FEDERAL REGISTER

Vol. 81 Thursday,
No. 111 June 9, 2016

Part VIII

Department of Health and Human Services

Semiannual Regulatory Agenda

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

21 CFR Ch. I

25 CFR Ch. V

42 CFR Chs. I–V

45 CFR Subtitle A; Subtitle B, Chs. II, III, and XIII

Regulatory Agenda

AGENCY: Office of the Secretary, HHS.

ACTION: Semiannual Regulatory Agenda.

SUMMARY: The Regulatory Flexibility Act of 1980 and Executive Order (EO) 12866 require the semiannual issuance of an inventory of rulemaking actions under development throughout the Department, offering for public review summarized information about forthcoming regulatory actions.

FOR FURTHER INFORMATION CONTACT: Wilma Robinson, Deputy Executive Secretary, Department of Health and Human Services, 200 Independence Avenue SW., Washington, DC 20201; (202) 690–5627.

SUPPLEMENTARY INFORMATION: The Department of Health and Human Services (HHS) is the Federal Government's lead agency for protecting the health of all Americans and providing essential human services, especially for those who are least able to help themselves. HHS enhances the health and well-being of Americans by promoting effective health and human services and by fostering sound, sustained advances in the sciences underlying medicine, public health, and social services.

This Agenda presents the rulemaking activities that the Department expects to undertake in the foreseeable future to advance this mission. The Agenda furthers several Departmental goals, including strengthening health care; advancing scientific knowledge and innovation; advancing the health, safety, and well-being of the American people; increasing efficiency, transparency, and accountability of HHS programs; and strengthening the nation's health and human services infrastructure and workforce.

HHS has an agency-wide effort to support the Agenda's purpose of encouraging more effective public participation in the regulatory process. For example, to encourage public participation, we regularly update our regulatory Web page (*http://www.HHS.gov/regulations*) which includes links to HHS rules currently open for public comment, and also provides a ''regulations toolkit'' with background information on regulations, the commenting process, how public comments influence the development of a rule, and how the public can provide effective comments. HHS also actively encourages meaningful public participation in its retrospective review of regulations, through a comment form on the HHS retrospective review Web page (*http://www.HHS.gov/RetrospectiveReview*).

The rulemaking abstracts included in this paper issue of the **Federal Register** cover, as required by the Regulatory Flexibility Act of 1980, those prospective HHS rulemakings likely to have a significant economic impact on a substantial number of small entities. The Department's complete Regulatory Agenda is accessible online at *http://www.RegInfo.gov.*

Wilma Robinson,

Deputy Executive Secretary to the Department.

OFFICE FOR CIVIL RIGHTS—FINAL RULE STAGE

Sequence No.	Title	Regulation Identifier No.
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OFFICE OF THE NATIONAL COORDINATOR FOR HEALTH INFORMATION TECHNOLOGY—PROPOSED RULE STAGE

Sequence No.	Title	Regulation Identifier No.
105	ONC Health IT Certification Program: Enhanced Oversight and Accountability	0955–AA00

FOOD AND DRUG ADMINISTRATION—PROPOSED RULE STAGE

Sequence No.	Title	Regulation Identifier No.
106	Over-the-Counter (OTC) Drug Review—Cough/Cold (Antihistamine) Products	0910–AF31
107	Over-the-Counter (OTC) Drug Review—Topical Antimicrobial Drug Products	0910–AF69
108	Updated Standards for Labeling of Pet Food	0910–AG09
109	Format and Content of Reports Intended to Demonstrate Substantial Equivalence	0910–AG96
110	Mammography Quality Standards Act; Regulatory Amendments	0910–AH04
111	Investigational New Drug Application Annual Reporting	0910–AH07
112	Requirements for Tobacco Product Manufacturing Practice	0910–AH22
113	Use of Ozone Depleting Substances **(Section 610 Review)**	0910–AH36

FOOD AND DRUG ADMINISTRATION—FINAL RULE STAGE

Sequence No.	Title	Regulation Identifier No.
114	Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs, Including Drugs That Are Regulated Under a Biologics License Application, and Animal Drugs.	0910–AA49
115	Postmarketing Safety Reporting Requirements for Human Drug and Biological Products	0910–AA97
116	Medical Gas Containers and Closures; Current Good Manufacturing Practice Requirements	0910–AC53

FOOD AND DRUG ADMINISTRATION—FINAL RULE STAGE—Continued

Sequence No.	Title	Regulation Identifier No.
117	Food Labeling: Revision of the Nutrition and Supplement Facts Labels	0910–AF22
118	Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed At One Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain RACCs.	0910–AF23
119	Abbreviated New Drug Applications and 505(b)(2)	0910–AF97
120	''Tobacco Products'' Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act.	0910–AG38
121	Human Subject Protection; Acceptance of Data From Clinical Investigations for Medical Devices	0910–AG48
122	Focused Mitigation Strategies To Protect Food Against Intentional Adulteration	0910–AG63
123	Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products	0910–AG94
124	Food Labeling; Gluten-Free Labeling of Fermented, Hydrolyzed, or Distilled Foods	0910–AH00
125	General and Plastic Surgery Devices: Sunlamp Products	0910–AH14

FOOD AND DRUG ADMINISTRATION—LONG-TERM ACTIONS

Sequence No.	Title	Regulation Identifier No.
126	Laser Products; Amendment to Performance Standard	0910–AF87
127	Requirements for the Testing and Reporting of Tobacco Product Constituents, Ingredients, and Additives	0910–AG59
128	Radiology Devices; Designation of Special Controls for the Computed Tomography X-Ray System	0910–AH03
129	Regulations on Human Drug Compounding Under Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act.	0910–AH10

FOOD AND DRUG ADMINISTRATION—COMPLETED ACTIONS

Sequence No.	Title	Regulation Identifier No.
130	Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption	0910–AG35
131	Foreign Supplier Verification Program	0910–AG64
132	Sanitary Transportation of Human and Animal Food	0910–AG98

CENTERS FOR MEDICARE & MEDICAID SERVICES—PROPOSED RULE STAGE

Sequence No.	Title	Regulation Identifier No.
133	Hospital and Critical Access Hospital (CAH) Changes to Promote Innovation, Flexibility, and Improvement in Patient Care (CMS–3295–P) **(Rulemaking Resulting From a Section 610 Review)**.	0938–AS21
134	Merit-Based Incentive Payment System (MIPS) and Alternative Payment Models (APMs) in Medicare Fee-for-Service (CMS–5517–P) **(Section 610 Review)**.	0938–AS69
135	Hospital Inpatient Prospective Payment System for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and FY 2017 Rates (CMS–1655–F) **(Section 610 Review)**.	0938–AS77
136	CY 2017 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model; and Home Health Quality Reporting Requirements **(Section 610 Review)**.	0938–AS80
137	CY 2017 Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Medicare Part B (CMS–1654–P) **(Section 610 Review)**.	0938–AS81
138	CY 2017 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates (CMS–1656–P) **(Section 610 Review)**.	0938–AS82

CENTERS FOR MEDICARE & MEDICAID SERVICES—FINAL RULE STAGE

Sequence No.	Title	Regulation Identifier No.
139	Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers (CMS–3178–F) **(Section 610 Review)**.	0938–AO91
140	Reform of Requirements for Long-Term Care Facilities (CMS–3260–F) **(Rulemaking Resulting From a Section 610 Review)**.	0938–AR61

CENTERS FOR MEDICARE & MEDICAID SERVICES—LONG-TERM ACTIONS

Sequence No.	Title	Regulation Identifier No.
141	Conditions of Participation for Home Health Agencies (CMS–3819–F) **(Rulemaking Resulting From a Section 610 Review)**.	0938–AG81

