

Congressional decision to allow a broader range of physicians and treating practitioners to prescribe POVs. This increased burden is offset by the new payments implemented in connection with the Final Rule, which is demonstrated by the shift in prescriptions from one class of equipment, power wheelchairs, to another class of equipment, POVs.

In addition, CMS believes that with the recent coverage decision on Mobility Assistive Equipment, the implementing details in the Final Rule (e.g. improved documentation for suppliers; physician and treating practitioner payments; improved classification of mobility equipment; the elimination of the certificate of medical necessity (CMN)), and the provider outreach and education provided by CMS, the DME program safeguard contractors (PSCs) and DME Medicare administrative contractors (MACs), the needs of mobility-impaired beneficiaries and the needs of suppliers have been better met. *Frequency*: Recordkeeping—On occasion; *Affected Public*: Business or for-profits, Not-for-profit institutions, and State, Local or Tribal governments; *Number of Respondents*: 38,000; *Total Annual Responses*: 342,000; *Total Annual Hours*: 48,600.

3. Type of Information Collection
Request: Extension of a currently approved collection; *Title of Information Collection*: Home Health Conditions of Participation (CoP) Information Collection Requirements and Supporting Regulations in 42 CFR 484.10, 484.12, 484.16, 484.18, 484.36, 484.48, 484.52; *Form Numbers*: CMS-R-39 (OMB#: 0938-0365); *Use*: The information collection requirements contained in this request are part of the requirements classified as the conditions of participation (CoPs) which are based on criteria prescribed in law and are standards designed to ensure that each facility has properly trained staff to provide the appropriate safe physical environment for patients. These particular standards reflect comparable standards developed by industry organizations such as the Joint Commission on Accreditation of Healthcare Organizations, and the Community Health Accreditation Program. The primary users of this information will be State agency surveyors, the regional home health intermediaries, CMS and home health agencies (HHAs) for the purpose of ensuring compliance with Medicare CoPs as well as ensuring the quality of care provided by HHA patients. *Frequency*: Recordkeeping and Reporting—Annually, On occasion; *Affected Public*: Business or for-profits,

Not-for-profit institutions, and State, Local or Tribal governments; *Number of Respondents*: 9,354; *Total Annual Responses*: 9,354; *Total Annual Hours*: 1,048,483.5.

4. Type of Information Collection
Request: Revision of a currently approved collection; *Title of Information Collection*: Health Insurance Common Claims Form and Supporting Regulations at 42 CFR Part 424, Subpart C; *Form Number*: CMS-1500(08-05), CMS-1490-S (OMB#: 0938-0999); *Use*: The Form CMS-1500 answers the needs of many health insurers. It is the basic form prescribed by CMS for the Medicare program for claims from physicians and suppliers. The Medicaid State Agencies, CHAMPUS/TriCare, Blue Cross/Blue Shield Plans, the Federal Employees Health Benefit Plan, and several private health plans also use it; it is the de facto standard “professional” claim form.

Medicare carriers use the data collected on the CMS-1500 and the CMS-1490S to determine the proper amount of reimbursement for Part B medical and other health services (as listed in section 1861(s) of the Social Security Act) provided by physicians and suppliers to beneficiaries. The CMS-1500 is submitted by physicians/suppliers for all Part B Medicare. Serving as a common claim form, the CMS-1500 can be used by other third-party payers (commercial and nonprofit health insurers) and other Federal programs (e.g., CHAMPUS/TriCare, Railroad Retirement Board (RRB), and Medicaid).

However, as the CMS-1500 displays data items required for other third-party payers in addition to Medicare, the form is considered too complex for use by beneficiaries when they file their own claims. Therefore, the CMS-1490S (Patient's Request for Medicare Payment) was explicitly developed for easy use by beneficiaries who file their own claims. The form can be obtained from any Social Security office or Medicare carrier.

Since the last submission of this information collection request, we discontinued form CMS-1490U which was used by employers, unions, employer-employee organizations that pay physicians and suppliers for their services to employees, group practice prepayment plans, and health maintenance organizations. Therefore, this collection will no longer contain the CMS-1490U.

