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

Semiannual Regulatory Agenda

AGENCY: Office of the Secretary, HHS.

ACTION: Semiannual regulatory agenda.

SUMMARY: The Regulatory Flexibility Act of 1980 and Executive Order 12866 require the Department semiannually to issue an inventory of rulemaking actions under development to provide the public a summary of forthcoming regulatory actions. This information will help the public more effectively participate in the Department's regulatory activity, and the Department welcomes comments on any aspect of this agenda.

FOR FURTHER INFORMATION CONTACT: Jennifer M. Cannistra, Executive Secretary, Department of Health and Human Services, 200 Independence Avenue SW., Washington, DC 20201; (202) 690-6827.

SUPPLEMENTARY INFORMATION: The Department of Health and Human Services (HHS) is the Federal Government's principal 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. The Department's Public Participation Task Force, which was created as part of the HHS Retrospective Review plan in response to Executive Order 13563 (Improving Regulation and Regulatory Review), regularly meets to identify ways to make the rulemaking process more accessible to the general public. For example, to encourage public participation, we regularly update our regulatory webpage (http://www.hhs.gov/regulations), which includes links to HHS rules currently open for public comment, and 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, including through a comment form on the HHS retrospective review webpage (http://www.HHS.gov/RetrospectiveReview). In addition, a cross-agency team at HHS is currently considering how to increase efficiency in rulemaking by organizing public comment on proposed rules.

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.

Dated: February 20, 2014.

NAME: Jennifer M. Cannistra,

Executive Secretary to the Department.

Substance Abuse and Mental Health Services Administration—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
120	SAMHSA User Fees for Publications	0930–AA18

Food and Drug Administration—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
121	Food Labeling; Revision of the Nutrition and Supplement Facts Labels	0910–AF22

122	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
123	Over-the-Counter (OTC) Drug Review—Cough/Cold (Antihistamine) Products	0910–AF31
124	Over-the-Counter (OTC) Drug Review—Internal Analgesic Products	0910–AF36
125	Over-the-Counter (OTC) Drug Review—Sunscreen Products	0910–AF43
126	Over-the-Counter (OTC) Drug Review—Topical Antimicrobial Drug Products	0910–AF69
127	Abbreviated New Drug Applications and 505(b)(2)	0910–AF97
128	Updated Standards for Labeling of Pet Food	0910–AG09
129	Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals	0910–AG10
130	Over-the-Counter (OTC) Drug Review—Pediatric Dosing for Cough/Cold Products	0910–AG12
131	Electronic Distribution of Prescribing Information for Human Prescription Drugs Including Biological Products	0910–AG18
132	Produce Safety Regulation	0910–AG35
133	Current Good Manufacturing and Hazard Analysis, and Risk-Based Preventive Controls for Human Food	0910–AG36
134	“Tobacco Products” Subject to the Federal Food, Drug, and	0910–AG38

	Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act	
135	Requirements for the Testing and Reporting of Tobacco Product Constituents, Ingredients, and Additives	0910–AG59
136	Foreign Supplier Verification Program	0910–AG64
137	Format and Content of Reports Intended to Demonstrate Substantial Equivalence	0910–AG96
138	Sanitary Transportation of Human and Animal Food	0910–AG98
139	Radiology Devices; Designation of Special Controls for the Computed Tomography X-Ray System	0910–AH03
140	Mammography Quality Standards Act; Regulatory Amendments	0910–AH04
141	Investigational New Drug Application Annual Reporting	0910–AH07

Food and Drug Administration—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
142	Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Pregnancy and Lactation Labeling	0910–AF11
143	Combinations of Bronchodilators With Nasal Decongestants or Expectorants; Cold, Cough, Allergy, Bronchodilator, and	0910–AF33

	Antiasthmatic Drug Products for Over-the-Counter Human Use	
144	Over-the-Counter (OTC) Drug Review—Laxative Drug Products	0910–AF38
145	Laser Products; Amendment to Performance Standard	0910–AF87
146	Human Subject Protection; Acceptance of Data From Clinical Studies for Medical Devices	0910–AG48
147	Food Labeling: Calorie Labeling of Articles of Food Sold in Vending Machines	0910–AG56
148	Food Labeling: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments	0910–AG57
149	Requirements for the Submission of Data Needed to Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Products	0910–AG81
150	Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products	0910–AG94
151	Veterinary Feed Directive	0910–AG95

Food and Drug Administration—Long-Term Actions

Sequence Number	Title	Regulation Identifier Number
152	Infant Formula: Current Good Manufacturing Practices; Quality Control Procedures; Notification Requirements; Records and	0910–AF27

	Reports; and Quality Factors	
153	Focused Mitigation Strategies To Protect Food Against Intentional Adulteration	0910–AG63

Food and Drug Administration—Completed Actions

Sequence Number	Title	Regulation Identifier Number
154	Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements, and Administrative Procedures **(Completion of a Section 610 Review)**	0910–AG14
155	General Hospital and Personal Use Devices: Issuance of Draft Special Controls Guidance for Infusion Pumps	0910–AG54
156	Food Labeling: Nutrient Content Claims; Alpha-Linolenic Acid, Eicosapentaenoic Acid, and Docosahexaenoic Acid Omega–3 Fatty Acids	0910–AH13

Centers for Medicare & Medicaid Services—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
157	Home Health Agency Conditions of Participation (CMS-3819-P)	0938–AG81

	(Rulemaking Resulting From a Section 610 Review)	
158	Hospital Inpatient Prospective Payment System for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Fiscal Year 2015 Rates (CMS-1607-P) **(Section 610 Review)**	0938–AS11
159	CY 2015 Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Medicare Part B (CMS-1612-P) **(Section 610 Review)**	0938–AS12
160	CY 2015 Hospital Outpatient Prospective Payment System (PPS) Policy Changes and Payment Rates, and CY 2015 Ambulatory Surgical Center Payment System Policy Changes and Payment Rates (CMS-1613-P) **(Section 610 Review)**	0938–AS15
161	CY 2016 Notice of Benefit and Payment Parameters (CMS-9944-P) **(Section 610 Review)**	0938–AS19
162	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