CENTERS FOR MEDICARE & MEDICAID SERVICES—LONG-TERM ACTIONS—Continued

Sequence No.	Title	Regulation Identifier No.
142	Medicare Clinical Diagnostic Laboratory Test Payment System (CMS–1621–F) **(Section 610 Review)**	0938–AS33
143	Imaging Accreditation (CMS–3309–P) **(Section 610 Review)**	0938–AS62

CENTERS FOR MEDICARE & MEDICAID SERVICES—COMPLETED ACTIONS

Sequence No.	Title	Regulation Identifier No.
144	Covered Outpatient Drugs (CMS–2345–FC) **(Completion of a Section 610 Review)**	0938–AQ41
145	CY 2016 Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Medicare Part B (CMS–1631–FC) **(Completion of a Section 610 Review)**.	0938–AS40
146	CY 2016 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates (CMS–1633–FC) **(Completion of a Section 610 Review)**.	0938–AS42
147	Comprehensive Care for Joint Replacement (CMS–5516–F) **(Completion of a Section 610 Review)**	0938–AS64

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Office for Civil Rights (OCR)

Final Rule Stage

104. Nondiscrimination Under the Patient Protection and Affordable Care Act

Legal Authority: 42 U.S.C. 18116

Abstract: This final rule implements prohibitions against discrimination on the basis of race, color, national origin, sex, age, and disability as provided in section 1557 of the Affordable Care Act. Section 1557 provides protection from discrimination in health programs and activities of covered entities. This section also identifies additional forms of Federal financial assistance to which the section will apply.

Timetable:

Action	Date	FR Cite
NPRM	09/08/15	80 FR 54172
NPRM Comment Period End.	11/09/15	
Final Action	05/00/16	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Eileen Hanrahan, Senior Civil Rights Analyst, Department of Health and Human Services, Office for Civil Rights, 200 Independence Avenue SW., Washington, DC 20201, *Phone:* 202 205–4925, *Email: eileen.hanrahan@hhs.gov.*

RIN: 0945–AA02

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Office of the National Coordinator for Health Information Technology (ONC)

Proposed Rule Stage

105. • ONC Health IT Certification Program: Enhanced Oversight and Accountability

Legal Authority: Not Yet Determined

Abstract: The rulemaking introduces modifications and new requirements under the ONC Health IT Certification Program (''Program''), including provisions related to the Office of the National Coordinator for Health Information Technology (ONC)'s role in the Program. The proposed rule proposes to establish processes for ONC to directly review health IT certified under the Program and take action when necessary, including requiring the correction of non-conformities found in health IT certified under the Program and suspending and terminating certifications issued to Complete EHRs and Health IT Modules. The proposed rule includes processes for ONC to authorize and oversee accredited testing laboratories under the Program. It also includes a provision for the increased transparency and availability of surveillance results.

Timetable:

Action	Date	FR Cite
NPRM	03/02/16	81 FR 11056
NPRM Comment Period End.	05/02/16	
Final Action	10/00/16	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Michael Lipinski, Policy Analyst, Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, Room 729D, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201, *Phone:* 202 690–7151.

RIN: 0955–AA00

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Food and Drug Administration (FDA)

Proposed Rule Stage

106. Over-the-Counter (OTC) Drug Review—Cough/Cold (Antihistamine) Products

Legal Authority: 21 U.S.C. 321p; 21 U.S.C. 331; 21 U.S.C. 351 to 353; 21 U.S.C. 355; 21 U.S.C. 360; 21 U.S.C. 371

Abstract: FDA will be proposing a rule to add the common cold indication to certain over-the-counter (OTC) antihistamine active ingredients. This proposed rule is the result of collaboration under the U.S.-Canada Regulatory Cooperation Council (RCC) as part of efforts to reduce unnecessary duplication and differences. This pilot exercise will help determine the feasibility of developing an ongoing mechanism for alignment in review and adoption of OTC drug monograph elements.

Timetable:

Action	Date	FR Cite
Reopening of Administrative Record.	08/25/00	65 FR 51780
Comment Period End.	11/24/00	
NPRM (Amendment) (Common Cold).	01/00/17	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Janice Adams-King, Regulatory Health Project Manager, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 22, Room 5416, 10903 New Hampshire Avenue, Silver Spring, MD 20993, *Phone:* 301 796–3713, *Fax:* 301 796–9899, *Email: janice.adams-king@fda.hhs.gov.*

RIN: 0910–AF31

107. Over-the-Counter (OTC) Drug Review—Topical Antimicrobial Drug Products

Legal Authority: 21 U.S.C. 321p; 21 U.S.C. 331; 21 U.S.C. 351 to 353; 21 U.S.C. 355; 21 U.S.C. 360; 21 U.S.C. 371

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective, and not misbranded. After a final monograph (*i.e.,* final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action addresses antimicrobial agents in consumer antiseptic hand wash.

Timetable:

Action	Date	FR Cite
NPRM (Healthcare).	06/17/94	59 FR 31402
Comment Period End.	12/15/95	
NPRM (Consumer Hand Wash Products).	12/17/13	78 FR 76443
NPRM (Consumer Hand Wash) Comment Period End.	06/16/14	
NPRM (Healthcare Antiseptic).	05/01/15	80 FR 25166
NPRM Comment Period End (Healthcare Antiseptic).	10/28/15	
NPRM (Consumer Hand Rub).	06/00/16	
Final Rule (Consumer Hand Wash).	09/00/16	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Janice Adams-King, Regulatory Health Project Manager, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 22, Room 5416, 10903 New Hampshire Avenue, Silver Spring, MD 20993, *Phone:* 301 796–3713, *Fax:* 301 796–9899, *Email: janice.adams-king@fda.hhs.gov.*

RIN: 0910–AF69

108. Updated Standards for Labeling of Pet Food

Legal Authority: 21 U.S.C. 343; 21 U.S.C. 371; Pub. L. 110–85, sec 1002(a)(3)

Abstract: FDA is proposing updated standards for the labeling of pet food that include nutritional and ingredient information, as well as style and formatting standards. FDA is taking this action to provide pet owners and animal health professionals more complete and consistent information about the nutrient content and ingredient composition of pet food products.

Timetable:

Action	Date	FR Cite
NPRM	10/00/16	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: William Burkholder, Veterinary Medical Officer, Department of Health and Human Services, Food and Drug Administration, Center for Veterinary Medicine, MPN–4, Room 2642, HFV–228, 7519 Standish Place, Rockville, MD 20855, *Phone:* 240 402–5900, *Email: william.burkholder@fda.hhs.gov.*

RIN: 0910–AG09

109. Format and Content of Reports Intended To Demonstrate Substantial Equivalence

Legal Authority: 21 U.S.C. 387e(j); 21 U.S.C. 387j(a); secs 905(j) and 910(a) of the Federal Food, Drug, and Cosmetic Act

Abstract: This regulation would establish the format and content of reports intended to demonstrate substantial equivalence. This regulation also would provide information as to how the Agency will review and act on these submissions.

Timetable:

Action	Date	FR Cite
NPRM	09/00/16	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Annette L. Marthaler, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Tobacco Products, Document Control Center, Building 71, Room G335, 10903 New Hampshire Avenue, Silver Spring, MD 20993, *Phone:* 877 287–1373, *Fax:* 877 287–1426, *Email: ctpregulations@fda.hhs.gov.*

RIN: 0910–AG96

110. Mammography Quality Standards Act; Regulatory Amendments

Legal Authority: 21 U.S.C. 360i; 21 U.S.C. 360nn; 21 U.S.C. 374(e); 42 U.S.C. 263b

Abstract: FDA is proposing to amend its regulations governing mammography. The amendments would update the regulations issued under the Mammography Quality Standards Act of 1992 (MQSA). FDA is taking this action to address changes in mammography technology and mammography processes that have occurred since the regulations were published in 1997 and to address breast density reporting to patient and health care providers.

