We base our projections for CY 2011 on— (1) current historical data; and (2) projection assumptions derived from current law and the Mid-Session Review of the President's Fiscal Year 2011 Budget.

We estimate that in CY 2011, 39,315,092 people aged 65 years and over will be entitled to benefits (without premium payment) and that they will incur about $212.435 billion in benefits and related administrative costs. Thus, the estimated monthly average per capita amount is $450.28 and the monthly premium is $450. The full monthly premium reduced by 45 percent is $248.

IV. Costs to Beneficiaries

The CY 2011 premium of $450 is approximately 2 percent lower than the CY 2010 premium of $461.

We estimate that approximately 571,000 enrollees will voluntarily enroll in Medicare Part A by paying the full premium. We estimate an additional 40,000 enrollees will pay the reduced premium. We estimate that the aggregate savings to enrollees paying these premiums in CY 2011, compared to the amount that they paid in CY 2010, will be about $78 million.

V. Waiver of Proposed Notice and Comment Period

We are not using notice and comment rulemaking in this notification of Medicare Part A premiums for CY 2011 as that procedure is unnecessary because of the lack of discretion in the statutory formula that is used to calculate the premium and the solely ministerial function that this notice serves. The Administrative Procedure Act (APA) permits agencies to 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 Statement

We have examined the impacts of this final rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). As stated in section IV of this notice, we estimate that the overall effect of these changes in the Part A premium will be a savings to voluntary enrollees (section 1818 and section 1818A of the Act) of about $78 million. Therefore, this notice is a not a major rule as defined in Title 5, United States Code, section 804(2) and is not an economically significant rule under Executive Order 12866.

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 government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $7 million to $34.5 million in any 1 year. Individuals and States are not included in the definition of a small entity. We have determined that this notice will not have a significant economic impact on a substantial number of small entities. Therefore, we are not preparing an analysis under the RFA.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. The Secretary has determined that this notice will not have a significant impact on the operations of a substantial number of small rural hospitals. Therefore, we are not preparing an analysis under section 1102(b) of the Act.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) 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 2010, that threshold is approximately $135 million. This notice has no consequential effect on State, local, or tribal governments or on the private sector. However, States are required to pay the premiums 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. This notice will not have a substantial effect on State or local governments.

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

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

Dated: September 9, 2010.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

Dated: October 29, 2010.

Kathleen Sebelius,

Secretary.

[FR Doc. 2010–28250 Filed 11–4–10; 2:15 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–8040–N]

RIN 0938–AP86

Medicare Program; Inpatient Hospital Deductible and Hospital and Extended Care Services Coinsurance Amounts for CY 2011

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) 2011 under Medicare's Hospital Insurance Program (Medicare Part A). The Medicare statute specifies the formulae used to determine these amounts. For CY 2011, the inpatient hospital

deductible will be $1132. The daily coinsurance amounts for CY 2011 will be—(a) $283 for the 61st through 90th day of hospitalization in a benefit period; (b) $566 for lifetime reserve days; and (c) $141.50 for the 21st through 100th day of extended care services in a skilled nursing facility in a benefit period.

DATES: *Effective Date:* This notice is effective on January 1, 2011.

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

SUPPLEMENTARY INFORMATION:

I. Background

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

II. Computing the Inpatient Hospital Deductible for CY 2011

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 2011 for hospitals paid under the inpatient prospective payment system is the market basket percentage increase, otherwise known as the market basket update, reduced by .25 percentage points. 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. 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.

Under section 1886(b)(3)(B)(ii)(VIII) of the Act, the percentage increase used to update the payment rates for FY 2011 for hospitals excluded from the inpatient prospective payment system is the market basket percentage increase reduced by .5 percentage points for Long Term Care Hospitals and reduced by .25 percentage points for Inpatient Rehabilitation facilities and Psychiatric Hospitals, defined according to section 1886(b)(3)(B)(iii) of the Act.

The market basket percentage increase for 2011 is 2.6 percent, as announced in the final rule with comment period published in the **Federal Register** on August 16, 2010 entitled, "Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and Fiscal Year 2011 Rates; and Changes to the Long-Term Care Hospital Prospective Payment System and Rate Years 2011 and 2010 Rates (IPPS/RY 2011 LTCH PPS) (75 FR 50042–50677)." Therefore, the percentage increase for hospitals paid under the inpatient prospective payment system is 2.35 percent. The average payment percentage increase for hospitals excluded from the inpatient prospective payment system is 2.73 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 2011 is 2.40 percent.

