2.9	5.7	3.5
2018	−0.2	1.9	4.9	−0.1	4.8	7.7	3.4	−2.0	−4.4	6.6

[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, 2015 THROUGH DECEMBER 31, 2018

	CY 2015	CY 2016	CY 2017	CY 2018
Covered services (at level recognized):				
Physician fee schedule	$75.43	$73.63	$72.71	$73.35
Durable medical equipment	6.28	5.57	5.27	5.48
Carrier lab [1]	4.33	4.18	4.27	4.23
Other carrier services [2]	22.51	23.72	24.47	25.26
Outpatient hospital	43.25	44.93	47.37	50.57
Home health	9.64	9.49	9.48	9.67
Hospital lab [3]	2.25	2.29	2.33	2.26
Other intermediary services [4]	17.25	17.44	17.92	16.94
Managed care	78.97	83.20	89.11	96.37
Total services	259.92	264.46	272.94	284.13
Cost sharing:				
Deductible	−5.64	−6.35	−7.00	−7.00
Coinsurance	−27.95	−27.65	−27.79	−28.27
Sequestration of benefits	−4.52	−4.61	−4.76	−4.97
HIT payment incentives	−1.08	−0.56	−0.02	0.17
Total benefits	220.73	225.29	233.37	244.04
Administrative expenses	2.82	4.07	3.45	3.87
Incurred expenditures	223.55	229.36	236.82	247.91
Value of interest	−1.86	−1.49	−1.67	−1.89
Contingency margin for projection error and to amortize the surplus or deficit	−11.89	9.73	26.75	15.88
Monthly actuarial rate	209.80	237.60	261.90	261.90

[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, 2015 THROUGH DECEMBER 31, 2018

	CY 2015	CY 2016	CY 2017	CY 2018
Covered services (at level recognized):				
Physician fee schedule	$80.64	$78.54	$77.23	$77.31
Durable medical equipment	12.28	11.17	10.85	11.18
Carrier lab [1]	7.19	6.08	6.09	5.98
Other carrier services [2]	25.33	26.16	27.12	27.88
Outpatient hospital	61.51	63.46	66.36	70.26
Home health	7.94	7.75	7.73	7.84
Hospital lab [3]	2.78	2.86	2.86	2.76
Other intermediary services [4]	45.11	46.59	48.13	50.79
Managed care	73.38	81.53	90.23	99.74
Total services	316.16	324.13	336.60	353.74
Cost sharing:				
Deductible	−5.27	−5.94	−6.54	−6.54
Coinsurance	−42.47	−42.17	−42.63	−43.95
Sequestration of benefits	−5.37	−5.52	−5.75	−6.06
HIT payment incentives	−1.14	−0.59	−0.02	0.17
Total benefits	261.92	269.91	281.67	297.36
Administrative expenses	3.34	4.88	5.70	6.34
Incurred expenditures	265.26	274.79	287.37	303.70
Value of interest	−2.21	−2.56	−3.63	−2.73
Contingency margin for projection error and to amortize the surplus or deficit	−8.25	10.37	−29.54	−5.97
Monthly actuarial rate	254.80	282.60	254.20	295.00

[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, 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, 2018

As of December 31,	2016	2017	2018
Actuarial status (in millions):			
Assets	$87,983	$79,236	$97,686
Liabilities	$28,494	$30,559	$32,089
Assets less liabilities	$59,489	$48,677	$65,598
Ratio [1]	18.9%	14.4%	17.8%
Low-cost projection:			
Actuarial status (in millions):			
Assets	$87,983	$96,444	$144,913
Liabilities	$28,494	$28,647	$30,722
Assets less liabilities	$59,489	$67,797	$114,191
Ratio [1]	20.2%	22.2%	35.6%
High-cost projection:			
Actuarial status (in millions):			
Assets	$87,983	$63,188	$50,044
Liabilities	$28,494	$32,342	$33,708
Assets less liabilities	$59,489	$30,846	$16,335
Ratio [1]	17.9%	8.3%	3.9%

[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 as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995, Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 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 notices with economically significant effects ($100 million or more in any one year). For 2018 the standard Part B premium rate, the Part B income-related premium rates, and the Part B deductible are the same as the respective amounts for 2017. However, approximately 70 percent of Part B enrollees who were held harmless from the full increase in the Part B premium in 2017 will pay an increase in their Part B premium, which will have an annual effect on the economy of $100 million or more. As a result, this notice is economically significant under section 3(f)(1) of Executive Order 12866 and is a major action as defined under the Congressional Review Act (5 U.S.C. 804(2)).