Timetable:

Action	Date	FR Cite
NPRM	08/00/16	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Nancy Pirt, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, WO 66, Room 4438, 10903 New Hampshire Avenue, Silver Spring, MD 20993, *Phone:* 301 796–6248, *Fax:* 301 847–8145, *Email: nancy.pirt@fda.hhs.gov.*

RIN: 0910–AH04

111. Investigational New Drug Application Annual Reporting

Legal Authority: 21 U.S.C. 321; 21 U.S.C. 331; 21 U.S.C. 351; 21 U.S.C. 352; 21 U.S.C. 353; 21 U.S.C. 355(i); 21 U.S.C. 371(a); 42 U.S.C. 262(a)

Abstract: This proposed rule would revise the requirements concerning annual reports submitted to investigational new drug applications (INDs) by replacing the current annual reporting requirement with a requirement that is generally consistent with the format, content, and timing of submission of the development safety update report devised by the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).

Timetable:

Action	Date	FR Cite
NPRM	10/00/16	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Ebla Ali Ibrahim, Project Manager, Department of Health and Human Services, Food and Drug Administration, Center for Drug

Evaluation and Research, Building 51, Room 6302, 10903 New Hampshire Avenue, Silver Spring, MD 20993, *Phone:* 301 796–3691, *Email: ebla.ali-ibrahim@fda.hhs.gov*.

RIN: 0910–AH07

112. Requirements for Tobacco Product Manufacturing Practice

Legal Authority: 21 U.S.C. 371; 21 U.S.C. 387b; 21 U.S.C. 387f

Abstract: FDA is proposing requirements that govern the methods used in, and the facilities and controls used for, the pre-production design validation, manufacture, packing, and storage of tobacco products.

Timetable:

Action	Date	FR Cite
ANPRM	03/19/13	78 FR 16824
ANPRM Comment Period End.	05/20/13	
NPRM	12/00/16	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Darin Achilles, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, 10903 New Hampshire Avenue, Document Control Center, Building 71, Room G335, Silver Spring, MD 20993, *Phone:* 877 287–1373, *Fax:* 301 595–1426, *Email: ctpregulations@fda.hhs.gov*.

RIN: 0910–AH22

113. • Use of Ozone Depleting Substances (Section 610 Review)

Legal Authority: 21 U.S.C. 321; 21 U.S.C. 331; 21 U.S.C. 335; 21 U.S.C. 342; 21 U.S.C. 346a; 21 U.S.C. 348; 21 U.S.C. 351; 21 U.S.C. 352; 21 U.S.C. 355; 21 U.S.C. 360b; 21 U.S.C. 361; 21 U.S.C. 371; 21 U.S.C. 372; 21 U.S.C. 374; 15 U.S.C. 402; 15 U.S.C. 409

Abstract: The Food and Drug Administration (FDA or the Agency) is proposing to amend its regulation (21 CFR 2.125) on uses of ozone-depleting substances (ODSs), including chlorofluorocarbons (CFCs), to remove designations for certain products as essential uses under the Clean Air Act. Essential-use products are exempt from FDA's ban on the use of CFC propellants in FDA-regulated products and the Environmental Protection Agency's (EPA's) ban on the use of CFCs and other ODSs in pressurized dispensers. This action, if finalized, will remove essential use exemptions for sterile aerosol talc administered intrapleurally by thoracoscopy for human use, metered-dose atropine sulfate aerosol human drugs administered by oral inhalation, and anesthetic drugs for topical use on accessible mucous membranes of humans where a cannula is used for application. FDA is proposing this action because alternative products that do not use ODSs are now available and because these products are no longer being marketed in approved versions that contain ODSs. On June 29, 2015, FDA published a notice and request for comment concerning its tentative conclusion that these products are no longer an essential use under the Clean Air Act (80 FR 36937). The Agency received no comments concerning removal of essential use designations for sterile aerosol talc and metered-dose atropine sulfate, and is proposing to remove these designations by direct final rule and a companion proposed rule in the event adverse comments are received. FDA received one comment concerning removal of anesthetic drugs for topical use in response to its 2015 notice and request for comment, and is proposing to remove this exemption through a separate notice. Because these products are not currently sold in the approved form, no significant economic impact is anticipated.

Timetable:

Action	Date	FR Cite
NPRM	08/00/16	

Regulatory Flexibility Analysis Required: No.

Agency Contact: Daniel Orr, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Building 51 Room 5199, 10993 New Hampshire Avenue, Silver Spring, MD 20993, *Phone:* 240 402–0979, *Email: daniel.orr@fda.hhs.gov*.

RIN: 0910–AH36

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Food and Drug Administration (FDA)

Final Rule Stage

114. Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs, Including Drugs That Are Regulated Under a Biologics License Application, and Animal Drugs

Legal Authority: 21 U.S.C. 321 and 331; 21 U.S.C. 351 to 353; 21 U.S.C. 355 to 356c; 21 U.S.C. 360 and 360b; 21 U.S.C. 360c to 360f; 21 U.S.C. 360h to 360j; 21 U.S.C. 371 and 374; 21 U.S.C. 379e and 381; 21 U.S.C. 393; 15 U.S.C. 1451 to 1561; 42 U.S.C. 262 and 264; 42 U.S.C. 271; and sec 122; Pub. L. 105–115, 11 Stat. 2322 (21 U.S.C. 355 note)

Abstract: The rule will reorganize, consolidate, clarify, and modify current regulations concerning who must register establishments and list human drugs, including certain biological drugs, and animal drugs. These regulations contain information on when, how, and where to register drug establishments and list drugs, and what information must be submitted. They also address National Drug Codes.

Timetable:

Action	Date	FR Cite
NPRM	08/29/06	71 FR 51276
NPRM Comment Period End.	02/26/07	
Final Action	07/00/16	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: David Joy, Senior Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, 10903 New Hampshire Avenue, Building 51, Room 6254, Silver Spring, MD 20993, *Phone:* 301 796–2242, *Email: david.joy@fda.hhs.gov*.

RIN: 0910–AA49

115. Postmarketing Safety Reporting Requirements for Human Drug and Biological Products

Legal Authority: 42 U.S.C. 216; 42 U.S.C. 241; 42 U.S.C. 242a; 42 U.S.C. 262 and 263; 42 U.S.C. 263a to 263n; 42 U.S.C. 264; 42 U.S.C. 300aa; 21 U.S.C. 321; 21 U.S.C. 331; 21 U.S.C. 351 to 353; 21 U.S.C. 355; 21 U.S.C. 360; 21 U.S.C. 360b to 360j; 21 U.S.C. 361a; 21 U.S.C. 371; 21 U.S.C. 374; 21 U.S.C. 375; 21 U.S.C. 379e; 21 U.S.C. 381

Abstract: The final rule would amend the postmarketing expedited and periodic safety reporting regulations for human drugs and biological products to revise certain definitions and reporting formats as recommended by the International Conference on Harmonisation and to define new terms; to add to or revise current reporting requirements; to revise certain reporting time frames; and to propose other revisions to these regulations to enhance the quality of safety reports received by FDA. These revisions were proposed as part of a single rulemaking (68 FR 12406) to clarify and revise both premarketing and postmarketing safety reporting requirements for human drug and biological products. FDA plans to finalize the premarket and postmarket safety reporting requirements in separate final rules. Premarketing safety reporting requirements were finalized in a separate final rule published on

September 29, 2010 (75 FR 59961). This final rule applies to postmarketing safety reporting requirements.

