

Centers of Excellence in Health Statistics, PA# 02193.

*Times and Dates:* 1 p.m.–1:30 p.m., September 5, 2002 (Open), 1:30 p.m.–5:30 p.m., September 5, 2002 (Closed).

*Place:* Teleconference number (800) 713–1971.

*Status:* Portions of the meeting will be closed to the public in accordance with provisions set forth in section 552b(c) (4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

*Matters to be Discussed:* The meeting will include the review, discussion, and evaluation of applications received in response to PA# 02193.

**CONTACT PERSON FOR MORE INFORMATION:** Linda Blankenbaker, Program Specialist, National Center for Health Statistics, CDC, 6525 Belcrest Road, Room 1140, Hyattsville, Maryland 20782, (301) 458–4612.

The Director, Management Analysis and Services Office has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: August 6, 2002.

**John Burckhardt,**

*Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).*

[FR Doc. 02–20559 Filed 8–13–02; 8:45 am]

**BILLING CODE 4160–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare and Medicaid Services

[Document Identifier: CMS–9042]

#### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Centers for Medicare and Medicaid Services.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare and Medicaid Services (CMS) (formerly known as the Health Care Financing Administration (HCFA)), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The

necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

#### *Type of Information Collection*

*Request:* Extension of a currently approved collection; *Title of Information Collection:* Request for Accelerated Payments and Supporting Regulations in 42 CFR Sections 412.116, 412.632, 413.64, 413.350, and 484.245; *Form No.:* CMS–9042; *Use:* These forms/instructions are used by fiscal intermediaries to access a provider's eligibility for accelerated payments. Such payment is granted if there is an unusual delay in processing bills. *Frequency:* On occasion; *Affected Public:* Business or other for-profit, and Not for-profit institutions; *Number of Respondents:* 750; *Total Annual Responses:* 750; *Total Annual Hours Requested:* 375.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS's Web Site address at <http://www.hcfa.gov/regs/prdact95.htm>, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@hcfa.gov](mailto:Paperwork@hcfa.gov), or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the CMS Paperwork Clearance Officer designated at the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development and Issuances, Attention: Dawn Willingham, CMS–9042, Room: N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: August 6, 2002.

**John P. Burke, III,**

*Paperwork Reduction Act Team Leader, CMS Reports Clearance Officer, Office of Strategic Operations and Strategic Affairs, Division of Regulations Development and Issuances.*

[FR Doc. 02–20520 Filed 8–13–02; 8:45 am]

**BILLING CODE 4120–03–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare and Medicaid Services

[Document Identifier: CMS–R–138]

#### Agency Information Collection Activities: Submission for OMB Review; Comment Request

**AGENCY:** Centers for Medicare and Medicaid Services.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare and Medicaid Services (CMS) (formerly known as the Health Care Financing Administration (HCFA)), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

#### *Type of Information Collection*

*Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicare Geographic Classification Review Board (MGCRG) Procedures and Criteria and Supporting Regulations in 42 CFR, Section 412.256 & 412.230; *Form No.:* CMS–R–138 (OMB# 0938–0573); *Use:* This collection sets up an application process for prospective payment system hospitals who choose to appeal their geographic status to the Medicare Geographic Classification Review Board (MGCRB). This also establishes procedural guidelines for the MGCRB.; *Frequency:* Annually; *Affected Public:* Business or other for-profit, and Not-for-profit institutions; *Number of Respondents:* 650; *Total Annual Responses:* 650; *Total Annual Hours:* 650.

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.hcfa.gov/regs/prdact95.htm>, or E-mail your request, including your address, phone number, OMB number, and CMS document

identifier, to [Paperwork@hcfa.gov](mailto:Paperwork@hcfa.gov), or call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Brenda Aguilar, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: August 7, 2002.

**John P. Burke, III,**

*Paperwork Reduction Act Team Leader, CMS Reports Clearance Officer, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development and Issuances.*

[FR Doc. 02-20521 Filed 8-13-02; 8:45 am]

BILLING CODE 4120-03-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 02D-0306]

#### Medical Devices; Class II Special Controls Guidance Document: Dental Sonography and Jaw Tracking Devices; Draft Guidance for Industry and FDA Reviewers; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Class II Special Controls Guidance Document: Dental Sonography and Jaw Tracking Devices; Draft Guidance for Industry and FDA Reviewers." This draft guidance document was developed as a special control guidance to support the classification of certain dental sonography and jaw tracking devices into class II. Elsewhere in this issue of the **Federal Register**, FDA is publishing a proposed rule to classify these device types. This guidance is neither final nor is it in effect at this time.

**DATES:** Submit written or electronic comments on the draft guidance by November 12, 2002.

**ADDRESSES:** Submit written requests for single copies on a 3.5" diskette of the draft guidance document entitled "Class II Special Controls Guidance Document: Dental Sonography and Jaw Tracking Devices; Draft Guidance for Industry and FDA Reviewers" to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ-220), Center for Devices and Radiological Health, Food and Drug Administration, 1350

Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301-443-8818.

Submit written comments concerning this draft guidance to the Dockets Management Branch (HFA-305), 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. Comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

#### FOR FURTHER INFORMATION CONTACT:

Mary S. Runner, Center for Devices and Radiological Health (HFZ-480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-827-5283.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA developed this draft guidance document as a special control guidance to support the classification of certain dental sonography and jaw tracking devices into class II. FDA believes that special controls, when combined with the general controls, will be sufficient to provide reasonable assurance of the safety and effectiveness of dental sonography and jaw tracking devices. This draft guidance document identifies the class, product code, and classification definition for these devices. In addition, it identifies the risks to health generally associated with this generic type of device, describes the device evaluation and labeling measures that FDA believes will mitigate those risks, explains how manufacturers should address those risks in a premarket notification submission, and serves as a special control that, when combined with the general controls, will address the risks associated with this generic device type.

##### II. Significance of Guidance

This draft guidance document represents the agency's current thinking on certain dental sonography and jaw tracking devices. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

The agency has adopted good guidance practices (GGPs), and published the final rule, which set forth the agency's regulations for the development, issuance, and use of

guidance documents (21 CFR 10.115). This guidance document is issued as a level 1 draft guidance in accordance with the GGP regulations.

##### III. Electronic Access

In order to receive the draft guidance entitled "Class II Special Controls Guidance Document: Dental Sonography and Jaw Tracking Devices; Draft Guidance for Industry and FDA Reviewers" via your fax machine, call the CDRH Facts-On-Demand system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt press 1 to order a document. Enter the document number (1393) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so using the Internet. The Center for Devices and Radiological Health (CDRH) maintains an entry on the Internet for easy access to information including text, graphics, and files that you may download to a personal computer. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. You may access the CDRH home page at <http://www.fda.gov/cdrh>. You may search for all CDRH guidance documents at <http://www.fda.gov/cdrh/guidance.html>. Guidance documents are also available at <http://www.fda.gov/ohrms/dockets>.

##### IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The burden hours associated with 21 CFR part 807, subpart E were approved under OMB control number 0910-0120.

##### V. Comments

You may submit to the Dockets Management Branch (see **ADDRESSES**) written comments regarding this draft guidance by November 12, 2002. You should submit two copies of any comments. Individuals may submit one copy. You must identify comments with the docket number found in brackets in the heading of this document. You may see the guidance document and any