Centers for Medicare & Medicaid Services—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
163	Covered Outpatient Drugs (CMS-2345-F) **(Section 610 Review)**	0938–AQ41

164	Prospective Payment System for Federally Qualified Health Centers; Changes to Contracting Policies for Rural Health Clinics and CLIA Enforcement Actions for Proficiency Testing Referral (CMS-1443-FC) **(Section 610 Review)**	0938–AR62
165	Adoption of Operating Rules for HIPAA Transactions (CMS-0036-IFC)	0938–AS01
166	Extension of Payment Adjustment for Low-Volume Hospitals and the Medicare-Dependent Hospital Program Under the FY 2014 Hospital Inpatient Prospective Payment System (CMS-1599-IFC2) **(Section 610 Review)**	0938–AS18

Centers for Medicare & Medicaid Services—Long-Term Actions

Sequence Number	Title	Regulation Identifier Number
167	Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers (CMS-3178-F)	0938–AO91

Centers for Medicare & Medicaid Services—Completed Actions

Sequence Number	Title	Regulation Identifier Number

168	CY 2014 Changes to the End-Stage Renal Disease (ESRD) Prospective Payment System, ESRD Quality Incentive Program, and Durable Medical Equipment (CMS-1526-F) **(Completion of a Section 610 Review)**	0938–AR55
169	Revisions to Payment Policies Under the Physician Fee Schedule and Medicare Part B for CY 2014 (CMS-1600-FC) **(Completion of a Section 610 Review)**	0938–AR56
170	CY 2015 Notice of Benefit and Payment Parameters (CMS-9954-F) **(Completion of a Section 610 Review)**	0938–AR89

Department of Health and Human Services (HHS)	**Proposed Rule Stage**
Substance Abuse and Mental Health Services Administration (SAMHSA)	

120. • SAMHSA USER FEES FOR PUBLICATIONS

Legal Authority: 31 USC 9701; 31 USC 1111; EO 8284; EO 11541; PL 113–76

Abstract: SAMSHA is proposing to implement a modest cost recovery program to partially offset the high costs of distributing its materials to the public. This user fee would apply only to “over-the-limit” non-governmental orders. An “over the limit” order is defined as an order that exceeds either the average weight value (3.75 lbs) or the average number of copies (8). The “non-governmental orders” do not include: SAMHSA's Recovery Month bulk orders; orders by SAMHSA staff for meetings or conferences; and orders from “.gov” and “.mil” addresses. Therefore, it is assumed that SAMHSA would not charge shipping for orders by other Federal, State, and local government agencies. The proposed rule would

implement recent legislation allowing the funds collected as part of a user fee for publications and data requests to be available to SAMHSA until expended.

Timetable:

Action	Date	FR Cite
NPRM	12/00/14	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Brian Altman, Legislative Director, Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, 1 Choke Cherry Road, Rockville, MD 02857

Phone: 240 276–2009

Email: brian.altman@samhsa.gov

RIN: 0930–AA18

Department of Health and Human Services (HHS)	Proposed Rule Stage
Food and Drug Administration (FDA)	

121. FOOD LABELING; REVISION OF THE NUTRITION AND SUPPLEMENT FACTS LABELS

Legal Authority: 21 USC 321; 21 USC 343; 21 USC 371

Abstract: FDA is proposing to amend 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. If finalized, this rule will modernize the nutrition information found on the Nutrition Facts label, as well as the format and appearance of the label.

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	

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), HFS–830, 5100 Paint Branch Parkway, College Park, MD 20740

Phone: 240 402–5429

Email: nutritionprogramstaff@fda.hhs.gov

RIN: 0910–AF22

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122. 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 USC 321; 21 USC 343; 21 USC 371

Abstract: FDA is proposing to amend its labeling regulations for foods to provide updated Reference Amounts Customarily Consumed (RACCs) for certain food categories. If finalized, 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 certain RACCs, FDA is also considering amending the definition of single-serving containers; amending the definition of serving size for breath mints; and providing for dual-column labeling, which would provide nutrition information per serving and per container or units, as applicable, under certain circumstances.

Timetable:

Action	Date	FR Cite
ANPRM	04/04/05	70 FR 17010
ANPRM Comment Period End	06/20/05	
NPRM	03/03/14	79 FR 11989
NPRM Comment Period End	06/02/14	

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

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123. OVER–THE–COUNTER (OTC) DRUG REVIEW—COUGH/COLD (ANTIHISTAMINE) PRODUCTS

Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 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)	09/00/14	

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

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124. OVER–THE–COUNTER (OTC) DRUG REVIEW—INTERNAL ANALGESIC PRODUCTS

Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371; 21 USC 374; 21 USC 379e

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. The first action addresses acetaminophen safety. The second action addresses products marketed for children under 2 years old and weight- and age-based dosing for children's products.

Timetable:

Action	Date	FR Cite
NPRM (Amendment) (Required Warnings and Other Labeling)	12/26/06	71 FR 77314

NPRM Comment Period End	05/25/07	
Final Action (Required Warnings and Other Labeling)	04/29/09	74 FR 19385
Final Action (Correction)	06/30/09	74 FR 31177
Final Action (Technical Amendment)	11/25/09	74 FR 61512
NPRM (Amendment) (Pediatric)	12/00/14	
NPRM (Amendment) (Acetaminophen)	12/00/14	

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–AF36

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125. OVER–THE–COUNTER (OTC) DRUG REVIEW—SUNSCREEN PRODUCTS

Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 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. The first of the future actions will address the safety of sunscreen active ingredients.