Timetable:

Action	Date	FR Cite
NPRM	03/14/03	68 FR 12406
NPRM Comment Period Extended.	06/18/03	
NPRM Comment Period End.	07/14/03	
NPRM Comment Period Extension End.	10/14/03	
Final Action	03/00/17	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Jane E. Baluss, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 51, Room 6362, 10903 New Hampshire Avenue, Silver Spring, MD 20993–0002, *Phone:* 301 796–3469, *Fax:* 301 847–8440, *Email: jane.baluss@fda.hhs.gov.*

RIN: 0910–AA97

116. Medical Gas Containers and Closures; Current Good Manufacturing Practice Requirements

Legal Authority: 21 U.S.C. 321; 21 U.S.C. 351 to 21 U.S.C. 353

Abstract: The Food and Drug Administration is amending its current good manufacturing practice regulations and other regulations to clarify and strengthen requirements for the label, color, dedication, and design of medical gas containers and closures. Despite existing regulatory requirements and industry standards for medical gases, there have been repeated incidents in which cryogenic containers of harmful industrial gases have been connected to medical oxygen supply systems in hospitals and nursing homes and subsequently administered to patients. These incidents have resulted in death and serious injury. There have also been several incidents involving high-pressure medical gas cylinders that have resulted in death and injuries to patients. These amendments, together with existing regulations, are intended to ensure that the types of incidents that have occurred in the past, as well as other types of foreseeable and potentially deadly medical gas accidents, do not occur in the future. FDA has described a number of proposals in the proposed rule including requiring that gas use outlet connections on portable cryogenic medical gas containers be securely attached to the valve body.

Timetable:

Action	Date	FR Cite
NPRM	04/10/06	71 FR 18039
NPRM Comment Period End.	07/10/06	
Final Action	07/00/16	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Patrick Raulerson, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 51, Room 6368, 10903 New Hampshire Avenue, Silver Spring, MD 20993–0002, *Phone:* 301 796–3522, *Fax:* 301 847–8440, *Email: patrick.raulerson@fda.hhs.gov.*

RIN: 0910–AC53

117. Food Labeling: Revision of the Nutrition and Supplement Facts Labels

Legal Authority: 21 U.S.C. 321; 21 U.S.C. 343; 21 U.S.C. 371

Abstract: FDA is amending the labeling regulations for conventional foods and dietary supplements to provide updated nutrition information on the label to assist consumers in maintaining healthy dietary practices. The rule would modernize the nutrition information found on the Nutrition Facts label, as well as the format and appearance of the label. On July 27, 2015, FDA issued a supplemental notice of proposed rulemaking accepting comments on limited additional provisions until October 13, 2015. Also on July 27, 2015, FDA reopened the comment period on the proposed rule as to specific documents until September 25, 2015. In addition, in response to requests for the raw data related to FDA's consumer studies on the nutrition label, FDA issued a notice on September 10, 2015 to make the raw data available for comment until October 13, 2015 and extended the comment period for the July 27, 2015 reopening as to specific documents to October 13, 2015. On October 20, 2015, FDA extended the comment period for the consumer studies and the supplemental proposal to October 23, 2015.

Timetable:

Action	Date	FR Cite
ANPRM	07/11/03	68 FR 41507
ANPRM Comment Period End.	10/09/03	
Second ANPRM	04/04/05	70 FR 17008
Second ANPRM Comment Period End.	06/20/05	
Third ANPRM	11/02/07	72 FR 62149
Third ANPRM Comment Period End.	01/31/08	
NPRM	03/03/14	79 FR 11879
NPRM Comment Period End.	06/02/14	
Reopening of Comment Period as to Specific Documents.	07/27/15	80 FR 44302
NPRM Comment Period End as to Specific Documents.	09/25/15	
Supplemental NPRM to Solicit Comment on Limited Additional Provisions.	07/27/15	80 FR 44303
Supplemental NPRM to Solicit Comment on Limited Additional Provisions Comment Period End.	10/13/15	
Administrative Docket Update; Extension of Comment Period.	09/10/15	80 FR 54446
Administrative Docket Update; Comment Period End.	10/13/15	
NPRM Reopening of Comment Period for Certain Documents.	10/20/15	80 FR 63477
NPRM Reopening of Comment Period for Certain Documents Comment Period End.	10/23/15	
Final Action	05/00/16	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Blakeley Fitzpatrick, Interdisciplinary Scientist, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition, HFS–830, 5100 Paint Branch Parkway, College Park, MD 20740, *Phone:* 240 402–5429, *Email: nutritionprogramstaff@fda.hhs.gov.*

RIN: 0910–AF22

118. Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed at One Eating Occasion; Dual—Column Labeling; Updating, Modifying, and Establishing Certain RACCS

Legal Authority: 21 U.S.C. 321; 21 U.S.C. 343; 21 U.S.C. 371; Pub. L. 101–535, sec 2(b)(1)(A)

Abstract: FDA is amending its labeling regulations for foods to provide update, modify, and establish Reference Amounts Customarily Consumed (RACCs) for certain food categories. This

rule would provide consumers with nutrition information based on the amount of food that is customarily consumed, which would assist consumers in maintaining healthy dietary practices. In addition to updating, modifying, and establishing certain RACCs, FDA is amending the definition of a single-serving containers; amending the label serving size for breath mints; and providing for dual-column labeling under certain circumstances, which would provide nutrition information per serving and per container or unit, as applicable; and making technical amendments to various aspects fo the serving size regulations.

Timetable:

Action	Date	FR Cite
ANPRM	04/04/05	70 FR 17010
ANPRM Comment Period End.	06/20/05	
NPRM/Comment Period Extended.	03/03/14	79 FR 11989
NPRM Comment Period End.	06/02/14	
NPRM Comment Period Extended.	05/27/14	79 FR 29699
NPRM Comment Period End.	08/01/14	
Final Action	05/00/16	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Cherisa Henderson, Nutritionist, Department of Health and Human Services, Food and Drug Administration, HFS–830, 5100 Paint Branch Parkway, College Park, MD 20740, *Phone:* 240 402–5429, *Fax:* 301 436–1191, *Email: nutritionprogramstaff@fda.hhs.gov*.

RIN: 0910–AF23

119. Abbreviated New Drug Applications and 505(B)(2)

Legal Authority: Pub. L. 108–173, title XI; 21 U.S.C. 355; 21 U.S.C. 371

Abstract: This proposed rule would make changes to certain procedures for Abbreviated New Drug Applications and related applications to patent certifications, notice to patent owners and application holders, the availability of a 30-month stay of approval, amendments and supplements, and the types of bioavailability and bioequivalence data that can be used to support these applications.

Timetable:

Action	Date	FR Cite
NPRM	02/06/15	80 FR 6802
NPRM Comment Period End.	05/07/15	
NPRM Comment Period Extended.	04/24/15	80 FR 22953
NPRM Comment Period Extended End.	06/08/15	
Final Action	08/00/16	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Janice L. Weiner, Senior Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Building 51, Room 6268, 10903 New Hampshire Avenue, Silver Spring, MD 20993–0002, *Phone:* 301 796–3601, *Fax:* 301 847–8440, *Email: janice.weiner@fda.hhs.gov*.

