**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

**42 CFR Part 410**

**[CMS-1503-F2]**

**RIN 0938-AP79**

**Medicare Program; Amendment to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2011**

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

**ACTION:** Final rule.

**SUMMARY:** This amendment rescinds the addition and definition of voluntary advance care planning as a specified element of the annual wellness visit that was finalized in the "Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2011" that appeared in the November 29, 2010 **Federal Register**.

**DATES:** Effective Date*:* This amendment is effective on **[OFR : Insert date of publication in the Federal Register.]**

**FOR FURTHER INFORMATION CONTACT:**

Dennis Wagoner, (410) 786-6841.

**SUPPLEMENTARY INFORMATION:**

## I. Background

The final rule with comment period entitled "Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2011" appeared in the November 29, 2010 **Federal Register (75 FR 73170)**. The November 29, 2010 final rule with comment period included the agency's responses to comments made by the

public in response to its Notice of Proposed Rulemaking (NPRM) published on July 13, 2010. In that NPRM, CMS sought to define the new annual wellness visit providing personalized prevention plan services as provided by the Patient Protection and Affordable Care Act (the Affordable Care Act or the Act). CMS proposed that the specified elements of the "first annual wellness visit" and the "subsequent annual wellness visit" be only those identified in the Act. In response, a number of commenters urged CMS to include voluntary advance care planning as an additional specified element of the annual wellness visit in the final rule. As described more fully below, we are rescinding this part of the final rule.

## II. Provisions of the Amendment

In the July 13, 2010 **Federal Register** (75 FR 40039), we published the proposed rule entitled "Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2011." In response to this publication, we received comments from health care providers, and others urging us to add voluntary advance care planning as a specified element of the definitions of both the "first annual wellness visit" and the "subsequent annual wellness visit." The commenters stated that their recommendations were based upon a number of recent research studies, and the inclusion by the Medicare initial preventive physical examination (IPPE) provisions of a similar element in the existing IPPE benefit.

CMS agreed with the commenters that voluntary advance care planning should be added as a specified element in the definitions of both the "first annual wellness visit" and the "subsequent annual wellness visit" based on the evidence provided and the inclusion of a similar element in the IPPE benefit (also referred to as the Welcome to Medicare

exam) since January 1, 2009, and incorporated it into the final rule.

It has since become apparent that we did not have an opportunity to consider prior to the issuance of the final rule the wide range of views on this subject held by a broad range of stakeholders (including members of Congress and those who were involved with this provision during the debate on the Affordable Care Act). Therefore, we are rescinding the provision of the final rule that includes voluntary advance care planning as a specified element of the annual wellness visits providing personalized prevention plan services, and returning to the policy that was proposed, which was limited to the elements specified in the Act. We are revising our regulation at §410.15(a) to remove voluntary advance care planning as a specified element from the definitions of "first annual wellness visit providing personalized prevention plan services" and "subsequent annual wellness visit providing personalized prevention plan services" and to remove the definition of "voluntary advance care planning."

## III. Waiver of Proposed Rulemaking and Delay in Effective Date

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposed rule before the provisions of the rule take effect in accordance with section 553(b) of the Administrative Procedure Act (5 U.S.C. 553(b)). The Physician Fee Schedule notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed, and the terms and substance of the proposed rule or a description of the subjects and issues involved. This notice and comment procedure can be waived, however, if an agency finds good cause that the procedure is impracticable, unnecessary, or contrary to the public interest, and incorporates a statement of the finding and its reasons for it in the rule. Section 553(d) of

the APA ordinarily requires a 30-day delay in the effective date of final rules after the date of their publication. This 30-day delay in effective date can be waived, however, if an agency finds for good cause that the delay is impracticable, unnecessary, or contrary to the public interest, and the agency incorporates a statement of the findings and its reasons in the rule issued.

As noted earlier, a number of commenters suggested in response to the NPRM that we should include voluntary advance care planning as an additional specified element of the new annual wellness visit. While we believe that we acted within our authority in including voluntary advance care planning as an additional specified element of the new annual wellness visit in the final rule, it has become apparent that we did not have an opportunity to consider prior to the issuance of the final rule the wide range of views on this subject held by a broad range of stakeholders (including members of Congress and those who were involved with this provision during the debate on the Affordable Care Act). Because we believe it is in the public interest to specify contemporaneous with the January 1, 2011 effective date the scope of the new "annual wellness visit for personalized prevention plan services" benefit, we believe it would be contrary to the public interest to provide for a 30-day delay in effective date. Therefore, we find good cause, based on the public interest, both to waive the notice of proposed rulemaking and the 30-day delay in effective date, and to issue this amendment effective January 1, 2011.

## IV. 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.

## V. Regulatory Impact Statement

We have examined the impact of this amendment 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 (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 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). This amendment does not reach the economic threshold and thus is not considered a major rule.

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 $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 are not preparing an analysis for the RFA because we have determined, and the Secretary certifies, that this amendment 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 for final rules 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. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this amendment 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 2010, that threshold is approximately $135 million. This amendment will have no consequential effect 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. Because this amendment does not impose any costs on State or local governments, the requirements of Executive Order 13132 are not

applicable.

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

**List of Subjects**

**42 CFR Part 410**

Health facilities, Health professions, Kidney diseases, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR part 410 as set forth below:

**PART 410--SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS**

1. The authority citation for part 410 continues to read as follows:

**Authority**: Secs. 1102, 1834, 1871, and 1893 of the Social Security Act (42 U.S.C. 1302, 1395m, 1395hh, and 1395ddd).

**Subpart B--Medical and Other Health Services**

**§ 410.15 [Amended]**

2. Section 410.15 is amended as follows:

A. In paragraph (a), in the definition of "First annual wellness visit providing personalized prevention plan services" removing paragraph (ix) and redesignating paragraph (x) as paragraph (ix).

B. In paragraph (a), in the definition of "Subsequent annual wellness visit providing personalized prevention plan services" removing paragraph (vii) and redesignating paragraph (viii) as paragraph (vii).

C. In paragraph (a), removing the definition of "voluntary advance care planning".

CMS-1503-F2

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare--Hospital Insurance; and Program No. 93.774, Medicare--Supplementary Medical Insurance Program)

**Dated**: January 3, 2011

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**Donald M. Berwick,**

Administrator,

Centers for Medicare & Medicaid Services.

**Approved**: January 4, 2011

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**Kathleen Sebelius,**

Secretary.

Department of Health and Human Services

**BILLING CODE 4120-01-P**

**[FR Doc. 2011-164 Filed 01/05/2011 at 4:15 pm; Publication Date: 01/10/2011]**