for the State of Washington to publish corresponding changes to the Washington State Medical Test Site Rules, which were effective March 19, 2005.

VIII. Collection of Information Requirements

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

VIX. Regulatory Impact Statement

This notice announces the continuance of the exemption of laboratories licensed by the State of Washington from the requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA). The State has established that the quality of laboratory services required under its Laboratory licensure program continues to be equal or more stringent than those required by the CLIA program. Washington also has established that it has a comparable program to monitor and evaluate compliance with its laboratory licensure program requirements. The effect of the continued exemption from CLIA requirements is that laboratories will remain under State, rather than Federal, regulation, with no discernible difference in the operations of the programs. Consequently, we anticipate that our continued approval of Washington's CLIA exemption will not affect the laboratories or the quality and availability of services provided.

We have examined the impact of this notice as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 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). This notice 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 government agencies. 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. 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 that this notice 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 notice 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. We are not preparing an analysis for section 1102(b) of the Act because we have 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 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 will have no consequential effect on the governments mentioned 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 regulation does not impose any costs on State or local governments, the requirements of E.O. 13132 are not applicable.

In accordance with the provisions of Executive Order 12866, this regulation was not reviewed by the Office of Management and Budget.

Authority: Section 353(p) of the Public Health Service Act (42 U.S.C. 263a).

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program; No. 93.773 Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: April 8, 2005.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 05–8286 Filed 4–22–05; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–5033–N4]

Medicare Program; Meeting of the Advisory Board on the Demonstration of a Bundled Case-Mix Adjusted Payment System for End-Stage Renal Disease Services—May 24, 2005

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

ACTION: Notice.

SUMMARY: This notice announces the second public meeting of the Advisory Board on the Demonstration of a Bundled Case-Mix Adjusted Payment System for End-Stage Renal Disease (ESRD) Services. Notice of this meeting is required by the Federal Advisory Committee Act (5 U.S.C. App. 2, section 10(a)(1) and (a)(2)). The Advisory Board will provide advice and recommendations with respect to the establishment and operation of the demonstration mandated by section 623(e) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

DATES: The meeting is on May 24, 2005 from 9 a.m. to 5 p.m., eastern standard time.

Special Accomodations: Persons attending the meeting, who are hearing or visually impaired, or have a condition that requires special assistance or accommodations, are asked to notify Pamela Kelly by May 17, 2005 by e-mail at *ESRDAdvisoryBoard@cms.hhs.gov* or by telephone at (410) 786–2461.

ADDRESSES: The meeting will be held at the Holiday Inn—BWI Airport, 890 Elkridge Landing Rd., Linthicum, MD 21090.

Attendance is limited to the space available, so seating will be on a first come, first served basis.

Web site: Up-to-date information on this meeting is located at *http://www.cms.hhs.gov/faca/esrd.*

Hotline: Up-to-date information on this meeting is located on the CMS Advisory Committee Hotline at 1 (877)

449–5659 (toll free) or in the Baltimore area at (410) 786–9379.

FOR FURTHER INFORMATION CONTACT: Pamela Kelly by e-mail at *ESRDAdvisoryBoard@cms.hhs.gov* or telephone at (410) 786–2461.

SUPPLEMENTARY INFORMATION: On June 2, 2004, we published a **Federal Register** notice requesting nominations for individuals to serve on the Advisory Board on the Demonstration of a Bundled Case-Mix Adjusted Payment System for End-Stage Renal Disease (ESRD) Services. The June 2, 2004 notice also announced the establishment of the Advisory Board and the signing by the Secretary on May 11, 2004 of the charter establishing the Advisory Board. On January 28, 2005, we published a **Federal Register** notice announcing the appointment of eleven individuals to serve as members of the Advisory Board on the Demonstration of a Bundled Case-Mix Adjusted Payment System for ESRD Services, including one individual to serve as co-chairperson, and one additional co-chairperson, who is employed by CMS. The first public meeting of the Advisory Board was held on February 16, 2005. The original meeting scheduled for April 13, 2005 was cancelled. This notice announces the second public meeting of this Advisory Board.