RIN: 0910–AF97

120. ''Tobacco Products'' Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act

Legal Authority: 21 U.S.C. 301 *et seq.;* The Federal Food, Drug, and Cosmetic Act; Pub. L. 111–31; The Family Smoking Prevention and Tobacco Control Act

Abstract: The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) provides the Food and Drug Administration (FDA) authority to regulate cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Tobacco Control Act, permits FDA to issue regulations deeming other tobacco products to be subject to the FD&C Act. This rule would deem additional products meeting the statutory definition of ''tobacco product'' to be subject to the FD&C Act, and would specify additional restrictions.

Timetable:

Action	Date	FR Cite
NPRM	04/25/14	79 FR 23142
NPRM Comment Period End.	07/09/14	
NPRM Comment Period Extended.	06/24/14	79 FR 35711
NPRM Comment Period Extended End.	08/08/14	
Final Action	05/00/16	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Gerie Voss, Senior Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Tobacco Products, Document Control Center, Building 71, Room G335, 10903 New Hampshire Avenue, Silver Spring, MD 20993, *Phone:* 877 287–1373, *Fax:* 301 595–1426, *Email: ctpregulations@fda.hhs.gov*.

RIN: 0910–AG38

121. Human Subject Protection; Acceptance of Data From Clinical Investigations for Medical Devices

Legal Authority: 21 U.S.C. 321; 21 U.S.C. 331; 21 U.S.C. 351; 21 U.S.C. 352; 21 U.S.C. 360; 21 U.S.C. 360c; 21 U.S.C. 360e; 21 U.S.C. 360i; 21 U.S.C. 360j; 21 U.S.C. 371; 21 U.S.C. 374; 21 U.S.C. 381; 21 U.S.C. 393; 42 U.S.C. 264; 42 U.S.C. 271; . . .

Abstract: This rule will amend FDA's regulations on acceptance of data for medical devices to require that clinical investigations submitted in support of a premarket approval application, humanitarian device exemption application, an investigational device exemption application, or a premarket notification submission be conducted in accordance with good clinical practice if conducted outside the United States.

Timetable:

Action	Date	FR Cite
NPRM	02/25/13	78 FR 12664
NPRM Comment Period End.	05/28/13	
Final Action	05/00/16	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Soma Kalb, Biomedical Engineer, Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, Building 66, Room 1534, 10903 New Hampshire Avenue, Silver Spring, MD 20993, *Phone:* 301 796–6359, *Email: soma.kalb@fda.hhs.gov*.

RIN: 0910–AG48

122. Focused Mitigation Strategies To Protect Food Against Intentional Adulteration

Legal Authority: 21 U.S.C. 331; 21 U.S.C. 342; 21 U.S.C. 350g; 21 U.S.C. 350i; 21 U.S.C. 371; 21 U.S.C. 374; Pub. L. 111–353

Abstract: This rule would require domestic and foreign food facilities that are required to register under the Federal Food, Drug, and Cosmetic Act to address hazards that may be intentionally introduced by acts of terrorism. These food facilities would be required to identify and implement focused mitigation strategies to significantly minimize or prevent significant vulnerabilities identified at actionable process steps in a food operation.

Timetable:

Action	Date	FR Cite
NPRM	12/24/13	78 FR 78014
NPRM Comment Period Extended.	03/25/14	79 FR 16251
NPRM Comment Period End.	03/31/14	
NPRM Comment Period Extended End.	06/30/14	
Final Rule	06/00/16	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Jody Menikheim, Supervisory General Health Scientist, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition (HFS–005), 5100 Paint Branch Parkway, College Park, MD 20740, *Phone:* 240 402–1864, *Fax:* 301 436–2633, *Email: fooddefense@fda.hhs.gov.*

RIN: 0910–AG63

123. Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products

Legal Authority: 21 U.S.C. 321; 21 U.S.C. 331; 21 U.S.C. 352; 21 U.S.C. 353; 21 U.S.C. 355; 21 U.S.C. 371; 42 U.S.C. 262; . . .

Abstract: This rule would amend the regulations regarding new drug applications (NDAs), abbreviated new drug applications (ANDAs), and biologics license application (BLAs) to revise and clarify procedures for changes to the labeling of an approved drug to reflect certain types of newly acquired information in advance of FDA's review of such change.

Timetable:

Action	Date	FR Cite
NPRM	11/13/13	78 FR 67985
NPRM Comment Period Extended.	12/27/13	78 FR 78796
NPRM Comment Period End.	01/13/14	
NPRM Comment Period Extended End.	03/13/14	
NPRM Comment Period Reopened.	02/18/15	80 FR 8577
NPRM Comment Period Reopened End.	04/27/15	
Final Rule	04/00/17	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Janice L. Weiner, Senior Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Building 51, Room 6268, 10903 New Hampshire Avenue, Silver Spring, MD 20993–0002, *Phone:* 301 796–3601, *Fax:* 301 847–8440, *Email: janice.weiner@fda.hhs.gov.*

RIN: 0910–AG94

124. Food Labeling; Gluten-Free Labeling of Fermented, Hydrolyzed, or Distilled Foods

Legal Authority: sec 206 of the Food Allergen Labeling and Consumer Protection Act; 21 U.S.C. 343(a)(1); 21 U.S.C. 321(n); 21 U.S.C. 371(a)

Abstract: This proposed rule would establish requirements concerning compliance for using a ''gluten-free'' labeling claim for those foods for which there is no scientifically valid analytical method available that can reliably detect and accurately quantify the presence of 20 parts per million (ppm) gluten in the food.

Timetable:

Action	Date	FR Cite
NPRM	11/18/15	80 FR 71990
NPRM Comment Period Reopened.	02/16/16	81 FR 3751
Comment Period Extended.	02/22/16	81 FR 8869
Final Action	04/00/17	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Carol D'Lima, Staff Fellow, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition, Room 4D022, HFS 820, 5100 Paint Branch Parkway, College Park, MD 20740, *Phone:* 240 402–2371, *Fax:* 301 436–2636, *Email: carol.dlima@fda.hhs.gov.*

RIN: 0910–AH00

125. General and Plastic Surgery Devices: Sunlamp Products

Legal Authority: 21 U.S.C. 360j(e)

Abstract: This proposed rule would apply device restrictions to sunlamp products.

Timetable:

Action	Date	FR Cite
NPRM	12/22/15	80 FR 79493
NPRM Comment Period End.	03/21/16	
Final Action	11/00/16	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Ian Ostermiller, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Building 66 Room 5515, 10903 New Hampshire Avenue, Silver Spring, MD 20993, *Phone:* 301 796–5678, *Email: ian.ostermiller@fda.hhs.gov.*

RIN: 0910–AH14

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Food and Drug Administration (FDA)

Long-Term Actions

126. Laser Products; Amendment to Performance Standard

Legal Authority: 21 U.S.C. 360hh to 360ss; 21 U.S.C. 371; 21 U.S.C. 393

Abstract: FDA is proposing to amend the 2013 proposed rule for the performance standard for laser products, which will amend the performance standard for laser products to achieve closer harmonization between the current standard and the recently amended International Electrotechnical Commission (IEC) standard for laser products and medical laser products. The amendment is intended to update FDA's performance standard to reflect advancements in technology.

