

effect on a date that precedes the 30-day period if the Secretary finds that waiver of this period is necessary to comply with statutory requirements, or is contrary to the public interest. In addition, it specifies that the issuance or publication must include a brief statement of the reasons for such finding.

This notice meets the waiver criteria described in section 1871(e)(1)(B)(ii) of the Act, since section 508 of Pub. L. 108-173 requires the Secretary to establish a one-time appeal process by January 1, 2004 and directs that the appeals be "filed as soon as possible after the date of enactment of the Act." In order for the process to be established and for appeals to be filed as soon as possible, the process must be in effect, and there can be no delay in the effective date.

V. Regulatory Impact Statement

We have examined the impact of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), 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). This notice would increase payments to hospitals by up to \$900 million, and thus is considered a major rule.

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 E.O. 13132 are not applicable.

We estimate the impact of this provision will be to increase payments to hospitals by up to \$900 million. As noted above, section 508 of Pub. L. 108-173 specifies that the aggregate amount of additional expenditures resulting from the application of this section shall not exceed \$900 million. Section 508(f) requires that hospitals previously reclassified by an act of Congress, but such reclassification expired effective with discharges on or after October 1,

2003, shall have their reclassifications reinstated effective April 1, 2004 through September 30, 2004. The extra payments for these reclassification extensions under section 508(f) are also subject to the \$900 million limit.

We estimate the increased payments under section 508(f) will total approximately \$33 million. The higher payments associated with reclassifications under this one-time appeals process are not expected to exceed a total of \$867 million (during the 3-year period covered by the provision).

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

Authority: Section 508(a) of the Public Law 108-173.

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

Dated: December 19, 2003.

Dennis G. Smith,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: December 29, 2003.

Tommy G. Thompson,

Secretary.

[FR Doc. 03-32337 Filed 12-31-03; 2:18 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-4065-N]

Medicare Program: Meeting of the Advisory Panel on Medicare Education

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

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, 5 U.S.C. Appendix 2, section 10(a) (Pub. L. 92-463), this notice announces a meeting of the Advisory Panel on Medicare Education (the Panel) on February 5, 2004. The Panel advises and makes recommendations to the Secretary of the Department of Health and Human Services and the Administrator of the Centers for Medicare & Medicaid Services on opportunities to enhance the effectiveness of consumer education strategies concerning the Medicare program. This meeting is open to the public.

DATES: The meeting is scheduled for February 5, 2004, from 9:15 a.m. to 4 p.m. e.s.t.

Deadline for Presentations and Comments: January 29, 2004, 12 noon e.s.t.

ADDRESSES: The meeting will be held at the Wyndham Washington Hotel, 1400 M Street, NW., Washington, DC 20005, (202) 429-1700.

FOR FURTHER INFORMATION CONTACT: Lynne Johnson, Health Insurance Specialist, Division of Partnership Development, Center for Beneficiary Choices, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mail Stop S2-23-05, Baltimore, MD 21244-1850, (410) 786-0090. Please refer to the CMS Advisory Committees' Information Line (1-877-449-5659 toll free)/(410-786-9379 local) or the Internet (<http://www.cms.hhs.gov/faca/apme/default.asp>) for additional information and updates on committee activities, or contact Ms. Johnson via e-mail at ljohnson3@cms.hhs.gov. Press inquiries are handled through the CMS Press Office at (202) 690-6145.

SUPPLEMENTARY INFORMATION: Section 222 of the Public Health Service Act (42 U.S.C. 217a), as amended, grants to the Secretary of the Department of Health and Human Services (the Secretary) the authority to establish an advisory panel if the Secretary finds the panel necessary and in the public interest. The Secretary signed the charter establishing this panel on January 21, 1999 (64 FR 7899), and approved the renewal of the charter on January 21, 2003. The panel advises and makes recommendations to the Secretary and the Administrator of the Centers for Medicare & Medicaid Services (CMS) on opportunities to enhance the effectiveness of consumer education strategies concerning the Medicare program.

The goals of the panel are as follows:

- To develop and implement a national Medicare education program that describes the options for selecting a health plan under Medicare.
- To enhance the Federal government's effectiveness in informing the Medicare consumer, including the appropriate use of public-private partnerships.
- To expand outreach to vulnerable and underserved communities, including racial and ethnic minorities, in the context of a national Medicare education program.
- To assemble an information base of best practices for helping consumers evaluate health plan options and build a community infrastructure for information, counseling, and assistance.