To develop the adjustment to reflect changes in real case-mix, we first calculated for each hospital an average case-mix that reflects the relative costliness of that hospital's mix of cases compared to those of other hospitals. We then computed the change in average case-mix for hospitals paid under the Medicare prospective payment system in FY 2010 compared to FY 2009. (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 2010. These bills represent a total of about 8.5 million Medicare discharges for FY 2010 and provide the most recent case-mix data available at this time. Based on these bills, the change in average case-mix in FY 2010 is 0.3 percent. Based on these bills and past experience, we expect the overall case mix change to be 0.5 percent as the year progresses and more FY 2010 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. In the FY 2011 IPPS/RY 2011 LTCH PPS final rule with comment period, we indicated that we believe the adoption of the Medicare severity-based diagnosis-related groups (MS–DRGs) led to increases in aggregate payments without a corresponding increase in actual patient severity of illness due to the incentives for improved documentation and coding. In that final rule with comment period, we estimated that changes in coding or classification that do not reflect real change in case-mix would be 0.0 percent for FY 2010. Therefore, since we are expecting overall case mix to increase by 0.5 percent and 0.0 percent of that to be caused by coding changes, real case mix changes resulted in an increase of 0.5 percent for FY 2010.

Thus, the estimate of the payment-weighted average of the applicable percentage increases used for updating the payment rates is 2.40 percent, and the real case-mix adjustment factor for the deductible is 0.5 percent. Therefore, under the statutory formula, the inpatient hospital deductible for services furnished in CY 2011 is $1132. This deductible amount is determined by multiplying $1100 (the inpatient hospital deductible for CY 2010) by the payment-weighted average increase in the payment rates of 1.0240 multiplied by the increase in real case-mix of 1.005, which equals $1132.03 and is rounded to $1132.

III. Computing the Inpatient Hospital and Extended Care Services Coinsurance Amounts for CY 2011

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 2011, 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 $283 (one-fourth of the inpatient hospital deductible); the daily

coinsurance for lifetime reserve days will be $566 (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 $141.50 (one-eighth of the inpatient hospital deductible).

IV. Cost to Medicare Beneficiaries

Table 1 below summarizes the deductible and coinsurance amounts for CYs 2010 and 2011, as well as the number of each that is estimated to be paid.

TABLE 1—PART A DEDUCTIBLE AND COINSURANCE AMOUNTS FOR CALENDAR YEARS 2010 AND 2011

Type of cost sharing	Value		Number paid (in millions)	
	2010	2011	2010	2011
Inpatient hospital deductible	$1100	$1132	8.40	8.59
Daily coinsurance for 61st–90th Day	$275	$283	2.25	2.30
Daily coinsurance for lifetime reserve days	$550	$566	1.13	1.16
SNF coinsurance	$137.50	$141.50	42.41	43.66

The estimated total increase in costs to beneficiaries is about $900 million (rounded to the nearest $10 million) due to— (1) the increase in the deductible and coinsurance amounts; and (2) the change 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 Statement

We have examined the impacts of this final rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C.804(2)).

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 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 $900 million due to— (1) The increase in the deductible and coinsurance amounts; and (2) the change in the number of deductibles and daily coinsurance amounts paid. Therefore, this notice is a major rule as defined in Title 5, United States Code, section 804(2), and is an economically significant rule under Executive Order 12866.

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 government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $7.0 million to $34.5 million in any 1 year. Individuals and States are not included in the definition of a small entity. We have determined that this notice will not have a significant economic impact on a substantial number of small entities. Therefore, we are not preparing an analysis under the RFA.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. The Secretary has determined that this notice will not have a significant impact on the operations of a substantial number of small rural hospitals. Therefore, we are not preparing an analysis under section 1102(b) of the Act.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) 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 2010, that threshold is approximately $135 million. This notice has no consequential effect 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. This notice will not have a substantial effect on State or local governments.

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

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

Dated: September 9, 2010.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

Dated: October 29, 2010.

Kathleen Sebelius,

Secretary.

[FR Doc. 2010–28251 Filed 11–4–10; 2:15 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Secretary's Advisory Committee on Heritable Disorders in Newborns and Children; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting:

Name: Secretary's Advisory Committee on Heritable Disorders in Newborns and Children.

Dates and Times: January 27, 2011, 8:30 a.m. to 5 p.m. January 28, 2011, 8:30 a.m. to 3:30 p.m.