Timetable:

Action	Date	FR Cite
NPRM	06/24/13	78 FR 37723
NPRM Comment Period End.	09/23/13	
NPRM (Reproposal).	06/00/17	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Erica Blake, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, WO 66, Room 4426, 10903 New Hampshire Avenue, Silver Spring, MD 20993, *Phone:* 301 796–6248, *Fax:* 301 847–8145, *Email: erica.blake@fda.hhs.gov.*

RIN: 0910–AF87

127. Requirements for the Testing and Reporting of Tobacco Product Constituents, Ingredients, and Additives

Legal Authority: 21 U.S.C. 301 *et seq.;* 21 U.S.C. 387; The Family Smoking Prevention and Tobacco Control Act

Abstract: The Federal Food, Drug, and Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Control Act, requires the Food and Drug Administration to promulgate regulations that require the testing and reporting of tobacco product constituents, ingredients, and additives, including smoke constituents, that the

Agency determines should be tested to protect the public health.

Timetable:

Action	Date	FR Cite
NPRM	06/00/17	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Laura Rich, Senior Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Tobacco Products, Building 71, G335, 10903 New Hampshire Avenue, Silver Spring, MD 20993, *Phone:* 877 287–1373, *Email: ctpregulations@fda.hhs.gov.*

RIN: 0910–AG59

128. Radiology Devices; Designation of Special Controls for the Computed Tomography X-Ray System

Legal Authority: 21 U.S.C. 360c

Abstract: The proposed rule would establish special controls for the computed tomography (CT) X-ray system. A CT X-ray system is a diagnostic X-ray imaging system intended to produce cross-sectional images of the body through use of a computer to reconstruct an image from the same axial plane taken at different angles. High doses of ionizing radiation can cause acute (deterministic) effects such as burns, reddening of the skin, cataracts, hair loss, sterility, and, in extremely high doses, radiation poisoning. The design of a CT X-ray system should balance the benefits of the device (*i.e.,* the ability of the device to produce a diagnostic quality image) with the known risks (*e.g.,* exposure to ionizing radiation). FDA is establishing proposed special controls, which are necessary to provide reasonable assurance of the safety and effectiveness of a class II CT X-ray system.

Timetable:

Action	Date	FR Cite
NPRM	05/00/17	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Erica Blake, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, WO 66, Room 4426, 10903 New Hampshire Avenue, Silver Spring, MD 20993, *Phone:* 301 796–6248, *Fax:* 301 847–8145, *Email: erica.blake@fda.hhs.gov.*

RIN: 0910–AH03

129. Regulations on Human Drug Compounding Under Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act

Legal Authority: 21 U.S.C. 353a; 21 U.S.C. 353b; 21 U.S.C. 371

Abstract: FDA will propose regulations to define and implement certain statutory conditions under which compounded products may qualify for exemptions from certain requirements.

Timetable:

Action	Date	FR Cite
NPRM	12/00/17	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Sarah Rothman, Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Building 51, Room 5197, 10903 New Hampshire Avenue, Silver Spring, MD 20993, *Phone:* 301 796–3536, *Email: sarah.rothman@fda.hhs.gov.*

RIN: 0910–AH10

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Food and Drug Administration (FDA)

Completed Actions

130. Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption

Legal Authority: 21 U.S.C. 342; 21 U.S.C. 350h; 21 U.S.C. 371; 42 U.S.C. 264; Pub. L. 111–353 (signed on January 4, 2011)

Abstract: This rule will establish science-based minimum standards for the safe production and harvesting of those types of fruits and vegetables that are raw agricultural commodities for which the Secretary has determined that such standards minimize the risk of serious adverse health consequences or death. The purpose of the rule is to reduce the risk of illness associated with fresh produce.

Timetable:

Action	Date	FR Cite
NPRM	01/16/13	78 FR 3503
NPRM Comment Period End.	05/16/13	
NPRM Comment Period Extended.	04/26/13	78 FR 24692
NPRM Comment Period Extended End.	09/16/13	
NPRM Comment Period Extended.	08/09/13	78 FR 48637
NPRM Comment Period Extended End.	11/15/13	
Notice of Intent To Prepare an Environmental Impact Statement for the Proposed Rule.	08/19/13	78 FR 50358
Notice of Intent To Prepare Environmental Impact Statement for the Proposed Rule Comment Period End.	11/15/13	
NPRM Comment Period Extended.	11/20/13	78 FR 69605
NPRM Comment Period Extended End.	11/22/13	
Environmental Impact Statement for the Proposed Rule; Comment Period Extended.	03/11/14	79 FR 13593
Environmental Impact Statement for the Proposed Rule; Comment Period Extended End.	04/18/14	
Supplemental NPRM.	09/29/14	79 FR 58433
Supplemental NPRM Comment Period End.	12/15/14	
Final Action—Draft Environmental Impact Statement.	01/14/15	80 FR 1852
Final Action—Draft Environmental Impact Statement Comment Period End.	03/13/15	
Final Action Effective.	01/26/16	
Final Rule	11/27/15	80 FR 74353

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Samir Assar, Supervisory Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Food Safety, 5100 Paint Branch Parkway, College Park, MD 20740, *Phone:* 240 402–1636, *Email: samir.assar@fda.hhs.gov.*

RIN: 0910–AG35

131. Foreign Supplier Verification Program

Legal Authority: 21 U.S.C. 384a; title III, sec 301 of FDA Food Safety Modernization Act; Pub. L. 111–353, establishing sec 805 of the Federal Food, Drug, and Cosmetic Act (FD&C Act)

Abstract: This rule describes what a food importer must do to verify that its foreign suppliers produce food that is as safe as food produced in the United States. FDA is taking this action to improve the safety of food that is imported into the United States.

Timetable:

Action	Date	FR Cite
NPRM	07/29/13	78 FR 45729
NPRM Comment Period End.	11/26/13	
NPRM Comment Period Extended.	11/20/13	78 FR 69602
NPRM Comment Period Extended End.	01/27/14	
Supplemental NPRM.	09/29/14	79 FR 58573
Supplemental NPRM Comment Period End.	12/15/14	
Final Rule	11/27/15	80 FR 74225
Final Rule Effective.	01/27/16	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Brian L. Pendleton, Senior Policy Advisor, Department of Health and Human Services, Food and Drug Administration, Office of Policy, WO 32, Room 4245, 10903 New Hampshire Avenue, Silver Spring, MD 20993–0002, *Phone:* 301 796–4614, *Fax:* 301 847–8616, *Email: brian.pendleton@fda.hhs.gov.*

RIN: 0910–AG64

132. Sanitary Transportation of Human and Animal Food

Legal Authority: 21 U.S.C. 350e; 21 U.S.C. 373; 21 U.S.C. 331; 21 U.S.C. 342; 21 U.S.C. 371; . . .

Abstract: This rule would establish requirements for parties including shippers, carriers by motor vehicle or rail vehicle, and receivers engaged in the transportation of food, including food for animals, to use sanitary transportation practices to ensure that food is not transported under conditions that may render the food adulterated.

Timetable:

Action	Date	FR Cite
ANPRM	04/30/10	75 FR 22713
ANPRM Comment Period End.	08/30/10	
NPRM	02/05/14	79 FR 7005
NPRM Comment Period Extended.	05/23/14	79 FR 29699
NPRM Comment Period End.	05/31/14	
NPRM Comment Period Extended End.	07/30/14	
Final Rule	04/06/16	81 FR 20092
Final Rule Effective.	06/06/16	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Michael E. Kashtock, Supervisory Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Food Safety, 5100 Paint Branch Parkway, College Park, MD 20740, *Phone:* 240 402–2022, *Fax:* 301 346–2632, *Email: michael.kashtock@fda.hhs.gov.*

RIN: 0910–AG98

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Centers for Medicare & Medicaid Services (CMS)

Proposed Rule Stage

133. Hospital and Critical Access Hospital (CAH) Changes to Promote Innovation, Flexibility, and Improvement in Patient Care (CMS–3295–P) (Rulemaking Resulting From a Section 610 Review)

Legal Authority: 42 U.S.C. 1302; 42 U.S.C. 1395hh and 1395rr

Abstract: This proposed rule would update the requirements that hospitals and Critical Access Hospitals (CAHs) must meet to participate in the Medicare and Medicaid programs. These proposals are intended to conform the requirements to current standards of practice and to support improvements in quality of care, reduce barriers to care, and reduce some issues that may exacerbate workforce shortage concerns.

