

waive notice and comment rulemaking when notice and public comment thereon are unnecessary. On this basis, we waive publication of a proposed notice and a solicitation of public comments.

VI. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

VII. Regulatory Impact Analysis

A. Statement of Need

Section 1818(d) of the Act requires the Secretary of the Department of Health and Human Services (the Secretary) during September of each year to determine and publish the amount to be paid, on an average per capita basis, from the Federal Hospital Insurance Trust Fund for services incurred in the impending calendar year (CY) (including the associated administrative costs) on behalf of individuals aged 65 and over who will be entitled to benefits under Medicare Part A.

B. Overall Impact

We have examined the impacts of this rule 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., Part I, Ch. 8).

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 1 year). As stated in section IV of this notice, we estimate that the overall effect of the changes in the Part A premium will be a savings to voluntary

enrollees (section 1818 and section 1818A of the Act) of about \$119 million. As a result, this notice is economically significant under section 3(f)(1) of Executive Order 12866 and thus, a major action under the Congressional Review Act. In accordance with the provisions of Executive Order 12866, this notice was reviewed by the Office of Management and Budget.

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 \$7.0 million to \$35.5 million in any 1 year (for details, see the Small Business Administration's Web site at http://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf).

Individuals and states are not included in the definition of a small entity. As discussed above, this annual notice announces Medicare's Hospital Insurance (Part A) premium for uninsured enrollees in calendar year (CY) 2014. 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 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 for Medicare payment regulations 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 2013, that threshold is approximately \$141 million. This notice does not impose mandates that will have a consequential effect of \$141 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. Since this notice does not impose any costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

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

Dated: September 20, 2013.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

Dated: October 18, 2013.

Kathleen Sebelius,

Secretary.

[FR Doc. 2013–25591 Filed 10–28–13; 11:15 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–8053–N]

RIN 0938–AR59

Medicare Program; Inpatient Hospital Deductible and Hospital and Extended Care Services Coinsurance Amounts for CY 2014

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

ACTION: Notice.

SUMMARY: This notice announces the inpatient hospital deductible and the hospital and extended care services coinsurance amounts for services furnished in calendar year (CY) 2014 under Medicare's Hospital Insurance Program (Medicare Part A). The Medicare statute specifies the formulae used to determine these amounts. For CY 2014, the inpatient hospital deductible will be \$1,216. The daily coinsurance amounts for CY 2014 will be: \$304 for the 61st through 90th day of hospitalization in a benefit period; \$608 for lifetime reserve days; and \$152 for the 21st through 100th day of extended care services in a skilled nursing facility in a benefit period.

DATES: *Effective Date:* This notice is effective on January 1, 2014.

FOR FURTHER INFORMATION CONTACT: Clare McFarland, (410) 786–6390 for

general information. Gregory J. Savord, (410) 786-1521 for case-mix analysis.

SUPPLEMENTARY INFORMATION:

I. Background

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

II. Computing the Inpatient Hospital Deductible for CY 2014

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

Under section 1886(b)(3)(B)(i)(XX) of the Act, the percentage increase used to update the payment rates for FY 2014 for hospitals paid under the inpatient prospective payment system is the market basket percentage increase, otherwise known as the market basket update, reduced by 0.3 percentage points (see section 1886(b)(3)(B)(xii)(II) of the Act), and an adjustment based on changes in the economy-wide productivity (the multifactor productivity (MFP) adjustment (see section 1886(b)(3)(B)(xi)(II) of the Act). Under section 1886(b)(3)(B)(viii) of the Act, hospitals will receive this update only if they submit quality data as specified by the Secretary of the Department of Health and Services (the Secretary). The update for hospitals that do not submit this data is reduced by

2.0 percentage points. We are estimating that after accounting for those hospitals receiving the lower market basket update in the payment-weighted average update, the calculated deductible will remain the same, as the majority of hospitals submit quality data and receive the full market basket update.