Place: Renaissance Washington, DC Dupont Circle Hotel, 1143 New Hampshire Avenue, NW., Washington, DC 20037.

Status: The meeting will be open to the public with attendance limited to space availability. Participants are asked to register for the meeting by going to the registration Web site at *http://altarum.cvent.com/event/SACHDNC012011.* The registration deadline is Tuesday, January 25, 2011. Individuals who need special assistance, such as sign language interpretation or other reasonable accommodations should indicate their needs on the registration Web site. The deadline for special accommodation requests is Friday, January 21, 2011. If there are technical problems gaining access to the Web site, please contact Maureen Ball, Meetings Coordinator at *conferences@altarum.org.*

Purpose: The Secretary's Advisory Committee on Heritable Disorders in Newborns and Children (Advisory Committee) was established to advise and guide the Secretary regarding the most appropriate application of universal newborn screening tests, technologies, policies, guidelines and programs for effectively reducing morbidity and mortality in newborns and children having or at risk for heritable disorders. The Advisory Committee also provides advice and recommendations concerning the grants and projects authorized under the Public Health Service Act, 42 U.S.C. 300b–10, (Heritable Disorders Program) as amended in the Newborn Screening Saves Lives Act of 2008.

Agenda: The meeting will include: (1) Presentations from the following Advisory Committee workgroups: Communications, Health Information Technology, and Evidence Review; (2) a report from a National Survey of Recent and Prospective Mothers about Newborn Screening; and (3) presentations on the continued work and reports of the Advisory Committee's subcommittees on laboratory standards and procedures, follow-up and treatment, and education and training. Proposed Agenda items are subject to change as priorities dictate. You can locate the Agenda, Committee Roster and Charter, presentations, and meeting materials at the home page of the Advisory Committee's Web site at *http://www.hrsa.gov/heritabledisorderscommittee/.*

Public Comments: Members of the public can present oral comments during the public comment periods of the meeting, which are scheduled for both days of the meeting. Those individuals who want to make a comment are requested to register online by Tuesday, January 25, 2011, at *http://altarum.cvent.com/event/SACHDNC012011.* Requests will contain the name, address, telephone number, and any professional or business affiliation of the person desiring to make an oral presentation. Groups having similar interests are requested to combine their comments and present them through a single representative. The list of public comment participants will be posted on the Web site. Written comments should be e-mailed via e-mail no later than Tuesday, January 25, 2011, for consideration. Comments should be submitted to Maureen Ball, Meetings Coordinator, Conference and Meetings Management, Altarum Institute, 1200 18th Street, NW., Suite 700, Washington, DC 20036, *telephone:* 202 828–5100; *fax:* 202 785–3083, or *e-mail: conferences@altarum.org.*

Contact Person: Anyone interested in obtaining other relevant information should write or contact Alaina M. Harris, Maternal and Child Health Bureau, Health Resources and Services Administration, Room 18A–19, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443–0721, *aharris@hrsa.gov.* More information on the Advisory Committee is available at *http://mchb.hrsa.gov/heritabledisorderscommittee.*

Dated: November 2, 2010.

Robert Hendricks,

Director, Division of Policy and Information Coordination.

[FR Doc. 2010–28188 Filed 11–8–10; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0369]

Report on the Performance of Drug and Biologics Firms in Conducting Postmarketing Requirements and Commitments; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: Under the Food and Drug Administration Modernization Act of 1997 (Modernization Act), the Food and Drug Administration (FDA) is required to report annually in the **Federal Register** on the status of postmarketing requirements and commitments required of, or agreed upon by, holders of approved drug and biological products. This notice is the Agency's report on the status of the studies and clinical trials that applicants have agreed to or are required to conduct.

FOR FURTHER INFORMATION CONTACT: Cathryn C. Lee, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6464, Silver Spring, MD 20993–0002, 301–796–0700; or

Robert Yetter, Center for Biologics Evaluation and Research (HFM–25), Food and Drug Administration, 1400 Rockville Pike, Rockville, MD 20852, 301–827–0373.

SUPPLEMENTARY INFORMATION:

I. Background

A. The Modernization Act

Section 130(a) of the Modernization Act (Pub. L. 105–115) amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) by adding a new provision requiring reports of certain postmarketing studies, including clinical trials, for human drug and biological products (section 506B of the FD&C Act (21 U.S.C. 356b)). Section 506B of the FD&C Act provides FDA with additional authority to monitor the progress of a postmarketing study or clinical trial that an applicant has been required to or has agreed to conduct by requiring the applicant to submit a report annually providing information