I. Topics of the Advisory Board Meeting

The Advisory Board on the Demonstration of a Bundled Case-Mix Adjusted Payment System for ESRD Services will study and make recommendations on the following issues:

- The drugs, biologicals, and clinical laboratory tests to be bundled into the demonstration payment rates.
- The method and approach to be used for the patient characteristics to be included in the fully case-mix adjusted demonstration payment system.
- The manner in which payment for bundled services provided by non-demonstration providers should be handled for beneficiaries participating in the demonstration.
- The feasibility of providing financial incentives and penalties to organizations operating under the demonstration that meet or fail to meet applicable quality standards.
- The specific quality standards to be used.
- The feasibility of using disease management techniques to improve quality and patient satisfaction and reduce costs of care for the beneficiaries participating in the demonstration.
- The selection criteria for demonstration organizations.

II. Procedure and Agenda of the Advisory Board Meeting

This meeting is open to the public. The Advisory Board will hear background presentations from CMS. The Advisory Board will then deliberate openly on the general topic and will make recommendations on specific topics for future meetings. The Advisory Board will also allow at least a 30-minute open public session. Interested parties may speak or ask questions during the public comment period. Comments may be limited by the time available. Written questions should be submitted by May 17, 2005 to *ESRDAdvisoryBoard@cms.hhs.gov.* Parties may also submit written comments following the meeting to the contact listed under the **FOR FURTHER INFORMATION CONTACT** section of this notice.

Authority: 5 U.S.C. App. 2, section 10(a). (Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: April 21, 2005.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 05–8386 Filed 4–28–05; 8:45 am]

BILLING CODE 4120–01–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1314–N]

Medicare Program; Meeting of the Practicing Physicians Advisory Council, May 23, 2005

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

ACTION: Notice.

SUMMARY: In accordance with section 10(a) of the Federal Advisory Committee Act, this notice announces a meeting of the Practicing Physicians Advisory Council (the Council). The Council will be meeting to discuss certain proposed changes in regulations and carrier manual instructions related to physicians' services, as identified by the Secretary of the Department of Health and Human Services (the Secretary). This meeting is open to the public.

DATES: The meeting is scheduled for Monday, May 23, 2005, from 8:30 a.m. until 5 p.m. e.d.t.

ADDRESSES: The meeting will be held in Room 705A, 7th floor, in the Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

Meeting Registration: Persons wishing to attend this meeting must contact the Designated Federal Official (DFO) by email at PPAC@cms.hhs.gov at least 72 hours in advance of the meeting to register. Persons not registered in advance will not be permitted into the Hubert H. Humphrey Building and will not be permitted to attend the Council meeting. Persons attending the meeting will be required to show a photographic identification, preferably a valid driver's license, before entering the building.

FOR FURTHER INFORMATION CONTACT: Kelly Buchanon, Designated Federal Official, Practicing Physicians Advisory Council, 7500 Security Blvd., Mail Stop C4–11–27, Baltimore, MD, 21244–1850, telephone (410) 786–6132, or e-mail *PPAC@cms.hhs.gov*. News media representatives must contact the CMS Press Office, (202) 690–6145. Please refer to the CMS Advisory Committees Information Line (1–877–449–5659 toll free) ((410) 786–9379 local) or the Internet at *http://www.cms.hhs.gov/faca/ppac/default.asp* for additional information and updates on committee activities.

SUPPLEMENTARY INFORMATION: The Secretary is mandated by section 1868(a) of the Social Security Act (the Act) to appoint a Practicing Physicians Advisory Council (the Council) based on nominations submitted by medical organizations representing physicians. The Council meets quarterly to discuss certain proposed changes in regulations and carrier manual instructions related to physicians' services, as identified by the Secretary. To the extent feasible and consistent with statutory deadlines, the consultation must occur before publication of the proposed changes. The Council submits an annual report on its recommendations to the Secretary and the Administrator of the Centers for Medicare & Medicaid Services not later than December 31 of each year.

The Council consists of 15 physicians, each of whom must have submitted at least 250 claims for physicians' services under Medicare in the previous year. Members of the Council include both participating and nonparticipating physicians, and physicians practicing in rural and underserved urban areas. At least 11 members of the Council must be physicians as described in section 1861(r)(1) of the Act; that is, State-licensed doctors of medicine or osteopathy. The remaining 4 members may include dentists, podiatrists, optometrists and chiropractors. Members serve for overlapping 4-year terms; terms of more than 2 years are contingent upon the renewal of the Council by appropriate action prior to