Dated: November 17, 2005.

Betsey Dunaway,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E5–6506 Filed 11–23–05; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Institute for Occupational Safety and Health Advisory Board on Radiation and Worker Health

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following committee meeting:

Name: Working Group of the Advisory Board on Radiation and Worker Health (ABRWH), National Institute for Occupational Safety and Health (NIOSH).

Audio Conference Call Time and Date: 10 a.m.–4 p.m., EST, Monday, November 28, 2005.

Place: Audio Conference Call via FTS Conferencing. The USA toll free dial in number is 1–888–810–8159 with a pass code of 69883.

Status: Open to the public, but without a public comment period.

Background: The ABRWH was established under the Energy Employees Occupational Illness Compensation Program Act (EEOICPA) of 2000 to advise the President, delegated to the Secretary, Department of Health and Human Services (HHS), on a variety of policy and technical functions required to implement and effectively manage the new compensation program. Key functions of the Board include providing advice on the development of probability of causation guidelines which have been promulgated by HHS as a final rule, advice on methods of dose reconstruction which have also been promulgated by HHS as a final rule, advice on the scientific validity and quality of dose estimation and reconstruction efforts being performed for purposes of the compensation program, and advice on petitions to add classes of workers to the Special Exposure Cohort (SEC). In December 2000, the President delegated responsibility for funding, staffing, and operating the Board to HHS, which subsequently delegated this authority to CDC. NIOSH implements this responsibility for CDC.

Purpose: This board is charged with (a) providing advice to the Secretary, HHS on the development of guidelines under Executive Order 13179; (b) providing advice to the Secretary, HHS on the scientific validity and quality of dose reconstruction efforts performed for this Program; and (c) upon request by the Secretary, HHS, advise the Secretary on whether there is a class of employees at any Department of Energy facility who were exposed to radiation but for whom it is not feasible to estimate their radiation dose, and on whether there is reasonable likelihood that such radiation doses may have endangered the health of members of this class.

Matters To Be Discussed: Agenda for the conference call includes reports from the Working Groups on the Bethlehem Steel Site Profile, Y–12 Site Profile, and a discussion concerning the Board's approach to making an SEC Petition.

The agenda is subject to change as priorities dictate.

In the event a member of the working group cannot attend, written comments may be submitted. Any written comments received will be provided at the meeting and should be submitted to the contact person below well in advance of the meeting.

For Further Information Contact: Dr. Lewis V. Wade, Executive Secretary, NIOSH, CDC, 4676 Columbia Parkway, Cincinnati, Ohio 45226, telephone 513/533–6825, fax 513/533–6826.

Due to administrative issues concerning the topics for discussion, which were not confirmed until this week, the **Federal Register** notice is being published less than fifteen days before the date of the meeting.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. E5–6508 Filed 11–23–05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1294–N]

RIN 0938–AN99

Medicare Program; Coverage and Payment of Ambulance Services; Inflation Update for CY 2006

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

ACTION: Notice.

SUMMARY: This notice announces an updated Ambulance Inflation Factor (AIF) for payment of ambulance services during calendar year (CY) 2006. The statute requires that this inflation factor be applied in determining the fee schedule amounts and payment limits for ambulance services. The updated AIF for 2006 applies to ambulance services furnished during the period January 1, 2006, through December 31, 2006.

DATES: *Effective date:* The AIF for 2006 is effective for ambulance services furnished during the period January 1, 2006, through December 31, 2006.

FOR FURTHER INFORMATION CONTACT: Anne E. Tayloe, (410) 786–4546.

SUPPLEMENTARY INFORMATION:

I. Background

A. Legislative and Regulatory History

Under section 1861(s)(7) of the Social Security Act (the Act), Medicare Part B (Supplementary Medical Insurance) covers and pays for ambulance services, to the extent prescribed in regulations at 42 CFR Part 410 and Part 414, when the use of other methods of transportation would be contraindicated. The House Ways and Means Committee and Senate Finance Committee Reports that accompanied the 1965 legislation creating the Act suggest that the Congress intended that: the ambulance benefit cover transportation services only if other means of transportation are contraindicated by the beneficiary's medical condition; and only ambulance service to local facilities be covered unless necessary services are not available locally, in which case, transportation to the nearest facility furnishing those services is covered (H.R. Rep. No. 213, 89th Cong., 1st Sess. 37 and S. Rep. No. 404, 89th Cong., 1st Sess., Pt I, 43 (1965)). The reports indicate that transportation may also be provided from one hospital to another, to the beneficiary's home, or to an extended care facility.