Timetable:

Action	Date	FR Cite
NPRM	05/00/16	

Regulatory Flexibility Analysis Required: No.

Agency Contact: CDR Scott Cooper, Senior Technical Advisor, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Clinical Standards and Quality, Mail Stop S3–01–02, 7500 Security Boulevard, Baltimore, MD 21244, *Phone:* 410 786–9465, *Email: scott.cooper@cms.hhs.gov.*

RIN: 0938–AS21

134. Merit-Based Incentive Payment System (MIPS) and Alternative Payment Models (APMS) in Medicare Fee-For-Service (CMS–5517–P) (Section 610 Review)

Legal Authority: Pub. L. 114–10, sec 101

Abstract: This proposed rule would implement provisions of the Medicare Access and CHIP Reauthorization Act (MACRA) related to MIPS and APMs. Section 101 of MACRA authorizes a new MIPS, which repeals the Medicare sustainable growth rate and improves Medicare payments for physician services. MACRA consolidates the current programs of the Physician Quality Reporting System, the Value-Based Modifier, and the Electronic Health Records Incentive Program into one program, MIPS, that streamlines and improves on the three distinct incentive programs. Additionally, MACRA authorizes incentive payments for providers who participate in eligible APMs.

Timetable:

Action	Date	FR Cite
NPRM	05/09/16	81 FR 28161
NPRM Comment Period End.	06/27/16	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: James Sharp, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare & Medicaid Innovation Center, MS: WB–06–05, 7500 Security Boulevard, Baltimore, MD 21244, *Phone:* 410 786–7388, *Email: james.sharp@cms.hhs.gov.*

RIN: 0938–AS69

135. Hospital Inpatient Prospective Payment System for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and FY 2017 Rates (CMS–1655–F) (Section 610 Review)

Legal Authority: 42 U.S.C. 1302; 42 U.S.C. 1395hh

Abstract: This annual final rule revises the Medicare hospital inpatient and long-term care hospital prospective payment systems for operating and capital-related costs. This rule implements changes arising from our continuing experience with these systems.

Timetable:

Action	Date	FR Cite
NPRM	04/27/16	81 FR 24946
NPRM Comment Period End.	06/17/16	
Final Action	08/00/16	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Donald Thompson, Deputy Director, Division of Acute Care, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, MS: C4–01–26, 7500 Security Boulevard, Baltimore, MD 21244, *Phone:* 410 786–6504, *Email: donald.thompson@cms.hhs.gov.*

RIN: 0938–AS77

136. CY 2017 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model; and Home Health Quality Reporting Requirements (Section 610 Review)

Legal Authority: 42 U.S.C. 1302; 42 U.S.C. 1395hh

Abstract: This annual proposed rule would update the 60-day national episode rate, the national per-visit rates used to calculate low utilization payment adjustments (LUPAs), and outlier payments under the Medicare prospective payment system for home health agencies. The rule would also update the provisions of the Home Health Value-Based Purchasing (HHVBP) program.

Timetable:

Action	Date	FR Cite
NPRM	06/00/16	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Hillary Loeffler, Deputy Director, Division of Home Health and Hospice, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, MS: C5–07–22, 7500 Security Boulevard, Baltimore, MD 21244, *Phone:* 410 786–0456, *Email: hillary.loeffler@cms.hhs.gov.*

RIN: 0938–AS80

137. CY 2017 Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Medicare Part B (CMS–1654–P) (Section 610 Review)

Legal Authority: 42 U.S.C. 1302; 42 U.S.C. 1395hh; Pub. L. 114–10

Abstract: This annual proposed rule would revise payment polices under the Medicare physician fee schedule, and make other policy changes to payment under Medicare Part B. These changes would apply to services furnished beginning January 1, 2017.

Timetable:

Action	Date	FR Cite
NPRM	06/00/16	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Ryan Howe, Director, Division of Practitioner Services, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, MS: C4–01–15, 7500 Security Boulevard, Baltimore, MD 21244, *Phone:* 410 786–3355, *Email: ryan.howe@cms.hhs.gov*.

RIN: 0938–AS81

138. CY 2017 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates (CMS–1656–P) (Section 610 Review)

Legal Authority: 42 U.S.C. 1302; 42 U.S.C. 1395hh

Abstract: This annual proposed rule would revise the Medicare hospital outpatient prospective payment system to implement statutory requirements and changes arising from our continuing experience with this system. The rule describes changes to the amounts and factors used to determine payment rates for services. In addition, the rule would change the ambulatory surgical center payment system list of services and rates.

Timetable:

Action	Date	FR Cite
NPRM	07/00/16	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Marjorie Baldo, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, MS: C4–03–06, 7500 Security Boulevard, Baltimore, MD 21244, *Phone:* 410 786–4617, *Email: marjorie.baldo@cms.hhs.gov.*

RIN: 0938–AS82

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Centers for Medicare & Medicaid Services (CMS)

Final Rule Stage

139. Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers (CMS–3178–F) (Section 610 Review)

Legal Authority: 42 U.S.C. 1821; 42 U.S.C. 1861ff (3)(B)(i)(ii); 42 U.S.C. 1913(c)(1) et al

Abstract: This rule finalizes emergency preparedness requirements for Medicare and Medicaid participating providers and suppliers to ensure that they adequately plan for both natural and man-made disasters and coordinate with Federal, State, tribal, regional, and local emergency preparedness systems. This rule ensures providers and suppliers are adequately prepared to meet the needs of patients, residents, clients, and participants during disasters and emergency situations.

Timetable:

Action	Date	FR Cite
NPRM	12/27/13	78 FR 79082
NPRM Comment Period Extended.	02/21/14	79 FR 9872
NPRM Comment Period End.	03/31/14	
Final Action	12/00/16	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Janice Graham, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Clincial Standards and Quality, Mail Stop S3–02–01, 7500 Security Boulevard, Baltimore, MD 21244–1850, *Phone:* 410 786–8020, *Email: janice.graham@cms.hhs.gov.*

RIN: 0938–AO91

140. Reform of Requirements for Long–Term Care Facilities (CMS–3260–F) (Rulemaking Resulting From a Section 610 Review)

Legal Authority: Pub. L. 111–148, sec 6102; 42 U.S.C. 263a; 42 U.S.C. 1302; 42 U.S.C. 1395hh; 42 U.S.C. 1395rr

Abstract: This final rule revises the requirements that long-term care facilities must meet to participate in the Medicare and Medicaid programs. These changes are necessary to reflect the substantial advances that have been made over the past several years in the theory and practice of service delivery and safety. The rule is also an integral part of CMS efforts to achieve broad-

based improvements both in the quality of health care furnished through federal programs, and in patient safety, while at the same time reducing procedural burdens on providers.