Timetable:

Action	Date	FR Cite
ANPRM (Sunscreen and Insect Repellent)	02/22/07	72 FR 7941
ANPRM Comment Period End	05/23/07	
NPRM (UVA/UVB)	08/27/07	72 FR 49070
NPRM Comment Period End	12/26/07	
Final Action (UVA/UVB)	06/17/11	76 FR 35620
NPRM (Effectiveness)	06/17/11	76 FR 35672
NPRM (Effectiveness) Comment Period End	09/15/11	
ANPRM (Dosage Forms)	06/17/11	76 FR 35669
ANPRM (Dosage Forms) Comment Period End	09/15/11	

Proposed Rule	03/00/15	

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–AF43

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126. OVER–THE–COUNTER (OTC) DRUG REVIEW—TOPICAL ANTIMICROBIAL DRUG PRODUCTS

Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 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 healthcare antiseptic products.

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 (Healthcare Antiseptic)	03/00/15	

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

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127. ABBREVIATED NEW DRUG APPLICATIONS AND 505(B)(2)

Legal Authority: PL 108–173, title XI; 21 USC 355; 21 USC 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	05/00/14	

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, WO 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

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128. UPDATED STANDARDS FOR LABELING OF PET FOOD

Legal Authority: 21 USC 343; 21 USC 371; PL 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 useful information about the nutrient content and ingredient composition of pet food products.

Timetable:

Action	Date	FR Cite
NPRM	10/00/14	

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, Room 2642 (MPN–4, HFV–228), 7519 Standish Place, Rockville, MD 20855

Phone: 240 453–6865

Email: william.burkholder@fda.hhs.gov

RIN: 0910–AG09

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129. CURRENT GOOD MANUFACTURING PRACTICE AND HAZARD ANALYSIS AND RISK–BASED PREVENTIVE CONTROLS FOR FOOD FOR ANIMALS

Legal Authority: 21 USC 321; 21 USC 331; 21 USC 342; 21 USC 350c; 21 USC 350d note; 21 USC 350g; 21 USC 350g note; 21 USC 371; 21 USC 374; 42 USC 264; 42 USC 243; 42 USC 271; . . .

Abstract: This rule establishes requirements for good manufacturing practice, and to require that certain facilities establish and implement hazard analysis and risk-based preventive controls for animal food, including ingredients and mixed animal feed. This action is intended to provide greater assurance that food marketed for all animals, including pets, is safe.

Timetable:

Action	Date	FR Cite
NPRM	10/29/13	78 FR 64736
NPRM Comment Period Extension	02/03/14	79 FR 6111
NPRM Comment Period End	02/26/14	
NPRM Comment Period	03/31/14	

Extension End		
Supplemental NPRM	07/00/14	
Final Rule	08/00/15	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Kim Young, Deputy Director, Division of Compliance, Department of Health and Human Services, Food and Drug Administration, Center for Veterinary Medicine, Room 106 (MPN–4, HFV–230), 7519 Standish Place, Rockville, MD 20855

Phone: 240 276–9207

Email: kim.young@fda.hhs.gov

RIN: 0910–AG10

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130. OVER–THE–COUNTER (OTC) DRUG REVIEW—PEDIATRIC DOSING FOR COUGH/COLD PRODUCTS

Legal Authority: 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 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 will propose changes to the final monograph to address safety and efficacy issues associated with pediatric cough and cold products.

Timetable:

Action	**Date**	**FR Cite**

NPRM	12/00/14	

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–AG12

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131. ELECTRONIC DISTRIBUTION OF PRESCRIBING INFORMATION FOR HUMAN PRESCRIPTION DRUGS INCLUDING BIOLOGICAL PRODUCTS

Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351; 21 USC 352; 21 USC 353; 21 USC 355; 21 USC 358; 21 USC 360; 21 USC 360b; 21 USC 360gg to 360ss; 21 USC 371; 21 USC 374; 21 USC 379e; 42 USC 216; 42 USC 241; 42 USC 262; 42 USC 264

Abstract: This rule would require electronic package inserts for human drug and biological prescription products with limited exceptions, in lieu of paper, which is currently used. These inserts contain prescribing information intended for healthcare practitioners. This would ensure that the information accompanying the product is the most up-to-date information regarding important safety and efficacy issues about these products.

Timetable:

Action	Date	FR Cite

NPRM	06/00/14	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Megan Velez, Policy Analyst, Department of Health and Human Services, Food and Drug Administration, Office of Policy, WO 32, Room 4249, 10903 New Hampshire Avenue, Silver Spring, MD 20993

Phone: 301 796–9301

Email: megan.velez@fda.hhs.gov

RIN: 0910–AG18

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132. PRODUCE SAFETY REGULATION

Legal Authority: 21 USC 342; 21 USC 350h; 21 USC 371; 42 USC 264; PL 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	04/26/13	78 FR 24692

Extended		
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 Enviromental Impact Statement for the Proposed Rule	08/19/13	78 FR 50358
Notice of Intent To Prepare Enviromental 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	11/18/13	78 FR 69006

Environmental Impact Statement for the Proposed Rule; Comment Period Extended End	03/14/14	
Supplemental NPRM	07/00/14	
Final Rule	10/00/15	

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

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133. CURRENT GOOD MANUFACTURING AND HAZARD ANALYSIS, AND RISK–BASED PREVENTIVE CONTROLS FOR HUMAN FOOD

Legal Authority: 21 USC 342; 21 USC 371; 42 USC 264; PL 111–353 (signed on Jan. 4, 2011)

Abstract: This rule would require a food facility to have and implement preventive controls to significantly minimize or prevent the occurrence of hazards that could affect food manufactured, processed, packed, or held by the facility. This action is intended to prevent or, at a minimum, quickly identify foodborne pathogens before they get into the food supply.

