no lower than the current indirect PE RVUs.

In comments on the CY 2006 PFS proposed rule, commenters indicated that they did not understand the mechanics of our proposals and that there was not enough information for specialties to analyze them. Many commenters requested a 1-year delay in implementation of our proposals to allow time for CMS to provide further information and to give other specialties an additional opportunity to submit their own supplementary survey.

After reviewing the CY 2006 PFS proposed rule comments, we determined that the proposal for revising the indirect PE was confusing to the public because the published PE values and impacts were incorrect. Therefore, in the CY 2006 PFS final rule (70 FR 70116), we withdrew the proposed PE revision for 2006 and used the 2005 PE RVUs for most services. The only exceptions were to price the codes that were new in 2006 and, as required by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L 108–173), to use the new urology PE data in the calculation of the drug administration codes used by their specialty.

As we indicated when we issued the CY 2006 PFS final rule (70 FR 70116), we intend to work with the medical community to ensure that any future proposals to change the PE methodology are understandable and informed by input from the medical community. As the initial step in this process, we are holding this Town Hall meeting to provide this opportunity.

II. Meeting Format

This meeting will begin with an overview of the objectives of the meeting along with an introduction of the topics to be discussed during the meeting which include:

- Clarifying our efforts to revise the PE methodology in the CY 2006 PFS proposed rule which include:

+ The change from a ''top-down'' methodology for calculating direct PE to a ''bottom-up'' approach utilizing the direct cost inputs;

+ The use of the accepted supplementary PE surveys from the seven specialties in the calculation of indirect PE;

+ The intended method of obtaining the indirect PE values; and

+ The elimination of the nonphysician workpool and the related impacts.

- A question and answer session that offers the meeting attendees an opportunity to clarify further the topics discussed.

- Soliciting input from individual attendees on each facet of our methodology: direct PE, indirect PE, supplementary surveys, and nonphysician workpool. The comments provided during this meeting will assist us in the preparation of the physician fee schedule proposed rule for CY 2007.

To provide a basis of understanding before the meeting we will be posting information concerning the PE methodology on our Web site at *http://www.cms.hhs.gov/PhysicianFeeSched/*. This information will include current PE values, examples for deriving PE values using the bottom-up methodology, and projected impacts of these revisions. We encourage individuals to familiarize themselves with this material before the meeting. Copies of this information will be available on the day of the meeting.

Authority

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

Dated: January 19, 2006.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 06–747 Filed 1–26–06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[CMS–1318–N]

Medicare Program; Meeting of the Practicing Physicians Advisory Council, March 6, 2006

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

ACTION: Notice.

SUMMARY: This notice announces a quarterly meeting of the Practicing Physicians Advisory Council (the Council). The Council will meet to discuss certain proposed changes in regulations and carrier manual instructions related to physicians' services, as identified by the Secretary of Health and Human Services (the Secretary). This meeting is open to the public.

DATES: The Council meeting is scheduled for Monday, March 6, 2006, from 8 a.m. until 5 p.m. e.s.t.

ADDRESS: 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 register by contacting Kelly Buchanan, the Designated Federal Official (DFO) by e-mail at *PPAC@cms.hhs.gov* or by telephone at (410) 786–6132, at least 72 hours in advance of the meeting. This meeting will be held in a Federal Government Building, Hubert H. Humphrey Building, and persons attending the meeting will be required to show a photographic identification, preferably a valid driver's license, and will be listed on an approved security list before persons are permitted entrance. 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.

FOR FURTHER INFORMATION CONTACT: Kelly Buchanan, (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: In accordance with section 10(a) of the Federal Advisory Committee Act, this notice announces the quarterly meeting of the Practicing Physicians Advisory Council (the Council). The Secretary is mandated by section 1868(a)(1) of the Social Security Act (the Act) to appoint a Practicing Physicians Advisory 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 Council's consultation must occur before **Federal Register** 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 and Medicaid Services (CMS) not later than December 31 of each year.

The Council consists of 15 physicians, including the Chair. 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 its termination.

Section 1868(a)(2) of the Act provides that the Council meet quarterly to discuss certain proposed changes in regulations and manual issuances that relate to physicians' services, identified by the Secretary. Council members are expected to participate in all meetings. Section 1868(a)(3) of the Act provides for payment of expenses and a per diem allowance for Council members at a rate equal to payment provided members of other advisory committees. In addition to making these payments, the Department of Health and Human Services and CMS provide management and support services to the Council. The Secretary will appoint new members to the Council from among those candidates determined to have the expertise required to meet specific agency needs in a manner to ensure appropriate balance of the Council's membership.

The Council held its first meeting on May 11, 1992. *The current members are:* Ronald Castellanos, M.D., Chairperson; Jose Azocar, M.D.; M. Leroy Sprang, M.D.; Rebecca Gaughan, M.D.; Peter Grimm, D.O.; Carlos R. Hamilton, M.D.; Dennis K. Iglar, M.D.; Joe Johnson, D.C.; Christopher Leggett, M.D.; Barbara McAneny, M.D.; Geraldine O'Shea, D.O.; Laura B. Powers, M.D.; Gregory J. Przybylski, M.D.; Anthony Senagore, M.D.; and Robert L. Urata, M.D.

The meeting will commence with the Council's Executive Director providing a status report and the CMS responses to the recommendations made by the Council at the December 5, 2005 meeting as well as prior meeting recommendations. Additionally, an update will be provided on the Physician Regulatory Issues Team. In accordance with the Council charter, we are requesting assistance with the following agenda topics:

- Moving Towards Pay for Performance.
- Update on Implementation of Part D Drug Program.
- Medicare Contractor Reform.
- Medicare Health Support.

For additional information and clarification on these topics, contact the DFO as provided in the **FOR FURTHER INFORMATION CONTACT** section of this notice. Individual physicians or medical organizations that represent physicians wishing to make a 5-minute oral presentation on agenda issues must contact the DFO by 12 noon, e.s.t., February 17, 2006, to be scheduled. Testimony is limited to agenda topics only. The number of oral presentations may be limited by the time available. A written copy of the presenter's oral remarks must be submitted to Kelly Buchanan, DFO, no later than 12 noon, e.s.t., February 17, 2006, for distribution to Council members for review prior to the meeting. Physicians and medical organizations not scheduled to speak may also submit written comments to the DFO for distribution no later than noon, e.s.t., February 17, 2006. The meeting is open to the public, but attendance is limited to the space available.

Special Accommodations: Individuals requiring sign language interpretation or other special accommodation must contact the DFO by e-mail at *PPAC@cms.hhs.gov* or by telephone at (410) 786–6132 at least 10 days before the meeting.

Authority: Section 1868 of the Social Security Act (42 U.S.C. 1395ee) and section 10(a) of Pub. L. 92–463 (5 U.S.C. App. 2, section 10(a)).

Dated: January 5, 2006.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E6–702 Filed 1–26–06; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004E–0314]

Determination of Regulatory Review Period for Purposes of Patent Extension; SPIRIVA HANDIHALER

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for SPIRIVA HANDIHALER and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent that claims that human drug product.

ADDRESSES: Submit written comments and petitions to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Claudia V. Grillo, Office of Regulatory Policy (HFD–013), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 240–453–6681.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted, as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product SPIRIVA HANDIHALER (tiotropium bromide monohydrate). SPIRIVA HANDIHALER is indicated for the long-term, once daily, maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for SPIRIVA HANDIHALER (U.S. Patent No. 5,610,163) from Boehringer Ingelheim Corporation, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated