assistance programs and other payers. The requirements must relate to the following elements: (1) Enrollment file sharing; (2) claims processing and payment; (3) claims reconciliation reports; (4) application of the protections against high out-of-pocket expenditures by tracking true out-of-pocket (TrOOP) expenditures; and (5) other processes that the Secretary determines. This information will be used by Part D plans, other health insurers or payers, pharmacies and CMS to coordinate prescription drug benefits provided to the Medicare beneficiary.; *Frequency:* Reporting—Monthly; *Affected Public:* Business or other for-profit, Federal, State, local and or tribal government; *Number of Respondents:* 56,320; *Total Annual Responses:* 2,153,767,270; *Total Annual Hours:* 1,017,914.

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.

Written comments and recommendations for the proposed information collections must be mailed or faxed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Carolyn Lovett, New Executive Office Building, Room 10235, Washington, DC 20503. Fax Number: (202) 395–6974.

Dated: March 24, 2006.

Michelle Shortt,

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

[FR Doc. E6–4631 Filed 3–30–06; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–R–30, CMS–10117,10118,10119,10135,10136 and CMS–R–206

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS) 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.

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Information Collection Requirements in the Hospice Conditions for Coverage and Supporting Regulations at 42 CFR 418.22, 418.24, 418.28, 418.56, 418.58, 418.70, 418.83, 418.96, and 418.100; *Use:* The information collection requirements contained in the Hospice Conditions for Coverage information collection request (ICR) serve to ensure compliance with the hospice conditions of participation. The State survey agencies utilize the furnished information during the certification and re-certification periods to assist in determining compliance with the statute and regulations. In addition, data collected will be used to produce statistical reports to the Congress, to establish reimbursement rates, and to provide increased information on the hospice industry.; *Form Number:* CMS–R–30 (OMB#: 0938–0302); *Frequency:* Reporting—Other—depending on program areas and data requirements; *Affected Public:* Business or other for-profit, Not-for-profit institutions, Federal government; *Number of Respondents:* 2,874; *Total Annual Responses:* 2,874; *Total Annual Hours:* 9,930,912.

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Qualification—Medicare Advantage Application For Coordinated Care, Private Fee-For-Service, Regional Preferred Provider Organization, Service Area Expansion For Coordinated Care and Private Fee-For-Service Plans, Medical Savings Account Plans; *Use:* An entity seeking a contract as an MA organization must be able to provide Medicare's basic benefits plus meet the organizational requirements set out under 42 CFR part 422. An applicant must demonstrate that it can meet the benefit and other requirements within the specific geographic area it is requesting. The application forms are designed to provide the information needed to determine the health plan's compliance. The regulatory requirements are incorporated into the MA applications. The MA application forms will be used to determine if an entity is eligible to enter into a contract to provide services to Medicare beneficiaries; *Form Number:* CMS–10117, 10118, 10119, 10135, 10136 (OMB#: 0938–0935); *Frequency:* Reporting: One time submission; *Affected Public:* Business or other for-profit, Not-for-profit institutions and State, local or tribal government; *Number of Respondents:* 80; *Total Annual Responses:* 110; *Total Annual Hours:* 3,400.

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Information Collection Requirements Referenced in HIPAA, Title 1, for the Group Market, Supporting Regulations at 45 CFR 146.111, 146.115, 146.117, 146.150, 146.152, 146.160, and 146.180, and forms/instructions; *Use:* The requirements of this information collection will ensure that group health plans and issuers in the group market comply with Health Insurance Portability and Accountability Act of 1996 (HIPAA). These requirements include providing individuals with certificates of creditable coverage, notifying individuals about their status with respect to preexisting condition exclusions, and giving individuals the special enrollment rights to which they are entitled. In addition, this collection gives states and the Federal government the flexibility necessary to enforce these HIPAA requirements.; *Form Number:* CMS–R–206 (OMB#: 0938–0702); *Frequency:* Recordkeeping, Third party disclosure and Reporting: On occasion; *Affected Public:* Individuals or Households, Business or other for-profit, Not-for-profit institutions and Federal, State, Local or Tribal Government; *Number of Respondents:* 2,800; *Total Annual Responses:* 37,002,217; *Total Annual Hours:* 446,679.