The current members of the Panel are: James L. Bildner, Chairman and Chief Executive Officer, Tier Technologies; Dr. Jane Delgado, Chief Executive Officer, National Alliance for Hispanic Health; Joyce Dubow, Senior Policy Advisor, Public Policy Institute, American Association of Retired Persons (AARP); Clayton Fong, President and Chief Executive Officer, National Asian Pacific Center on Aging; Timothy Fuller, Executive Director, National Gray Panthers; John Graham IV, President and Chief Executive Officer, American Society of Association Executives; Dr. William Haggett, Senior Vice President, Government Programs, Independence Blue Cross; Thomas Hall, Chairman and Chief Executive Officer, Cardio-Kinetics, Inc.; David Knutson, Director, Health System Studies, Park Nicollet Institute for Research and Education; Brian Lindberg, Executive Director, Consumer Coalition for Quality Health Care; Katherine Metzger, Director, Medicare and Medicaid Programs, Fallon Community Health Plan; Dr. Laurie Powers, Co-Director, Center on Self-Determination, Oregon Health Sciences University; Dr. Marlon Priest, Professor of Emergency Medicine, University of Alabama at Birmingham; Dr. Susan Reinhard, Co-Director, Center for State Health Policy, Rutgers University and Chairperson of the Advisory Panel on Medicare Education; Dr. Everard Rutledge, Vice President of Community Health, Bon Secours Health Systems, Inc.; Jay Sackman, Executive Vice President, 1199 Service Employees International Union; Dallas Salisbury, President and Chief Executive Officer, Employee Benefit Research Institute; Rosemarie Sweeney, Vice President, Socioeconomic Affairs and Policy Analysis, American Academy of Family Physicians; and Bruce Taylor, Director, Employee Benefit Policy and Plans, Verizon Communications.

The agenda for the February 5, 2004, meeting will include the following:

- Recap of the previous (November 20, 2003) meeting.
- Centers for Medicare & Medicaid Services update/ Center for Beneficiary Choices update.
- Medicare Prescription Drug, Improvement and Modernization Act update.
- Public comment.
- Listening session with CMS leadership.
- Next steps.

Individuals or organizations that wish to make a 5-minute oral presentation on an agenda topic must submit a written copy of the oral presentation to Lynne Johnson, Health Insurance Specialist,

Division of Partnership Development, Center for Beneficiary Choices, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mail Stop S2-23-05, Baltimore, MD 21244-1850 or by email at 1johnson3@cms.hhs.gov no later than 12 noon, e.s.t., January 29, 2004. The number of oral presentations may be limited by the time available. Individuals not wishing to make a presentation may submit written comments to Ms. Johnson by 12 noon, (e.s.t.), January 29, 2004. The meeting is open to the public, but attendance is limited to the space available.

Special Accommodation: Individuals requiring sign language interpretation or other special accommodations must contact Ms. Johnson at least 15 days before the meeting.

Authority: Sec. 222 of the Public Health Service Act (42 U.S.C. 217a) and sec. 10(a) of Pub. L. 92-463 (5 U.S.C. App. 2, sec. 10(a) and 41 CFR 102-3). (Catalog of Federal Domestic Assistance Program No. 93.733, Medicare—Hospital Insurance Program; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program.)

Dated: December 29, 2003.

Dennis G. Smith,

Administrator (Acting), Centers for Medicare & Medicaid Services.

[FR Doc. 03-32321 Filed 12-31-03; 11:38 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 2003M-0442, 2003M-0443, 2003M-0444, 2003M-0445, 2003M-0446, and 2003M-0447]

Medical Devices Regulated by the Center for Biologics Evaluation and Research; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of premarket approval applications (PMAs) that have been approved by the Center for Biologics Evaluation and Research (CBER). This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMAs through the Internet and the agency's Division of Dockets Management.

ADDRESSES: Submit written requests for copies of summaries of safety and effectiveness to the Division of Dockets

Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please cite the appropriate docket number as listed in table 1 of this document when submitting a written request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the summaries of safety and effectiveness.

FOR FURTHER INFORMATION CONTACT: Nathaniel L. Geary, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 30, 1998 (63 FR 4571), FDA published a final rule that revised 21 CFR 814.44(d) and 814.45(d) to discontinue individual publication of PMA approvals and denials in the **Federal Register**, providing instead to post this information on the Internet at <http://www.fda.gov>. In addition, the regulations provide that FDA publish a quarterly list of available safety and effectiveness summaries of PMA approvals and denials that were announced during the quarter. FDA believes that this procedure expedites public notification of these actions because announcements can be placed on the Internet more quickly than they can be published in the **Federal Register**, and FDA believes that the Internet is accessible to more people than the **Federal Register**.

In accordance with section 515(d)(4) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(4) and (e)(2)), notification of an order approving, denying, or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515(g) of the act. The 30-day period for requesting reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA begins on the day the notice is placed on the Internet. Section 10.33(b) provides that FDA may, for good cause, extend this 30-day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the applicant; in these cases, the 30-day period will begin when the applicant is notified by FDA in writing of its decision.

The following is a list of PMAs approved by CBER for which summaries of safety and effectiveness were placed on the Internet from December 5, 2001, through September 30, 2003. There were