Timetable:

Action	Date	FR Cite
NPRM	01/16/13	78 FR 3646
NPRM Comment Period End	05/16/13	
NPRM Comment Period Extended	04/26/13	78 FR 24691
NPRM Comment Period Extended End	09/16/13	
NPRM Comment Period Extended	08/09/13	78 FR 48636
NPRM Comment Period Extended End	11/15/13	
NPRM Comment Period Extended	11/20/13	78 FR 69604
NPRM Comment Period Extended End	11/22/13	
Supplemental NPRM	07/00/14	
Final Rule	08/00/15	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Jenny Scott, Senior Advisor, Department of Health and Human Services, Food and Drug Administration, Office of Food Safety, 5100 Paint Branch Parkway, College Park, MD 20740

Phone: 240 402–1488

Email: jenny.scott@fda.hhs.gov

RIN: 0910–AG36

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134. "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 USC 301 et seq; The Federal Food, Drug, and Cosmetic Act; PL 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 proposed rule would deem 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	
Final Action	06/00/15	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: May Nelson, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Tobacco Products, 9200 Corporate Boulevard, Rockville, MD 20850

Phone: 877 287–1373

Fax: 240 276–3904

Email: may.nelson@fda.hhs.gov

RIN: 0910–AG38

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135. REQUIREMENTS FOR THE TESTING AND REPORTING OF TOBACCO PRODUCT CONSTITUENTS, INGREDIENTS, AND ADDITIVES

Legal Authority: 21 USC 301 et seq; 21 USC 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	11/00/14	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Carol Drew, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Tobacco Products, 9200 Corporate Boulevard, Room 240 H, Rockville, MD 20850

Phone: 877 287–1373

Fax: 240 276–3904

Email: carol.drew@fda.hhs.gov

RIN: 0910–AG59

136. FOREIGN SUPPLIER VERIFICATION PROGRAM

Legal Authority: 21 USC 384a; title III, sec 301 of FDA Food Safety Modernization Act, PL 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	07/00/14	
Final Rule	10/00/15	

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

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137. FORMAT AND CONTENT OF REPORTS INTENDED TO DEMONSTRATE SUBSTANTIAL EQUIVALENCE

Legal Authority: 21 USC 387e(j); 21 USC 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 and compliance with the FD&C Act (sections 905(j) and 910(a) of the FD&C Act). This regulation also would provide information as to how the Agency will review and act on these submissions.

Timetable:

Action	Date	FR Cite
NPRM	02/00/15	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Gerie Voss, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Tobacco Products, 9200 Corporate Boulevard, Rockville, MD 20850

Phone: 877 287–1373

Fax: 240 276–4193

Email: gerie.voss@fda.hhs.gov

RIN: 0910–AG96

138. SANITARY TRANSPORTATION OF HUMAN AND ANIMAL FOOD

Legal Authority: 21 USC 350e; 21 USC 373; 21 USC 331; 21 USC 342; 21 USC 371; . . .

Abstract: This rule would establish requirements for 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 End	05/31/14	
Final Rule	03/00/16	

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

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139. RADIOLOGY DEVICES; DESIGNATION OF SPECIAL CONTROLS FOR THE COMPUTED TOMOGRAPHY X–RAY SYSTEM

Legal Authority: 21 USC 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, when combined with the general controls, would provide reasonable assurance of the safety and effectiveness of a class II CT X-ray system.

Timetable:

Action	Date	FR Cite
NPRM	12/00/14	

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

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140. MAMMOGRAPHY QUALITY STANDARDS ACT; REGULATORY AMENDMENTS

Legal Authority: 21 USC 360i; 21 USC 360nn; 21 USC 374(e); 42 USC 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, such as breast density reporting, that have occurred since the regulations were published in 1997.

Timetable:

Action	Date	FR Cite
NPRM	12/00/14	

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

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141. • INVESTIGATIONAL NEW DRUG APPLICATION ANNUAL REPORTING

Legal Authority: 21 USC 355(i); 21 USC 371(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 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	03/00/15	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Peter A. Taschenberger, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, 10903 New Hampshire Avenue, Building 51, Room 6312, Silver Spring, MD 20993

Phone: 301 796–0018

Fax: 301 847–3529

Email: peter.taschenberger@fda.hhs.gov

RIN: 0910–AH07

Department of Health and Human Services (HHS)	Final Rule Stage

Food and Drug Administration (FDA)	

142. CONTENT AND FORMAT OF LABELING FOR HUMAN PRESCRIPTION DRUGS AND BIOLOGICS; REQUIREMENTS FOR PREGNANCY AND LACTATION LABELING

Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 358; 21 USC 360; 21 USC 360b; 21 USC 360gg to 360ss; 21 USC 371; 21 USC 374; 21 USC 379e; 42 USC 216; 42 USC 241; 42 USC 262; 42 USC 264

Abstract: This final rule will amend the content and format of the "Pregnancy," "Labor and delivery," and "Nursing mothers" subsections of the "Use in Specific Populations" section of regulations regarding the labeling for human prescription drug and biological products to better communicate risks.

Timetable:

Action	Date	FR Cite
NPRM	05/29/08	73 FR 30831
NPRM Comment Period End	08/27/08	
Final Action	07/00/14	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Molly Flannery, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 51, Room 6246, 10903 New Hampshire Avenue, Silver Spring, MD 20993

Phone: 301 796–3543

Email: molly.flannery@fda.hhs.gov

RIN: 0910–AF11

143. COMBINATIONS OF BRONCHODILATORS WITH NASAL DECONGESTANTS OR EXPECTORANTS; COLD, COUGH, ALLERGY, BRONCHODILATOR, AND ANTIASTHMATIC DRUG PRODUCTS FOR OVER–THE–COUNTER HUMAN USE

Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 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. These actions address cough/cold drug products containing an oral bronchodilator (ephedrine and its salts) in combination with any expectorant or any oral nasal decongestant.