Timetable:

Action	Date	FR Cite
NPRM	07/16/15	80 FR 42167
NPRM Comment Period Extension.	09/15/15	80 FR 55284
NPRM Comment Period End.	09/14/15	
NPRM Comment Period Extended End.	10/14/15	
Final Action	09/00/16	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Ronisha Blackstone, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Clinical Standards and Quality, MS: S3–02–01, 7500 Security Boulevard, Baltimore, MD 21244, *Phone:* 410 786–6882, *Email: ronisha.blackstone@cms.hhs.gov.*

RIN: 0938–AR61

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Long-Term Actions

Centers for Medicare & Medicaid Services (CMS)

141. Conditions of Participation for Home Health Agencies (CMS–3819–F) (Rulemaking Resulting From a Section 610 Review)

Legal Authority: 42 U.S.C. 1302; 42 U.S.C. 1395x; 42 U.S.C. 1395cc(a); 42 U.S.C. 1395hh; 42 U.S.C. 1395bb

Abstract: This final rule revises the conditions of participation (CoPs) that home health agencies (HHAs) must meet in order to participate in the Medicare and Medicaid programs. The requirements focus on the care delivered to patients by HHAs, reflect an interdisciplinary view of patient care, allow HHAs greater flexibility in meeting quality care standards, and eliminate unnecessary procedural requirements. These changes are an integral part of our overall effort to achieve broad-based, measurable improvements in the quality of care furnished through the Medicare and Medicaid programs, while at the same time eliminating unnecessary procedural burdens on providers.

Timetable:

Action	Date	FR Cite
NPRM	03/10/97	62 FR 11005
NPRM Comment Period End.	06/09/97	
Second NPRM	10/09/14	79 FR 61163
NPRM Comment Period Extended.	12/01/14	79 FR 71081
NPRM Comment Period End.	12/08/14	
NPRM Comment Period Extended End.	01/07/15	
Final Action	10/00/17	

Regulatory Flexibility Analysis Required: No.

Agency Contact: Danielle Shearer, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Clinical Standards & Quality, 7500 Security Boulevard, MS: S3–02–01, Baltimore, MD 21244, *Phone:* 410 786–6617, *Email: danielle.shearer@cms.hhs.gov*.

RIN: 0938–AG81

142. Medicare Clinical Diagnostic Laboratory Test Payment System (CMS–1621–F) (Section 610 Review)

Legal Authority: Pub. L. 113–93, sec 216

Abstract: This final rule revises the Medicare payment system for clinical diagnostic laboratory tests and implements other changes required by section 216 of the Protecting Access to Medicare Act of 2014.

Timetable:

Action	Date	FR Cite
NPRM	10/01/15	80 FR 59385
NPRM Comment Period End.	11/25/15	
Final Action	10/00/18	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Valerie Miller, Deputy Director, Division of Ambulatory Services, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, Mail Stop C4–01–26, 7500 Security Boulevard, Baltimore, MD 21244, *Phone:* 410 786–4535, *Email: valerie.miller@cms.hhs.gov*.

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RIN: 0938–AS33

143. Imaging Accreditation (CMS–3309–P) (Section 610 Review)

Legal Authority: 42 U.S.C. 1395hh; 42 U.S.C. 1102

Abstract: This proposed rule would establish standards for Imaging Accreditation. These proposed standards would address qualifications for clinical personnel, standards to ensure that suppliers have established policies and procedures governing the use of equipment in furnishing the technical component of advanced diagnostic imaging, and the establishment and maintenance of a quality assurance and quality control program to ensure reliability, clarity, and accuracy of the diagnostic images.

Timetable:

Action	Date	FR Cite
NPRM	To Be	Determined

Regulatory Flexibility Analysis Required: Yes.

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RIN: 0938–AS62

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Completed Actions

Centers for Medicare & Medicaid Services (CMS)

144. Covered Outpatient Drugs (CMS–2345–FC) (Completion of a Section 610 Review)

Legal Authority: Pub. L. 111–48, sec 2501; Pub. L. 111–48, 2503; Pub. L. 111–48, 3301(d)(2); Pub. L. 111–152, sec 1206; Pub. L. 111–8, sec 221

Abstract: This final rule revises requirements pertaining to Medicaid reimbursement for covered outpatient drugs to implement provisions of the Affordable Care Act. This rule also revises other requirements related to covered outpatient drugs, including key aspects of Medicaid coverage, payment, and the drug rebate program.

Timetable:

Action	Date	FR Cite
NPRM	02/02/12	77 FR 5318
NPRM Comment Period End.	04/02/12	
Final Action	02/01/16	81 FR 5170

Action	Date	FR Cite
Final Action Effective.	04/01/16	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Wendy Tuttle, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicaid and State Operations, Mail Stop S2–14–26, 7500 Security Boulevard, Baltimore, MD 21244, *Phone:* 410 786–8690, *Email: wendy.tuttle@cms.hhs.gov*.

RIN: 0938–AQ41

145. CY 2016 Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Medicare Part B (CMS–1631–FC) (Completion of a Section 610 Review)

Legal Authority: 42 U.S.C. 405(a), 1302, 1395x, 1395y(a), 1395ff, 1395kk, 1395rr and 1395ww(k); 42 U.S.C. 263a; 42 U.S.C. 1395m, 1395hh, and 1395ddd; 42 U.S.C. 1395w–101 through 1395w–152, and 1395nn; ...

Abstract: This annual final rule revises payment polices under the Medicare physician fee schedule, and makes other policy changes to payment under Medicare Part B. These changes apply to services furnished beginning January 1, 2016.

Timetable:

Action	Date	FR Cite
NPRM	07/15/15	80 FR 41686
NPRM Comment Period End.	09/08/15	
Final Action	11/16/15	80 FR 70886
Final Action Effective.	01/01/16	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Ryan Howe, Director, Division of Practitioner Services, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, MS: C4–01–15, 7500 Security Boulevard, Baltimore, MD 21244, *Phone:* 410 786–3355, *Email: ryan.howe@cms.hhs.gov*.

RIN: 0938–AS40

146. CY 2016 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates (CMS–1633–FC) (Completion of a Section 610 Review)

Legal Authority: 42 U.S.C. 1302, 1395m, 1395hh, and 1395ddd

Abstract: This annual final rule revises the Medicare hospital outpatient prospective payment system to implement statutory requirements and changes arising from our continuing experience with this system. The rule describes changes to the amounts and factors used to determine payment rates for services. In addition, the rule changes the ambulatory surgical center payment system list of services and rates.

Timetable:

Action	Date	FR Cite
NPRM	07/08/15	80 FR 39200
NPRM Comment Period End.	08/31/15	
Final Action	11/13/15	80 FR 70298
Final Action Effective.	01/01/16	

Regulatory Flexibility Analysis Required: Yes.

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RIN: 0938–AS42

147. Comprehensive Care for Joint Replacement (CMS–5516–F) (Completion of a Section 610 Review)

Legal Authority: Social Security Act, sec 1115A

Abstract: This final rule implements a new Medicare Part A and B payment model under section 1115A of the Social Security Act, called the Comprehensive Care Joint Replacement Model, in which acute care hospitals in certain selected geographic areas receive retrospective bundled payments for episodes of care for lower extremity joint replacement or reattachment of a lower extremity. All related care within 90 days of hospital discharge from the joint replacement procedures would be included in the episode of care. We believe this model furthers our goals in improving the efficiency and quality of care for Medicare beneficiaries for these common medical procedures.

Timetable:

Action	Date	FR Cite
NPRM	07/14/15	80 FR 41198
NPRM Comment Period End.	09/08/15	
Final Action	11/24/15	80 FR 73273
Final Action Effective.	01/15/16	

Regulatory Flexibility Analysis Required: Yes.

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RIN: 0938–AS64

[FR Doc. 2016–12904 Filed 6–8–16; 8:45 am]

BILLING CODE 4150–03–P