outpatient glucose monitoring is a determinant of glycemic control and clinical outcomes in the Medicare populations. The role of variables such as the type of diabetes, the therapeutic regimen employed, the age of hyperglycemic onset, the duration of diabetes, the duration of poor glycemic control, the level of hyperglycemia, and concomitant disease will be discussed. The impediments to glucose monitoring and use of monitoring data will be considered. In addition to evaluating the available data, the Committee will identify areas in which the current data are deficient and in which additional research is warranted.

Background information about this topic, including panel materials, is available on the Internet at *http://www.cms.hhs.gov/coverage/*.

II. Meeting Procedures

This meeting is open to the public. The Committee will hear oral presentations from the public for approximately 45 minutes. The Committee may limit the number and duration of oral presentations to the time available. If you wish to make formal presentations, you must notify the Executive Secretary (see **FOR FURTHER INFORMATION CONTACT**) and submit the following to the address listed in the **ADDRESSES** section of this notice by the date listed in the *Deadlines* section of this notice: (1) A brief statement of the general nature of the evidence or arguments you wish to present; (2) the names and addresses of proposed participants; and (3) a written copy of your presentation. Your presentation should consider the questions we have posed to the Committee and focus on the issues specific to the topic. The questions will be available on the following Web site: *http://www.cms.hhs.gov/FACA/02_MCAC.asp#TopOfPage.* We require that you declare at the meeting whether you have any financial involvement with manufacturers of any items or services being discussed (or with their competitors).

After the public and CMS presentations, the Committee will deliberate openly on the topic. Interested persons may observe the deliberations, but the Committee will not hear further comments during this time except at the request of the chairperson. The Committee will also allow a 15 minute unscheduled open public session for any attendee to address issues specific to the topic. At the conclusion of the day, the members will vote and the Committee will make its recommendation.

III. Registration Instructions

The Coverage and Analysis Group is coordinating meeting registration. While there is no registration fee, individuals must register to attend. Register by contacting Maria Ellis at the address listed in the **ADDRESSES** section of this notice. Please provide your name, address, organization, telephone and fax numbers, and e-mail address.

You will receive a registration confirmation with instructions for your arrival at the CMS complex. You will be notified if the seating capacity has been reached.

This meeting is located on Federal property; therefore, for security reasons, any individuals wishing to attend this meeting must register by 5 p.m. e.s.t. on August 24, 2006.

IV. Security, Building, and Parking Guidelines

This meeting will be held in a Federal government building; therefore, Federal security measures are applicable. In planning your arrival time, we recommend allowing additional time to clear security.

In order to gain access to the building and grounds, individuals must present photographic identification to the Federal Protective Service or Guard Service personnel before being allowed entrance.

Security measures also include inspection of vehicles, inside and out, at the entrance to the grounds. In addition, all individuals entering the building must pass through a metal detector. All items brought to CMS, whether personal or for the purpose of demonstration or to support a demonstration, 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 demonstration or to support a demonstration.

Parking permits and instructions will be issued upon arrival.

Note: Individuals who are not registered in advance will not be permitted to enter the building and will be unable to attend the meeting. The public may not enter the building earlier than 30 to 45 minutes prior to the convening of the meeting.

All visitors must be escorted in areas other than the lower and first floor levels in the Central Building.

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: June 7, 2006.

Barry M. Straube,

Chief Medical Officer and Director, Office of Clinical Standards and Quality, Centers for Medicare & Medicaid Services.

[FR Doc. E6–9480 Filed 6–22–06; 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: 015

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: 015'' (Recognition List Number: 015), 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: 015'' 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.gov*. This document may also be accessed on FDA's Internet 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: 015 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., 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), November 8, 2005 (70 FR 67713), and March 31, 2006 (71 FR 16313), 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 Internet 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: 015

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: 015'' 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. Biocompatibility			
21	AAMI/ANSI/ISO10993–11:1993, Biological Evaluation of Medical Devices—Part 11: Tests for Systemic Toxicity	Extent of recognition	
66	ASTM F2148–01, Standard Practice for Evaluation of Delayed Contact Hypersensitivity Using the Murine Local Lymph Node Assay	Contact person, processes affected, and extent of recognition	
67	ASTM F756–00, Standard Practice for Assessment of Hemolytic Properties of Materials	Contact person, processes affected, and extent of recognition	
73	ASTM F2065–00e1, Standard Practice for Testing for Alternative Pathway Complement Activation in Serum by Solid Materials	Contact person, processes affected, and extent of recognition	
82	ASTM F2147–01, Standard Practice for Guinea Pigs: Split Adjuvant and Closed Patch Testing for Contact Allergens	Contact person, and processes affected	
101	USP 29–NF21Biological Tests <87>, Biological Reactivity Test, In Vitro—Direct Contact Test	Withdrawn and replaced with newer version	109
102	USP 29–NF21Biological Tests <87>, Biological Reactivity Test, In Vitro—Elution Test	Withdrawn and replaced with newer version	110
103	USP 29–NF21Biological Tests <88>, Biological Reactivity Test, In Vivo Procedure—Preparation of Sample	Withdrawn and replaced with newer version	111
104	USP 29–NF21Biological Tests <88>, Biological Reactivity Test, In Vitro, Classification of Plastics—Intracutaneous Test	Withdrawn and replaced with newer version	112