Timetable:

Action	Date	FR Cite
NPRM (Amendment)	07/13/05	70 FR 40232
NPRM Comment Period End	11/10/05	
Final Action (Technical Amendment)	03/19/07	72 FR 12730
Final Action (Oral Bronchodilator and Oral Nasal Decongestant)	12/00/14	
Final Action (Oral Bronchodilator and Expectorant)	12/00/14	

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–AF33

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144. OVER–THE–COUNTER (OTC) DRUG REVIEW—LAXATIVE DRUG PRODUCTS

Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360 to 360a; 21 USC 371 to 371a

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. The final rule listed will address the professional labeling for sodium phosphate drug products.

Timetable:

Action	**Date**	**FR Cite**
Final Action (Granular Psyllium)	03/29/07	72 FR 14669
NPRM (Professional Labeling—Sodium	02/11/11	76 FR 7743

Phosphate)		
NPRM Comment Period End	03/14/11	
Final Action (Professional Labeling—Sodium Phosphate)	12/00/14	

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–AF38

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145. LASER PRODUCTS; AMENDMENT TO PERFORMANCE STANDARD

Legal Authority: 21 USC 360hh to 360ss; 21 USC 371; 21 USC 393

Abstract: The regulation will amend the performance standard for laser products to achieve closer harmonization between the current standard and the 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	
Final Action	12/00/14	

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–AF87

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146. HUMAN SUBJECT PROTECTION; ACCEPTANCE OF DATA FROM CLINICAL STUDIES FOR MEDICAL DEVICES

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

Abstract: This rule will amend FDA's regulations on acceptance of data from clinical studies for medical devices to require that clinical studies conducted outside the United States 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.

Timetable:

Action	Date	FR Cite
NPRM	02/25/13	78 FR 12664
NPRM Comment Period End	05/28/13	
Final Action	12/00/14	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Sheila Anne Brown, Policy Analyst, Investigational Device Exemptions Staff, Department of Health and Human Services, Food and Drug Administration, WO 66, Room 1651, 10903 New Hampshire Avenue, Silver Spring, MD 20993

Phone: 301 796–6563

Fax: 301 847–8120

Email: sheila.brown@fda.hhs.gov

RIN: 0910–AG48

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147. FOOD LABELING: CALORIE LABELING OF ARTICLES OF FOOD SOLD IN VENDING MACHINES

Legal Authority: 21 USC 321; 21 USC 343; 21 USC 371

Abstract: FDA published a proposed rule to establish requirements for nutrition labeling of certain food items sold in certain vending machines. FDA also proposed the terms and conditions for vending machine operators registering to voluntarily be subject to the requirements. FDA is issuing a final rule, and taking this action to carry out section 4205 of the Patient Protection and Affordable Care Act.

Timetable:

Action	Date	FR Cite
NPRM	04/06/11	76 FR 19238
NPRM Comment Period End	07/05/11	
Final Action	06/00/14	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Daniel Reese, Food Technologist, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition (HFS–820), 5100 Paint Branch Parkway, College Park, MD 20740

Phone: 240 402–2126

Email: daniel.reese@fda.hhs.gov

RIN: 0910–AG56

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148. FOOD LABELING: NUTRITION LABELING OF STANDARD MENU ITEMS IN RESTAURANTS AND SIMILAR RETAIL FOOD ESTABLISHMENTS

Legal Authority: 21 USC 321; 21 USC 343; 21 USC 371

Abstract: FDA published a proposed rule in the Federal Register to establish requirements for nutrition labeling of standard menu items in chain restaurants and similar retail food establishments. FDA also proposed the terms and conditions for restaurants and similar retail food establishments registering to voluntarily be subject to the Federal requirements. FDA is issuing a final rule, and taking this action to carry out section 4205 of the Patient Protection and Affordable Care Act.

Timetable:

Action	Date	FR Cite
NPRM	04/06/11	76 FR 19192
NPRM Comment Period End	07/05/11	
Final Action	06/00/14	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Daniel Reese, Food Technologist, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition (HFS–820), 5100 Paint Branch Parkway, College Park, MD 20740

Phone: 240 402–2126

Email: daniel.reese@fda.hhs.gov

RIN: 0910–AG57

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149. REQUIREMENTS FOR THE SUBMISSION OF DATA NEEDED TO CALCULATE USER FEES FOR DOMESTIC MANUFACTURERS AND IMPORTERS OF TOBACCO PRODUCTS

Legal Authority: 21 USC 371; 21 USC 387s; PL 111–31

Abstract: This rule will require manufacturers and importers of tobacco products to submit certain market share data to FDA. USDA currently collects such data, but its program sunsets at the end of September 2014, and USDA will cease collection of this information. FDA is taking this action so that it may continue to calculate market share percentages needed to compute user fees.

Timetable:

Action	Date	FR Cite

NPRM	05/31/13	78 FR 32581
NPRM Comment Period End	08/14/13	
Final Action	06/00/14	

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, Room 340K, 9200 Corporate Boulevard, Rockville, MD 20850

Phone: 877 287–1373

Fax: 240 276–3904

Email: annette.marthaler@fda.hhs.gov

RIN: 0910–AG81

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150. SUPPLEMENTAL APPLICATIONS PROPOSING LABELING CHANGES FOR APPROVED DRUGS AND BIOLOGICAL PRODUCTS

Legal Authority: 21 USC 321; 21 USC 331; 21 USC 352; 21 USC 353; 21 USC 355; 21 USC 371; 42 USC 262; . . .

Abstract: This rule would amend the regulations regarding new drug applications (NDAs), abbreviated new drug applications (ANDAs), and biologics license applications (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. This rule would describe the process by which information regarding “changes being effected” (CBE) labeling supplement submitted by an NDA or ANDA holder would be made publicly available during FDA's review of the labeling change.