In sum, the CMS-1500 and CMS-1490S result in less paperwork burden placed on the public. The CMS-1500 provides efficiency in office procedures for physicians and suppliers; the CMS-

1490S provides beneficiaries with a relatively easy form to use when filing their claims. Without the collection of this information, claims for reimbursement relating to the provision of Part B medical services/supplies could not be acted upon. This would result in a nationwide paralysis of the operation of the Federal Government's Medicare Part B program, and major problems for the other health plans that use the CMS-1500, inflicting severe physical and financial hardship on providers/suppliers as well as beneficiaries. *Frequency*: Reporting—On occasion; *Affected Public*: State, Local, or Tribal Government, Business or other-for-profit, Not-for-profit institutions; *Number of Respondents*: 1,048,243; *Total Annual Responses*: 970,174,260; *Total Annual Hours*: 33,067,757.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web Site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov, or call the Reports Clearance Office on (410) 786-1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received at the address below, no later than 5 p.m. on June 26, 2007.

CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development—B, Attention: William N. Parham, III, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: April 20, 2007.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-1387-N]

Medicare Program; Meeting of the Practicing Physicians Advisory Council, May 21, 2007

AGENCY: Centers for Medicare & 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 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: *Meeting Date:* Monday, May 21, 2007, from 8:30 a.m. to 5 p.m. e.d.t.

Deadline for Registration without Oral Presentation: Friday, May 18, 2007, 12 noon, e.d.t.

Deadline for Registration of Oral Presentations: Friday, May 4, 2007, 12 noon, e.d.t.

Deadline for Submission of Oral Remarks and Written Comments: Wednesday, May 9, 2007, 12 noon, e.d.t.

Deadline for Requesting Special Accommodations: Monday, May 14, 2007, 12 noon, e.d.t.

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

Submission of Testimony: Testimonies should be mailed to Kelly Buchanan, DFO, Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Mail stop C4-13-07, Baltimore, MD 21244-1850, or contact the DFO via e-mail at PPAC@cms.hhs.gov.

FOR FURTHER INFORMATION CONTACT: Kelly Buchanan, the Designated Federal Official (DFO), (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/home/regsguidance.asp> for additional information and updates on committee activities.

SUPPLEMENTARY INFORMATION:

I. Background

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 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 & 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.

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. Section 1868(a)(3) of the Act provides for payment of expenses and per diem for Council members in the same manner as members of other advisory committees appointed by the Secretary. 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: Anthony Senagore, M.D., Chairperson; Jose Azocar, M.D.; M. Leroy Sprang, M.D.; Karen S. Williams, M.D.; Peter Grimm, D.O.; Jonathon E. Siff, M.D., MBA; John E. Arradondo, M.D., MPH; Helena Wachslicht Rodbard, M.D.; Vincent J. Bufalino, M.D.; Tye J. Ouzounian, M.D.; Geraldine O'Shea, D.O.; Arthur D. Snow, Jr., M.D.; Gregory J. Przybylski, M.D.; Jeffrey A. Ross, DPM, M.D.; and Roger L. Jordan, O.D.

II. Meeting Format and Agenda

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 March 5, 2007 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:

- Post Acute Care Project.
- National Provider Identifier (NPI).
- Physician Quality Reporting Initiative (PQRI).
- Personal Health Records.
- Durable Medical Equipment (DME) Final Rule.

- Contractor Reform Update.

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 present a 5-minute oral testimony on agenda issues must register with the DFO by the date listed in the **DATES** section of this notice. Testimony is limited to agenda topics only. The number of oral testimonies may be limited by the time available. A written copy of the presenter's oral remarks must be submitted to the DFO for distribution to Council members for review before the meeting by the date listed in the **DATES** section of this notice. Physicians and medical organizations not scheduled to speak may also submit written comments to the DFO for distribution by the date listed in the **DATES** section of this notice.

III. Meeting Registration and Security Information

The meeting is open to the public, but attendance is limited to the space available. Persons wishing to attend this meeting must register by contacting the DFO at the address listed in the **ADDRESSES** section of this notice or by telephone at (410) 786-6132 by the date specified in the **DATES** section of this notice.

Since this meeting will be held in a Federal Government Building, the Hubert H. Humphrey Building, Federal security measures are applicable. As noted above, in planning your arrival time, we recommend allowing additional time to clear security. In order to gain access to the building, participants will be required to show a government-issued photo identification (for example, driver's license, or passport), and must 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.

All persons entering the building must pass through a metal detector. In addition, all items brought to the Hubert

H. Humphrey Building, whether personal or for the purpose of presentation, are subject to inspection. We cannot assume responsibility for coordinating the receipt, transfer, transport, storage, set-up, safety, or timely arrival of any personal belongings or items used for the purpose of presentation.