Our regulations relating to ambulance services are located at 42 CFR Part 410, subpart B and Part 414, subpart H. Section 410.10(i) lists ambulance services as one of the covered medical and other health services under Medicare Part B. Ambulance services are subject to basic conditions and limitations set forth at § 410.12 and to specific conditions and limitations included at § 410.40. Part 414, subpart H describes how payment is made for ambulance services covered by Medicare.

Ambulance services are divided into different levels of services based on the medically necessary treatment provided during transport as well as into ground (including water) and air ambulance services. These services include the following levels of service.

For Ground:

- Basic Life Support (BLS)
- Advanced Life Support, Level 1 (ALS1)
- Advanced Life Support, Level 2 (ALS2)

- Specialty Care Transport (SCT)
- Paramedic ALS Intercept (PI)

For Air:

- Fixed Wing Air Ambulance (FW)
- Rotary Wing Air Ambulance (RW)

Historically, payment levels for ambulance services depended, in part, upon the entity that furnished the services. Prior to implementation of the ambulance fee schedule on April 1, 2002, providers (hospitals, including critical access hospitals, skilled nursing facilities, and home health agencies) were paid on a retrospective reasonable cost basis. Suppliers, which are entities that are independent of any provider, were paid on a reasonable charge basis.

On February 27, 2002, the Fee Schedule for Payment of Ambulance Services and Revisions to the Physician Certification Requirements for Coverage of Non-Emergency Ambulance Services final rule was published in the **Federal Register** (67 FR 9100). That final rule implemented section 1834(l) of the Act (which was added by the Balanced Budget Act of 1997) and established a fee schedule for the payment of ambulance services under the Medicare program effective for services furnished on or after April 1, 2002. The fee schedule described in the final rule replaced the retrospective reasonable cost payment system for providers and the reasonable charge system for suppliers of ambulance services. In addition, that final rule: Implemented the requirement in section 1834(l)(6) of the Act that ambulance suppliers accept Medicare assignment; codified the establishment of new Health Care Common Procedure Coding System (HCPCS) codes to be reported on claims for ambulance services; established increased payment under the fee schedule for ambulance services furnished in rural areas based on the location of the beneficiary at the time the beneficiary is placed on board the ambulance; and revised the certification requirements for coverage of non-emergency ambulance services. That final rule also provided for a 5-year transition period during which program payment for Medicare covered ambulance services would be based upon a blended rate comprised of a fee schedule portion and a reasonable cost (providers) or reasonable charge (suppliers) portion. We are now in the fourth year of that transition over to full payment based solely on the fee schedule amount.

B. Ambulance Inflation Factor (AIF) for CY 2006

Section 1834(l)(3)(B) of the Act provides the basis for updating payment amounts for ambulance services. Our implementing regulations at § 414.610(f) provide that the ambulance fee schedule must be updated by the AIF annually, based on the consumer price index for all urban consumers (CPI–U) (U.S. city average) for the 12-month period ending with June of the previous year.

Our regulations at § 414.620 provide that changes in payment rates resulting from incorporation of the AIF will be announced by notice in the **Federal Register** without opportunity for prior comment. We find it unnecessary to undertake notice and comment rulemaking because the statute and regulations specify the methods of computation of annual updates. This notice does not change policy, but merely applies the update methods specified in the statute and regulations.

II. Provisions of the Notice

A. Ambulance Inflation Factor (AIF) for 2006

Section 1834(l)(3)(B) of the Act, as specified in § 414.610(f), provides for an update in payments for CY 2006 that is equal to the percentage increase in the CPI for all urban consumers (CPI–U), for the 12-month period ending with June of the previous year (that is, June 2005). For CY 2006 that percentage is 2.5 percent.