Timetable:

Action	Date	FR Cite
NPRM	11/13/13	78 FR 67985
NPRM Comment Period End	01/13/14	
Final Rule	12/00/14	

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, WO 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

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151. VETERINARY FEED DIRECTIVE

Legal Authority: 21 USC 354; 21 USC 360b; 21 USC 360ccc; 21 USC 360ccc –1; 21 USC 371

Abstract: The Animal Drug Availability Act created a new category of products called veterinary feed directive (VFD) drug. This rulemaking is intended to provide for the increased efficiency of the VFD program.

Timetable:

Action	Date	FR Cite

ANPRM	03/29/10	75 FR 15387
ANPRM Comment Period End	06/28/10	
NPRM	12/12/13	78 FR 75515
NPRM Comment Period End	03/12/14	
Final Rule	04/00/15	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Sharon Benz, Supervisory Animal Scientist, Department of Health and Human Services, Food and Drug Administration, Center for Veterinary Medicine, MPN–4, Room 2648, HFV–220, 7529 Standish Place, Rockville, MD 20855

Phone: 240 453–6864

Email: sharon.benz@fda.hhs.gov

RIN: 0910–AG95

Department of Health and Human Services (HHS)	**Long-Term Actions**
Food and Drug Administration (FDA)	

152. INFANT FORMULA: CURRENT GOOD MANUFACTURING PRACTICES; QUALITY CONTROL PROCEDURES; NOTIFICATION REQUIREMENTS; RECORDS AND REPORTS; AND QUALITY FACTORS

Legal Authority: 21 USC 321; 21 USC 342; 21 USC 350a; 21 USC 371

Abstract: The Food and Drug Administration (FDA) is revising its infant formula regulations to establish requirements for current good manufacturing practices (CGMP), including audits; to establish requirements for quality factors; and to amend FDA's quality control procedures, notification, and record and reporting requirements for infant formula. FDA is taking this action to improve the protection of infants who consume infant formula products.

Timetable:

Action	Date	FR Cite
NPRM	07/09/96	61 FR 36154
NPRM Comment Period End	12/06/96	
NPRM Comment Period Reopened	04/28/03	68 FR 22341
NPRM Comment Period Extended	06/27/03	68 FR 38247
NPRM Comment Period End	08/26/03	
NPRM Comment Period Reopened	08/01/06	71 FR 43392
NPRM Comment Period End	09/15/06	
Interim Final Rule	02/10/14	79 FR 7934
Interim Final Rule Comment Period End	03/27/14	

Final Rule	07/00/15	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Benson Silverman, Staff Director, Infant Formula and Medical Foods, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition (HFS–850), 5100 Paint Branch Parkway, College Park, MD 20740

Phone: 240 402–1459

Email: benson.silverman@fda.hhs.gov

RIN: 0910–AF27

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153. FOCUSED MITIGATION STRATEGIES TO PROTECT FOOD AGAINST INTENTIONAL ADULTERATION

Legal Authority: 21 USC 331; 21 USC 342; 21 USC 350g; 21 USC 350i; 21 USC 371; 21 USC 374; PL 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 End	03/31/14	

Final Rule	05/00/16	

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

Department of Health and Human Services (HHS)	**Completed Actions**
Food and Drug Administration (FDA)	

154. PRESCRIPTION DRUG MARKETING ACT OF 1987; PRESCRIPTION DRUG AMENDMENTS OF 1992; POLICIES, REQUIREMENTS, AND ADMINISTRATIVE PROCEDURES (COMPLETION OF A SECTION 610 REVIEW)

Legal Authority: 21 USC 331; 21 USC 333; 21 USC 351 to 353; 21 USC 360; 21 USC 371; 21 USC 374; 21 USC 381

Abstract: FDA has completed their review of the regulations promulgated under the Prescription Drug Marketing Act. The review was done to determine whether the regulations should be changed or rescinded to minimize adverse impacts on a substantial number of small entities.

Timetable:

Action	Date	FR Cite
Begin Review of Current Regulation	11/24/08	
End Review of Current Regulation	11/29/13	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Howard Muller, Office of Regulatory Policy, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 51, Room 6234, 10903 New Hampshire Avenue, Silver Spring, MD 20993–0002

Phone: 301 796–3601

Fax: 301 847–8440

Email: pdma610(c)review@fda.hhs.gov

RIN: 0910–AG14

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155. GENERAL HOSPITAL AND PERSONAL USE DEVICES: ISSUANCE OF DRAFT SPECIAL CONTROLS GUIDANCE FOR INFUSION PUMPS

Legal Authority: 21 USC 351; 21 USC 360; 21 USC 360c; 21 USC 360e; 21 USC 360j; 21 USC 371

Abstract: FDA is proposing to amend the classification of infusion pumps from class II (performance standards) to class II (special controls). FDA is taking this action to provide reasonable assurance of the safety and effectiveness of these devices.

Timetable:

Action	Date	FR Cite
Withdrawn	04/24/14	

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–AG54

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156. • FOOD LABELING: NUTRIENT CONTENT CLAIMS; ALPHA–LINOLENIC ACID, EICOSAPENTAENOIC ACID, AND DOCOSAHEXAENOIC ACID OMEGA–3 FATTY ACIDS

Legal Authority: 21 USC 343; 21 USC 371

Abstract: The final rule addresses the nutrient content claims for docosahexaenoic acid and eicosapentaenoic acid set forth in notifications submitted by (1) Alaska General Seafoods, Ocean Beauty Seafoods Inc., and Trans-Ocean Products Inc. (the seafood processors notification), (2) Martek Biosciences Corp. (the Martek notification), and (3) Ocean Nutrition Canada Ltd. The final rule also addresses the nutrient content claims for alpha-linolenic acid set forth in the seafood processors notification and the Martek notification.