TABLE 1.—Continued

Old Item No.	Standard	Change	Replacement Item No.
105	USP 29–NF21Biological Tests <88>, Biological Reactivity Test, In Vitro, Classification of Plastics—Systemic Injection Test	Withdrawn and replaced with newer version	113
B. Dental/Ear, Nose, and Throat			
83	ISO 11498 Dental Handpieces: Dental Low Voltage Electrical Motors	Contact person, and processes affected	
127	ANSI/ADA Specification No. 58:2004, Root Canal Files, Type H (Hedstrom)	Contact person	
C. General Hospital/General Plastic Surgery			
133	USP 29: 2006 Nonabsorbable Surgical Suture	Withdrawn and replaced with newer version	151
134	USP 29<11>: 2006 Sterile Sodium Chloride for Irrigation	Withdrawn and replaced with newer version	152
135	USP 29: 2006 Absorbable Surgical Suture	Withdrawn and replaced with newer version	153
136	USP 29<881>: 2006 Tensile Strength	Withdrawn and replaced with newer version	154
137	USP 29<861>: 2006 Sutures—Diameter	Withdrawn and replaced with newer version	155
138	USP 29<871>: 2006 Sutures Needle Attachment	Withdrawn and replaced with newer version	156
139	USP 29<11>: 2006 Sterile Water for Irrigation	Withdrawn and replaced with newer version	157
140	USP 29<11>: 2006 Heparin Lock Flush Solution	Withdrawn and replaced with newer version	158
141	USP 29<11>: 2006 Sodium Chloride Injection	Withdrawn and replaced with newer version	159
D. Sterility			
52	ANSI/AAMI ST59:1999, Sterilization of Health Care Products—Biological Indicators Part 1: General	Contact person and relevant guidance	
70	AAMI/ANSI/ISO 14161:2000, Sterilization of Health Care Products—Biological Indicators—Guidance for the Selection, Use and Interpretation of Results, 2 ed.	Contact person	
72	ANSI/AAMI ST33:1996, Guidelines for the Selection and Use of Reusable Rigid Sterilization Container Systems for Ethylene Oxide Sterilization in Health Care Facilities	Contact person and processes affected	
94	AOAC 6.2.01:2005, Official Method 955.14, Testing Disinfectants Against Salmonella Choleraesuis, Use-Dilution Method	Withdrawn and replaced with newer version	172
95	AOAC 6.2.02:2005, Official Method 991.47, Testing Disinfectants Against Salmonella Choleraesuis, Hard Surface Carrier Test Method	Withdrawn and replaced with newer version	173
96	AOAC 6.2.03:2005, Official Method 991.48, Testing Disinfectants Against Staphylococcus Aureus, Hard Surface Carrier Test Method	Withdrawn and replaced with newer version	174
97	AOAC 6.2.04:2005, Official Method 955.15, Testing Disinfectants Against Staphylococcus Aureus, Use-Dilution Method	Withdrawn and replaced with newer version	175

TABLE 1.—Continued

Old Item No.	Standard	Change	Replacement Item No.
98	AOAC 6.2.05:2005, Official Method 991.49, Testing Disinfectants Against Pseudomonas Aeruginosa, Hard Surface Carrier Test Method	Withdrawn and replaced with newer version	176
99	AOAC 6.2.06:2005, Official Method 964.02, Testing Disinfectants Against Pseudomonas Aeruginosa, Use-Dilution Method	Withdrawn and replaced with newer version	177
100	AOAC 6.3.02:2005, Official Method 955.17, Fungicidal Activity of Disinfectants Using Trichophyton Mentagrophytes	Withdrawn and replaced with newer version	178
101	AOAC 6.3.05:2005, Official Method 966.04, Sporicidal Activity of Disinfectants	Withdrawn and replaced with newer version	179
102	AOAC 6.3.06:2005, Official Method 965.12, Tuberculocidal Activity of Disinfectants	Withdrawn and replaced with newer version	180
104	AAMI/ANSI ST58:2005, Safe Use and Handling of Glutaraldehyde-Based Products in Health Care Facilities	Withdrawn and replaced with newer version	181
116	ANSI/AAMI ST72:2002, Bacterial Endotoxins—Test Methodologies, Routine Monitoring, and Alternatives to Batch Testing	Relevant guidance	
117	ANSI/AAMI ST35:2003, Safe Handling and Biological Decontamination of Medical Devices in Health Care Facilities and in Nonclinical Settings	Relevant guidance	
153	USP 29:2006, Biological Indicator for Dry Heat Sterilization, Paper Carrier	Withdrawn and replaced with newer version	182
154	USP 29:2006, Biological Indicator for Ethylene Oxide Sterilization, Paper Carrier	Withdrawn and replaced with newer version	183
155	USP 29:2006, Biological Indicator for Steam Sterilization, Paper Carrier	Withdrawn and replaced with newer version	184
156	USP29:2006, <61> Microbial Limits Test	Withdrawn and replaced with newer version	185
157	USP 29:2006, <71>, Microbiological Tests, Sterility Tests	Withdrawn and replaced with newer version	186
158	USP29:2006, <85>, Biological Tests and Assays, Bacterial Endotoxin Test (LAL)	Withdrawn and replaced with newer version	187
159	USP29:2006 <151>, Pyrogen Test (USP Rabbit Test)	Withdrawn and replaced with newer version	188
160	USP29:2006 <1211>, Sterilization and Sterility Assurance of Compendial Articles	Withdrawn	
161	USP29:2006 <161>, Transfusion and Infusion Assemblies and Similar Medical Devices	Withdrawn and replaced with newer version	189
162	USP 29:2006, Biological Indicator for Steam Sterilization—Self-Contained	Withdrawn and replaced with newer version	190
164	ANSI/AAMI ST81:2004, Sterilization of Medical Devices—Information to be Provided by the Manufacturer for the Processing of Resterilizable Devices	Relevant guidance	