The national fee schedule for ambulance services has been phased in over a five-year transition period beginning April 1, 2002. (*See* § 414.615). According to section 414 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) (Pub. L. 108–173), CMS established new § 414.617 which specifies that for ambulance services furnished during the period July 1, 2004 through December 31, 2009, the ground ambulance base rate is subject to a floor amount, which is determined by establishing nine fee schedules based on each of the nine census divisions, and using the same methodology as was used to establish the national fee schedule. If the regional fee schedule methodology for a given census division results in an amount that is lower than or equal to the national ground base rate, then it is not used, and the national fee schedule amount applies for all providers and suppliers in the census division. If the regional fee schedule methodology for a given census division results in an amount that is greater than the national ground base rate, then the fee schedule portion of the base rate for that census division is equal to a blend of the national rate and the regional rate. For CY 2006, this blend would be 40 percent regional ground base rate and 60 percent national ground base rate. Prior to January 1, 2006, during the transition period, the AIF was applied to both the fee schedule portion of the blended payment amount (both national and regional (if it applied)) and to the reasonable cost or charge portion of the blended payment amount separately, respectively, for each ambulance provider or supplier. Then, these two amounts were added together to determine the total payment amount for each provider or supplier. As of January 1, 2006, the total payment amount for air ambulance providers and suppliers will be based on 100 percent of the national ambulance fee schedule, while the total payment amount for ground ambulance providers and suppliers will be based on either 100 percent of the national ambulance fee schedule or 60 percent of the national ambulance fee schedule and 40 percent of the regional ambulance fee schedule.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 30-day notice in the **Federal Register** and when a collection of information requirement is submitted to the OMB for review and approval. In order to fairly evaluate whether OMB should approve an information collection, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we examine the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

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).

IV. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** to provide a period of public comment before the provisions of a notice such as this take effect. We can waive this procedure, however, if we find good cause that a notice and comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporate a statement of

finding and its reasons in the notice issued.

We find it unnecessary to undertake notice and comment rulemaking because the statute and regulation specify the methods of computation of annual updates, and we have no discretion in this matter. Further, this notice does not change substantive policy, but merely applies the update methods specified in statute and regulation. Therefore, for good cause, we waive notice and comment procedures.

Under the Congressional Review Act, major rules generally cannot take effect until 60 days after the rule is published in the **Federal Register**. However, section 808(2) of the Congressional Review Act states that agencies may waive this 60-day requirement for ''good cause'' and establish an earlier effective date. As explained above, we believe that there is ''good cause'' for waiver of the APA requirement for notice and comment rulemaking because it would be unnecessary for us to fulfill that requirement. For the same reason, we believe that the ''good cause'' exception applies to the 60-day effective date requirement for major rules in the Congressional Review Act.

V. Regulatory Impact Statement

We have examined the impacts of this notice as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 16, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132.

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 above, the AIF (equal to the percentage increase in the CPI–U of June 30, 2005 as compared to June 30, 2004) for 2006 is 2.5 percent. We estimate that the application of the AIF will result in this notice being considered a major rule because it will result in an additional total program expenditure of approximately $112 million in CY 2006.

The RFA requires agencies to analyze options for regulatory relief of small businesses. 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 $6 million to $29 million in any 1 year. For purposes of the RFA, all ambulance providers or suppliers are considered to be small entities. Individuals and States are not included in the definition of a small entity.

The Department of Health and Human Services (HHS) considers that a substantial number of entities are affected if the rule impacts more than 5 percent of the total number of small entities as it does in this notice. This notice will impact every ambulance provider and supplier in the same way because all ambulance payment rates for all ambulance services furnished by all types of ambulance providers and suppliers are increased by the same ambulance inflation factor. While all ambulance payment rates are increased by the 2.5 percent AIF, the impact of this increase does not meet the threshold established by HHS to be considered a significant impact.

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. 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. We have no data to indicate that a substantial number of small rural hospitals will be impacted by this notice.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of $110 million. This notice does not result in expenditures in any 1 year by State, local, or tribal governments of $110 million.

Executive Order 13132 establishes certain requirements that an agency must meet when it publishes a notice 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.

We estimate that the total program expenditure for CY 2006 for ambulance services covered by the Medicare program is approximately $4.5 billion. Application of an AIF of 2.5 percent will result in an additional total program expenditure of approximately $112 million over CY 2005.

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

Authority: Section 1834(l) of the Social Security Act (42 U.S.C. 1395m(l)).

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

Dated: August 9, 2005.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

Approved: October 7, 2005.

Michael O. Leavitt,

Secretary.

[FR Doc. 05–23163 Filed 11–23–05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0443]

Agency Information Collection Activities; Proposed Collection; Comment Request; Focus Groups as Used by the Food and Drug Administration

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on focus groups as used by FDA to gauge public opinion. Policymakers can use focus group results to test and refine their ideas so they can conduct further research, as well as, adopt new policies and to allocate or redirect significant resources to support these policies.

DATES: Submit written or electronic comments on the collection of information by January 24, 2006.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments.* Submit written comments on the collection of information to the Division of Dockets