Timetable:

Action	Date	FR Cite

NPRM	11/27/07	72 FR 66103
NPRM Comment Period End	02/11/08	
Final Action	04/28/14	79 FR 23262

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Vincent De Jesus, Nutritionist, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition, (HFS–830), Room 3D–031, 5100 Paint Branch Parkway, College Park, MD 20740

Phone: 240 402–1774

Fax: 301 436–1191

Email: vincent.dejesus@fda.hhs.gov

RIN: 0910–AH13

Department of Health and Human Services (HHS)	**Proposed Rule Stage**
Centers for Medicare & Medicaid Services (CMS)	

157. HOME HEALTH AGENCY CONDITIONS OF PARTICIPATION (CMS–3819–P) (RULEMAKING RESULTING FROM A SECTION 610 REVIEW)

Legal Authority: 42 USC 1302; 42 USC 1395x; 42 USC 1395cc(a); 42 USC 1395hh; 42 USC 1395bb

Abstract: This proposed rule would revise the existing Conditions of Participation that Home Health Agencies must meet to participate in the Medicare program. The new requirements would focus on the

actual care delivered to patients by HHAs, reflect an interdisciplinary view of patient care, allow HHAs greater flexibility in meeting quality standards, and eliminate unnecessary procedural requirements. These changes are an integral part of our efforts to improve patient safety and achieve broad-based improvements in the quality of care furnished through Federal programs, while at the same time reducing 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	05/00/14	

Regulatory Flexibility Analysis Required: No

Agency Contact: Danielle Shearer, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Clinical Standards & Quality, Mail Stop S3–02–01, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786–6617

Email: danielle.shearer@cms.hhs.gov

RIN: 0938–AG81

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158. HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEM FOR ACUTE CARE HOSPITALS AND THE LONG–TERM CARE HOSPITAL PROSPECTIVE PAYMENT SYSTEM AND FISCAL YEAR 2015 RATES (CMS–1607–P) (SECTION 610 REVIEW)

Legal Authority: sec 1886(d) of the Social Security Act

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

Timetable:

Action	Date	FR Cite
NPRM	05/14/14	79 FR 27977
NPRM Comment Period End	06/30/14	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Brian Slater, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mail Stop C4–07–07, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786–6229

Email: brian.slater@cms.hhs.gov

RIN: 0938–AS11

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159. CY 2015 REVISIONS TO PAYMENT POLICIES UNDER THE PHYSICIAN FEE SCHEDULE AND OTHER REVISIONS TO MEDICARE PART B (CMS–1612–P) (SECTION 610 REVIEW)

Legal Authority: Social Security Act, secs 1102, 1871 and 1848

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, 2015.

Timetable:

Action	Date	FR Cite
NPRM	06/00/14	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Kathy Bryant, Director, Division of Practitioner Services, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mail Stop C4–01–27, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786–3448

Email: kathy.bryant@cms.hhs.gov

RIN: 0938–AS12

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160. CY 2015 HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM (PPS) POLICY CHANGES AND PAYMENT RATES, AND CY 2015 AMBULATORY SURGICAL CENTER PAYMENT SYSTEM POLICY CHANGES AND PAYMENT RATES (CMS–1613–P) (SECTION 610 REVIEW)

Legal Authority: sec 1833 of the Social Security Act

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

Timetable:

Action	Date	FR Cite
NPRM	07/00/14	

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 Management, Mail Stop C4–03–06, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786–4617

Email: marjorie.baldo@cms.hhs.gov

RIN: 0938–AS15

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161. • CY 2016 NOTICE OF BENEFIT AND PAYMENT PARAMETERS (CMS–9944–P) (SECTION 610 REVIEW)

Legal Authority: PL 111–148, title I

Abstract: This proposed rule would establish the CY 2016 payment parameters for the cost-sharing reductions, advance payments of the premium tax credit, reinsurance, and risk adjustment programs as required by the Affordable Care Act.

Timetable:

Action	Date	FR Cite
NPRM	11/00/14	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Sharon Arnold, Director, Payment Policy and Financial Management Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Consumer Information & Insurance Oversight, Mail Stop 733H.02, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 301 492–4286

Email: sharon.arnold@cms.hhs.gov

RIN: 0938–AS19

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162. • 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 USC 1302; 42 USC 1395hh and 1395rr

Abstract: This proposed rule would revise the requirements that hospitals and CAHs must meet to participate in the Medicare and Medicaid programs. These changes are necessary to reflect substantial advances in healthcare delivery and in patient safety knowledge and practices, and would allow hospitals and CAHs the flexibility to implement innovative patient care practices. The changes are also an integral part of our efforts to achieve broad-based improvements in patient safety and in the quality of health care furnished through Federal programs.

Timetable:

Action	Date	FR Cite
NPRM	09/00/14	

Regulatory Flexibility Analysis Required: Yes

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

Department of Health and Human Services (HHS)	Final Rule Stage
Centers for Medicare & Medicaid Services (CMS)	

163. COVERED OUTPATIENT DRUGS (CMS–2345–F) (SECTION 610 REVIEW)

Legal Authority: PL 111– 48, secs 2501, 2503, 3301(d)(2); PL 111–152, sec 1206; PL 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	06/00/14	

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

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164. PROSPECTIVE PAYMENT SYSTEM FOR FEDERALLY QUALIFIED HEALTH CENTERS; CHANGES TO CONTRACTING POLICIES FOR RURAL HEALTH CLINICS AND CLIA ENFORCEMENT ACTIONS FOR PROFICIENCY TESTING REFERRAL (CMS–1443–FC) (SECTION 610 REVIEW)

Legal Authority: PL 111–148, sec 10501

Abstract: This final rule establishes methodology and payment rates for a prospective payment system (PPS) for Federally qualified health center (FQHC) services under Medicare Part B beginning on October 1, 2014, in compliance with the statutory requirement of the Affordable Care Act. This rule also establishes a policy which would allow rural health clinics (RHCs) to contract with nonphysician practitioners when statutory requirements for employment of nurse practitioners and physician assistants are met, and makes other technical and conforming changes to the RHC and FQHC regulations. Finally, this rule makes changes to the Clinical Laboratory Improvement Amendments (CLIA) regulations regarding enforcement actions for proficiency testing referral.