As discussed earlier, this notice announces that the monthly actuarial rates applicable for 2018 are $261.90 for enrollees age 65 and over and $295.00 for disabled enrollees under age 65. It also announces the 2018 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	$134.00
Greater than $85,000 and less than or equal to $107,000.	Greater than $170,000 and less than or equal to $214,000.	53.50	187.50
Greater than $107,000 and less than or equal to $133,500.	Greater than $214,000 and less than or equal to $267,000.	133.90	267.90
Greater than $133,500 and less than or equal to $160,000.	Greater than $267,000 and less than or equal to $320,000.	214.30	348.30
Greater than $160,000	Greater than $320,000	294.60	428.60

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	$134.00
Greater than $85,000	294.60	428.60

The RFA requires agencies to analyze options for regulatory relief of small businesses, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Individuals and states are not included in the definition of a small entity. This notice announces the monthly actuarial rates for aged (age 65 and over) and disabled (under 65) beneficiaries enrolled in Part B of the Medicare SMI program beginning January 1, 2018. 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 2017, that threshold is approximately $156

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 2018 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.

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

V. Waiver of Proposed Notice

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

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

Dated: October 27, 2017.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: November 1, 2017.

Eric D. Hargan,

Acting Secretary, Department of Health and Human Services.

[FR Doc. 2017–24877 Filed 11–17–17; 4:15 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2017–P–3989, FDA–2017–P–4195, FDA–2017–P–5114, FDA–2017–P–5909, FDA–2017–P–5910, and FDA–2017–P–5967]

Determination That TRINTELLIX (Vortioxetine Hydrobromide) Oral Tablet, EQ 15 Milligram Base, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that TRINTELLIX (vortioxetine hydrobromide) oral tablet, equivalent to (EQ) 15 milligram (mg) base, was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for vortioxetine hydrobromide oral tablet, 15 mg base, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Meadow W. Platt, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6228, Silver Spring, MD 20993–0002, 301–796–1830.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

TRINTELLIX (vortioxetine hydrobromide) oral tablets, EQ 5 mg base, EQ 10 mg base, EQ 15 mg base, and EQ 20 mg base, are the subject of NDA 204447, held by Takeda Pharmaceuticals, USA, Inc., and initially approved on September 30, 2013. TRINTELLIX is indicated for the treatment of major depressive disorder.

TRINTELLIX (vortioxetine hydrobromide) oral tablets, EQ 5 mg base, EQ 10 mg base, and EQ 20 mg base, are listed in the ''Prescription Drug Product List'' section of the Orange Book, and TRINTELLIX (vortioxetine hydrobromide) oral tablet, EQ 15 mg base, is listed in the ''Discontinued Drug Product List'' section of the Orange Book. Takeda Pharmaceuticals, USA, Inc., has never marketed TRINTELLIX (vortioxetine hydrobromide) oral tablet, EQ 15 mg base. In previous instances (see, *e.g.,* 72 FR 9763 (March 5, 2007), 61 FR 25497 (May 21, 1996)), the Agency has determined that, for purposes of §§ 314.161 and 314.162, never marketing an approved drug product is equivalent to withdrawing the drug from sale.

Lachman Consultant Services, Inc.; INC Research, LLC; Locke Lord, LLP; Goodwin Procter, LLP; Cipla USA Inc.; and Apotex, Inc., submitted citizen petitions dated June 29, 2017; July 12, 2017; August 21, 2017; September 25, 2017; September 25, 2017; and September 27, 2017, respectively (Docket Nos. FDA–2017–P–3989, FDA–