III. Listing of New Entries

The listing of new entries and consensus standards added as modifications to the list of recognized standards under Recognition List Number: 015, follows:

TABLE 2.

Item No.	Title of Standard	Reference No. and Date
A. Sterility		
191	Aseptic Processing of Health Care Products—Part 4: Clean-in-Place Technologies	ISO 13408–4:2005

IV. List of Recognized Standards

FDA maintains the agency's current list of FDA recognized consensus standards in a searchable database that may be accessed directly at FDA's Internet site at *http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm*. FDA will incorporate the modifications and minor revisions described in this notice into the database and, upon publication in the **Federal Register**, this recognition of consensus standards will be effective. FDA will announce additional modifications and minor revisions to the list of recognized consensus standards, as needed, in the **Federal Register** once a year, or more often, if necessary.

V. Recommendation of Standards for Recognition by FDA

Any person may recommend consensus standards as candidates for recognition under section 514 of the act by submitting such recommendations, with reasons for the recommendation, to the contact person (see **FOR FURTHER INFORMATION CONTACT**). To be properly considered such recommendations should contain, at a minimum, the following information: (1) Title of the standard, (2) any reference number and date, (3) name and address of the national or international standards development organization, (4) a proposed list of devices for which a declaration of conformity to this standard should routinely apply, and (5) a brief identification of the testing or performance or other characteristics of the device(s) that would be addressed by a declaration of conformity.

VI. Electronic Access

You may obtain a copy of ''Guidance on the Recognition and Use of Consensus Standards'' by using the Internet. CDRH maintains a site on the Internet for easy access to information including text, graphics, and files that you may download to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page includes the guidance as well as the current list of recognized standards and other standards related documents. After publication in the **Federal Register**, this notice announcing ''Modifications to the List of Recognized Standards, Recognition List Number: 015'' will be available on the CDRH home page. You may access the CDRH home page at *http://www.fda.gov/cdrh*.

You may access ''Guidance on the Recognition and Use of Consensus Standards,'' and the searchable database for ''FDA Recognized Consensus Standards'' through the hyperlink at *http://www.fda.gov/cdrh/stdsprog.html*.

This **Federal Register** document on modifications in FDA's recognition of consensus standards is available at *http://www.fda.gov/cdrh/fedregin.html*.

VII. Submission of Comments and Effective Date

Interested persons may submit to the contact person (see **FOR FURTHER INFORMATION CONTACT**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. FDA will consider any comments received in determining whether to amend the current listing of modifications to the list of recognized standards, Recognition List Number: 015. These modifications to the list of recognized standards are effective upon publication of this notice in the **Federal Register**.

Dated: June 13, 2006.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. E6–9959 Filed 6–22–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Regulations To Implement SAMHSA's Charitable Choice Statutory Provisions—42 CFR Parts 54 and 54a (OMB No. 0930–0242)—Extension

Section 1955 of the Public Health Service Act (42 U.S.C. 300x–65), as amended by the Children's Health Act of 2000 (Pub. L. 106–310) and sections 581–584 of the Public Health Service Act (42 U.S.C. 290kk et seq., as added by the Consolidated Appropriations Act (Pub. L. 106–554)), set forth various provisions which aim to ensure that religious organizations are able to compete on an equal footing for Federal funds to provide substance abuse services. These provisions allow religious organizations to offer substance abuse services to individuals without impairing the religious character of the organizations or the religious freedom of the individuals who receive the services. The provisions apply to the Substance Abuse Prevention and Treatment Block Grant (SAPT BG), to the Projects for Assistance in Transition from Homelessness (PATH) formula grant program, and to certain Substance