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 May 30, 2006.

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: March 24, 2006.

Michelle Shortt,

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

[FR Doc. E6–4633 Filed 3–30–06; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0226]

Food and Drug Administration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 014

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a publication containing modifications the agency is making to the list of standards FDA recognizes for use in premarket reviews (FDA recognized consensus standards). This publication, entitled ''Modifications to the List of Recognized Standards, Recognition List Number: 014'' (Recognition List Number: 014), will assist manufacturers who elect to declare conformity with consensus standards to meet certain requirements for medical devices.

DATES: Submit written or electronic comments concerning this document at any time. See section VII of this document for the effective date of the recognition of standards announced in this document.

ADDRESSES: Submit written requests for single copies of ''Modifications to the List of Recognized Standards, Recognition List Number: 014'' to the Division of Small Manufacturers, International and Consumer Assistance, Center for Devices and Radiological Health (HFZ–220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your requests, or fax your request to 301–443–8818. Submit written comments concerning this document, or recommendations for additional standards for recognition, to the contact person (see **FOR FURTHER INFORMATION CONTACT**). Submit electronic comments by e-mail: *standards@cdrh.fda.hhs.gov*. This document may also be accessed on FDA's Web site at *http://www.fda.gov/cdrh/fedregin.html*. See section VI of this document for electronic access to the searchable database for the current list of FDA recognized consensus standards, including Recognition List Number: 014 modifications and other standards related information.

FOR FURTHER INFORMATION CONTACT: Carol L. Herman, Center for Devices and Radiological Health (HFZ–84), Food and Drug Administration, 12720 Twinbrook Pkwy., Rockville, MD 20857, 301–827–0021.

SUPPLEMENTARY INFORMATION:

I. Background

Section 204 of the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Public Law 105–115) amended section 514 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360d). Amended section 514 allows FDA to recognize consensus standards developed by international and national organizations for use in satisfying portions of device premarket review submissions or other requirements.

In a notice published in the **Federal Register** of February 25, 1998 (63 FR 9561), FDA announced the availability of a guidance entitled ''Recognition and Use of Consensus Standards.'' The notice described how FDA would implement its standard recognition program and provided the initial list of recognized standards.

In **Federal Register** notices published on October 16, 1998 (63 FR 55617), July 12, 1999 (64 FR 37546), November 15, 2000 (65 FR 69022), May 7, 2001 (66 FR 23032), January 14, 2002 (67 FR 1774), October 2, 2002 (67 FR 61893), April 28, 2003 (68 FR 22391), March 8, 2004 (69 FR 10712), June 18, 2004 (69 FR 34176), October 4, 2004 (69 FR 59240), May 27, 2005 (70 FR 30756), and November 8, 2005 (70 FR 67713), FDA modified its initial list of FDA recognized consensus standards. These notices describe the addition, withdrawal, and revision of certain standards recognized by FDA. The agency maintains ''hypertext markup language'' (HTML) and ''portable document format'' (PDF) versions of the list of ''FDA Recognized Consensus Standards.'' Both versions are publicly accessible at the agency's Web site. See section VI of this document for electronic access information. Interested persons should review the supplementary information sheet for the standard to understand fully the extent to which FDA recognizes the standard.

II. Modifications to the List of Recognized Standards, Recognition List Number: 014

FDA is announcing the addition, withdrawal, correction, and revision of certain consensus standards the agency will recognize for use in satisfying premarket reviews and other requirements for devices. FDA will incorporate these modifications in the list of FDA Recognized Consensus Standards in the agency's searchable database. FDA will use the term ''Recognition List Number: 014'' to identify these current modifications.

In table 1 of this document, FDA describes the following modifications: (1) The withdrawal of standards and their replacement by others, (2) the correction of errors made by FDA in listing previously recognized standards, and (3) the changes to the supplementary information sheets of recognized standards that describe revisions to the applicability of the standards.

In section III of this document, FDA lists modifications the agency is making that involve the initial addition of standards not previously recognized by FDA.

TABLE 1.

Old Item No.	Standard	Change	Replacement Item No.
A. Anesthesia			