Timetable:

Action	Date	FR Cite
NPRM	09/23/13	78 FR 58386
NPRM Comment Period End	11/18/13	
Final Rule	05/02/14	79 FR 25436

Final Rule With Comment Period End	07/01/14	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Corinne Axelrod, Health Insurance Specialist, Hospital and Ambulatory Policy Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop C5–14–03, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786–5620

Email: corinne.axelrod@cms.hhs.gov

RIN: 0938–AR62

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165. ADOPTION OF OPERATING RULES FOR HIPAA TRANSACTIONS (CMS–0036–IFC)

Legal Authority: PL 104–191, sec 1104

Abstract: Under the Affordable Care Act, this interim final rule adopts operating rules for HIPAA transactions for health care claims or equivalent encounter information, enrollment and disenrollment of a health plan, health plan premium payments, and referral certification and authorization.

Timetable:

Action	Date	FR Cite
Interim Final Rule	03/00/15	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Geanelle Herring, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Administrative Simplification Group, Office of E–Health Standards and Services, Mail Stop S2–26–17, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786–4466

Email: geanelle.herring@cms.hhs.gov

RIN: 0938–AS01

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166. • EXTENSION OF PAYMENT ADJUSTMENT FOR LOW–VOLUME HOSPITALS AND THE MEDICARE–DEPENDENT HOSPITAL PROGRAM UNDER THE FY 2014 HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEM (CMS–1599–IFC2) (SECTION 610 REVIEW)

Legal Authority: PL 113–67, secs 1105 and 1106

Abstract: This interim final rule implements changes to the payment adjustment for low-volume hospitals and to the Medicare-dependent hospital program under the hospital inpatient prospective payment systems for FY 2014 (through March 31, 2014) in accordance with sections 1105 and 1106, respectively, of the Pathway for SGR Reform Act of 2013.

Timetable:

Action	Date	FR Cite
Interim Final Rule	03/18/14	79 FR 15022
Interim Final Rule Comment Period End	05/12/14	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Michele Hudson, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mail Stop C4–10–07, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786–5490

Email: michele.hudson@cms.hhs.gov

RIN: 0938–AS18

Department of Health and Human Services (HHS)	**Long-Term Actions**
Centers for Medicare & Medicaid Services (CMS)	

167. EMERGENCY PREPAREDNESS REQUIREMENTS FOR MEDICARE AND MEDICAID PARTICIPATING PROVIDERS AND SUPPLIERS (CMS–3178–F)

Legal Authority: 42 USC 1821; 42 USC 1861ff (3)(B)(i)(ii); 42 USC 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

Department of Health and Human Services (HHS)	**Completed Actions**
Centers for Medicare & Medicaid Services (CMS)	

168. CY 2014 CHANGES TO THE END–STAGE RENAL DISEASE (ESRD) PROSPECTIVE PAYMENT SYSTEM, ESRD QUALITY INCENTIVE PROGRAM, AND DURABLE MEDICAL EQUIPMENT (CMS–1526–F) (COMPLETION OF A SECTION 610 REVIEW)

Legal Authority: MIPPA; sec 153(b); PL 111–148 ; sec 3401(h); ATRA ; sec 632(a)

Abstract: This final rule updates the bundled payment system for End Stage Renal Disease (ESRD) facilities by 1/1/13. The rule also updates the Quality Incentives in the ESRD Program. In addition, this

rule clarifies the grandfathering provision related to the 3-year minimum lifetime requirement for Durable Medical Equipment (DME). It also provides clarification of the definition of routinely purchased DME.

Timetable:

Action	Date	FR Cite
NPRM	07/08/13	78 FR 40835
NPRM Comment Period End	08/30/13	
Final Action	12/02/13	78 FR 72156

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Michelle Cruse, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mail Stop C5–05–27, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786–7540

Email: michelle.cruse@cms.hhs.gov

RIN: 0938–AR55

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169. REVISIONS TO PAYMENT POLICIES UNDER THE PHYSICIAN FEE SCHEDULE AND MEDICARE PART B FOR CY 2014 (CMS–1600–FC) (COMPLETION OF A SECTION 610 REVIEW)

Legal Authority: Social Security Act, secs 1102, 1871, 1848

Abstract: This final rule revises payment polices under the Medicare physician fee schedule, and make other policy changes to payment under Medicare Part B. These changes are applicable to services furnished on or after January 1, annually.

Timetable:

Action	Date	FR Cite
NPRM	07/19/13	78 FR 43282
NPRM Comment Period End	09/06/13	
Final Action	12/10/13	78 FR 74230

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Kathy Bryant, Director, Division of Practitioner Services, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mail Stop C4–01–27, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786–3448

Email: kathy.bryant@cms.hhs.gov

RIN: 0938–AR56

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170. CY 2015 NOTICE OF BENEFIT AND PAYMENT PARAMETERS (CMS–9954–F) (COMPLETION OF A SECTION 610 REVIEW)

Legal Authority: PL 111–148

Abstract: This final rule establishes the CY 2015 payment parameters for the cost-sharing reductions, advance premium tax credit, reinsurance, and risk adjustment programs as required by the Affordable Care Act.

Timetable:

Action	Date	FR Cite
NPRM	12/02/13	78 FR 72322

NPRM Comment Period End	12/26/13	
Final Action	03/11/14	79 FR 13743
Final Action Effective	05/12/14	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Sharon Arnold, Director, Payment Policy and Financial Management Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Consumer Information & Insurance Oversight, Mail Stop 733H.02, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 301 492–4286

Email: sharon.arnold@cms.hhs.gov

RIN: 0938–AR89

[FR Doc. Filed 05–19–14; :00 am]

BILLING CODE 4150–24–S

[FR Doc. 2014-13125 Filed 06/12/2014 at 8:45 am; Publication Date: 06/13/2014]