Under section 1886(b)(3)(B)(ii)(VIII) of the Act, the percentage increase used to update the payment rates for FY 2014 for hospitals excluded from the inpatient prospective payment system is as follows:

- For FY 2014, the percentage increase for long term care hospitals is the market basket percentage increase reduced by 0.3 percentage points and the MFP adjustment (see sections 1886(m)(3)(A) and 1886(m)(4)(C) of the Act).
- For FY 2014, the percentage increase for inpatient rehabilitation facilities is the market basket percentage increase reduced by 0.3 percentage points and the MFP adjustment (see sections 1886(j)(3)(C) and 1886(j)(3)(D)(ii) of the Act).
- For FY 2014, the percentage increase used to update the payment rate for psychiatric hospitals is the market basket percentage increase reduced by 0.1 percentage points and the MFP adjustment (see sections 1886(s)(2)(A)(ii) and 1886(s)(3)(B) of the Act).

The Inpatient Prospective Payment System market basket percentage increase for 2014 is 2.5 percent and the MFP adjustment is 0.5 percent, as announced in the final rule with comment period published in the **Federal Register** on August 19, 2013 entitled, "Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Fiscal Year 2014 Rates; Quality Reporting Requirements for Specific Providers; Hospital Conditions of Participation; Payment Policies Related to Patient Status" (78 FR 50608). Therefore, the percentage increase for hospitals paid under the inpatient prospective payment system is 1.7 percent. The average payment percentage increase for hospitals excluded from the inpatient prospective payment system is 1.94 percent. Weighting these percentages in accordance with payment volume, our best estimate of the payment-weighted average of the increases in the payment rates for FY 2014 is 1.73 percent.

To develop the adjustment to reflect changes in real case-mix, we first calculated an average case-mix for each hospital that reflects the relative costliness of that hospital's mix of cases

compared to those of other hospitals. We then computed the change in average case-mix for hospitals paid under the Medicare prospective payment system in FY 2013 compared to FY 2012. (We excluded from this calculation hospitals whose payments are not based on the inpatient prospective payment system because their payments are based on alternate prospective payment systems or reasonable costs.) We used Medicare bills from prospective payment hospitals that we received as of July 2013. These bills represent a total of about 7.8 million Medicare discharges for FY 2013 and provide the most recent case-mix data available at this time. Based on these bills, the change in average case-mix in FY 2013 is 0.89 percent. Based on these bills and past experience, we expect the overall case mix change to be 1.0 percent as the year progresses and more FY 2013 data become available.

Section 1813 of the Act requires that the inpatient hospital deductible be adjusted only by that portion of the case-mix change that is determined to be real. We estimate that the change in real case mix will be 1.0 percent.

Thus, the estimate of the payment-weighted average of the applicable percentage increases used for updating the payment rates is 1.73 percent, and the real case-mix adjustment factor for the deductible is 1.0 percent. Therefore, under the statutory formula, the inpatient hospital deductible for services furnished in CY 2014 is \$1,216. This deductible amount is determined by multiplying \$1,184 (the inpatient hospital deductible for CY 2013) by the payment-weighted average increase in the payment rates of 1.0173 multiplied by the increase in real case-mix of 1.01, which equals \$1,216.53 and is rounded to \$1,216.

III. Computing the Inpatient Hospital and Extended Care Services Coinsurance Amounts for CY 2014

The coinsurance amounts provided for in section 1813 of the Act are defined as fixed percentages of the inpatient hospital deductible for services furnished in the same CY. The increase in the deductible generates increases in the coinsurance amounts. For inpatient hospital and extended care services furnished in CY 2014, in accordance with the fixed percentages defined in the law, the daily coinsurance for the 61st through 90th day of hospitalization in a benefit period will be \$304 (one-fourth of the inpatient hospital deductible); the daily coinsurance for lifetime reserve days will be \$608 (one-half of the inpatient

hospital deductible); and the daily coinsurance for the 21st through 100th day of extended care services in a skilled nursing facility in a benefit

period will be \$152 (one-eighth of the inpatient hospital deductible).

IV. Cost to Medicare Beneficiaries

Table 1 below summarizes the deductible and coinsurance amounts for

CYs 2013 and 2014, as well as the number of each that is estimated to be paid.

TABLE 1—PART A DEDUCTIBLE AND COINSURANCE AMOUNTS FOR CALENDAR YEARS 2013 AND 2014 TYPE OF COST SHARING

	Value		Number paid (in millions)	
	2013	2014	2013	2014
Inpatient hospital deductible	\$1,184	\$1,216	7.91	8.07
Daily coinsurance for 61st–90th Day	296	304	2.04	2.09
Daily coinsurance for lifetime reserve days	592	608	1.02	1.04
SNF coinsurance	148	152	42.10	43.40

The estimated total increase in costs to beneficiaries is about \$870 million (rounded to the nearest \$10 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.