Individuals requiring sign language interpretation or other special accommodation must contact the DFO via the contact information specified in the **FOR FUTURE INFORMATION CONTACT** section of this notice by the date listed in the **DATES** section of this notice.

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: April 10, 2007.

Leslie V. Norwalk,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E7-7382 Filed 4-26-07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N-0018]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Human Cells, Tissues, and Cellular and Tissue-Based Products: Establishment Registration and Listing; Form Food and Drug Administration 3356; Eligibility Determination for Donors; and Current Good Tissue Practice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by May 29, 2007.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-6974. All comments should be identified with the OMB control number 0910-0543. Also include the FDA

docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Jonna Capezzuto, Office of the Chief Information Officer (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

SUPPLEMENTARY INFORMATION:

In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Human Cells, Tissues, and Cellular and Tissue-Based Products: Establishment Registration and Listing; Form Food and Drug Administration 3356; Eligibility Determination for Donors; and Current Good Tissue Practice (OMB Control Number 0910-0543)—Extension

Under section 361 of the Public Health Service Act (the PHS Act) (42 U.S.C. 264), FDA may issue and enforce regulations necessary to prevent the introduction, transmission, or spread of communicable diseases between the States or possessions or from foreign countries into the States. As derivatives of the human body, all human cells, tissues, and cellular and tissue-based products (HCT/Ps) pose some risk of carrying pathogens that could potentially infect recipients or handlers. FDA has issued regulations related to HCT/Ps involving establishment registration and listing using Form FDA 3356; eligibility determination for donors; and current good tissue practice (CGTP).

Establishment Registration and Listing; Form FDA 3356

The regulations in part 1271 (21 CFR part 1271) require domestic and foreign establishments that recover, process, store, label, package, or distribute any HCT/Ps, or that perform screening or testing of the cell or tissue donor to register with FDA (§ 1271.10(b)(1)) and submit a list of each HCT/P manufactured (§ 1271.10(b)(2)). Section 1271.21(a) requires the initial establishment registration, and § 1271.25(a) and (b) identifies the required initial registration and HCT/P listing information. Section 1271.21(b) requires an annual update of the establishment registration. Section 1271.21(c)(ii) requires establishments to submit HCT/P listing updates when an HCT/P is changed as described in § 1271.25(c). Section 1271.25(c) identifies the required HCT/P listing update information. Section 1271.26 requires establishments to submit an amendment if ownership or location of

the establishment changes. FDA requires the use of a registration and listing form (Form FDA 3356: Establishment Registration and Listing for Human Cells, Tissues, and Cellular and Tissue-Based Products to submit the required information (§§ 1271.10, 1271.21, 1271.25, and 1271.26)). To further facilitate the ease and speed of submissions, electronic submission is accepted (<http://www.fda.gov/cber/tissue/tisreg.htm>).

Eligibility Determination for Donors

FDA requires HCT/P establishments described in § 1271.1(b) to screen and test the donors of cells and tissue used in those products for risk factors for and clinical evidence of relevant communicable diseases agents and diseases. The documented determination of a donor's eligibility is made by a responsible person and is based on the results of required donor screening, which includes a donor medical history interview (defined in § 1271.3(n)), and testing (§ 1271.50(a)). HCT/P establishments are permitted to ship an HCT/P only if it is accompanied by documentation of the donor-eligibility determination (§ 1271.55(a)). This requirement applies to an HCT/P from a donor determined to be eligible as well as to a product from a donor who is determined to be ineligible and made available for use under certain provisions. The accompanying documentation must contain a summary of records used to determine donor eligibility, and a statement whether, based on the results of the screening and testing of the donor, that the donor is determined to be eligible or ineligible. Records used in determining the eligibility of a donor, i.e., results and interpretations of screening and testing, the donor eligibility determination, the name and address of the testing laboratory or laboratories, and the name of the responsible person who made the determination and the date, must be maintained (§ 1271.55(d)(1)). If any information on the donor is not in English, the HCT/P establishment must retain the original record and the statement of authenticity from the translator (§ 1271.55(d)(2)). HCT/P establishments must retain the records pertaining to HCT/Ps at least 10 years after the date of administration, distribution, disposition, or expiration, whichever is latest (§ 1271.55(d)(4)).

When a product is shipped in quarantine, before completion of screening and testing, the HCT/P establishment must provide the donor identification, a statement that the donor-eligibility determination is not completed and that the product is not to