V. Waiver of Proposed Notice and Comment Period

The Medicare statute, as discussed previously, requires publication of the Medicare Part A inpatient hospital deductible and the hospital and extended care services coinsurance amounts for services for each CY. The amounts are determined according to the statute. As has been our custom, we use general notices, rather than notice and comment rulemaking procedures, to make the announcements. In doing so, we acknowledge that, under the Administrative Procedure Act (APA), 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 good cause that prior notice and comment are impracticable, unnecessary, or contrary to the public interest. We find that the procedure for notice and comment is unnecessary because the formulae used to calculate the inpatient hospital deductible and hospital and extended care services coinsurance amounts are statutorily directed, and we can exercise no discretion in following the formulae. Moreover, the statute establishes the time period for which the deductible and coinsurance amounts will apply and delaying publication would be contrary to the public interest. Therefore, we find good cause to waive

publication of a proposed notice and solicitation of public comments.

VI. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

VII. Regulatory Impact Analysis

A. Statement of Need

Section 1813(b)(2) of the Act requires the Secretary to determine and publish, between September 1 and September 15 of each year, the amount of the inpatient hospital deductible and the hospital and extended care services coinsurance amounts applicable for services furnished in the following calendar year (CY).

B. Overall Impact

We have examined the impacts of this rule 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., Part I, Ch. 8).

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 1 year). As stated in section IV of this notice, we estimate that the total increase in costs to beneficiaries associated with this notice is about \$870 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. As a result, this notice is economically significant under section 3(f)(1) of Executive Order 12866 and thus, is a major action under the Congressional Review Act. In accordance with the provisions of Executive Order 12866, this notice was reviewed by the Office of Management and Budget.

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 \$7.0 million to \$35.5 million in any 1 year (for details, see the Small Business Administration's Web site at http://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf).

Individuals and states are not included in the definition of a small entity. As discussed above, this annual notice announces the inpatient hospital deductible and the hospital and extended care services coinsurance amounts for services furnished in CY 2014 under Medicare's Hospital Insurance Program (Medicare Part A). 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 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 for Medicare payment regulations 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. For 2013, that threshold accounting for inflation is approximately \$141 million. This notice does not impose mandates that will have a consequential effect of \$141 million or more on state, local, or tribal governments or on the private sector. However, states may be required to pay the deductibles and coinsurance for dually-eligible beneficiaries.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. Since this notice does not impose any costs on state or local governments, preempt state law or have Federalism implications, the requirements of Executive Order 13132 are not applicable.

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

Dated: September 20, 2013.

Marilyn Tavenner,
Administrator, Centers for Medicare & Medicaid Services.

Dated: October 18, 2013.

Kathleen Sebelius,
Secretary.

[FR Doc. 2013-25595 Filed 10-28-13; 11:15 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0001]

Endocrinologic and Metabolic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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

Name of Committee: Endocrinologic and Metabolic Drugs Advisory Committee.

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

Date and Time: The meeting will be held on December 11, 2013, from 8 a.m. to 5 p.m.

Location: FDA White Oak Campus, Building 31, the Great Room, White Oak Conference Center (rm. 1503), 10903 New Hampshire Ave., Silver Spring, MD 20993-0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/default.htm>; under the heading "Resources for You," click on "Public Meetings at the FDA White Oak Campus." Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Karen Abraham-Burrell, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, FAX: 301-847-8533, email: EMDAC@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: The committee will discuss the safety and efficacy of biologic license application (BLA) 125390, metreleptin for injection, sponsored by Amylin Pharmaceuticals, LLC, a wholly owned subsidiary of Bristol-Myers Squibb. The proposed indication for metreleptin is the treatment of metabolic disorders associated with lipodystrophy, including diabetes mellitus and/or hypertriglyceridemia (elevated triglyceride levels in the blood) in pediatric and adult patients with inherited or acquired lipodystrophy. (Lipodystrophies are rare medical conditions of abnormal loss of the body's fatty tissues.)

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

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before November 26, 2013. Oral presentations from the public will be scheduled between approximately 1:30 p.m. and 2:30 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before November 18, 2013. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by November 19, 2013.

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

FDA welcomes the attendance of the public at its advisory committee