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 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, Washington, DC 20201.

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, HHS regularly updates its main 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** only 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: August 21, 2013.

NAME: Jennifer M. Cannistra,

Executive Secretary to the Department.

Food and Drug Administration—Prerule Stage

Sequence Number	Title	Regulation Identifier Number
274	Over-the-Counter (OTC) Drug Review—Sunscreen Products	0910–AF43
275	Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements, and Administrative Procedures **(Section 610 Review)**	0910–AG14

Food and Drug Administration—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
276	Food Labeling; Revision of the Nutrition and Supplement Facts Labels **(Reg Plan Seq No. 49)**	0910–AF22
277	Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed At One-Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain RACCs **(Reg Plan**	0910–AF23

	Seq No. 50)	
278	Over-the-Counter (OTC) Drug Review—Cough/Cold (Antihistamine) Products	0910–AF31
279	Over-the-Counter (OTC) Drug Review—Internal Analgesic Products	0910–AF36
280	Updated Standards for Labeling of Pet Food	0910–AG09
281	Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals **(Reg Plan Seq No. 51)**	0910–AG10
282	Over-the-Counter (OTC) Drug Review—Pediatric Dosing for Cough/Cold Products	0910–AG12
283	Electronic Distribution of Prescribing Information for Human Prescription Drugs Including Biological Products	0910–AG18
284	Produce Safety Regulation	0910–AG35
285	Hazard Analysis and Risk-Based Preventive Controls	0910–AG36
286	"Tobacco Products" Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act **(Reg Plan Seq No. 52)**	0910–AG38
287	Requirements for the Testing and Reporting of Tobacco Product Constituents, Ingredients, and Additives	0910–AG59
288	Foreign Supplier Verification Program	0910–AG64
289	Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products **(Reg Plan Seq No. 55)**	0910–AG94
290	Veterinary Feed Directive **(Reg Plan Seq No. 56)**	0910–AG95
291	Format and Content of Reports Intended to Demonstrate Substantial Equivalence	0910–AG96
292	Radiology Devices; Designation of Special Controls for the	0910–AH03

	Computed Tomography X-Ray System	
293	Mammography Quality Standards Act; Regulatory Amendments	0910–AH04

References in boldface appear in The Regulatory Plan in part II of this issue of the **Federal Register**.

Food and Drug Administration—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
294	Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Pregnancy and Lactation Labeling	0910–AF11
295	Infant Formula: Current Good Manufacturing Practices; Quality Control Procedures; Notification Requirements; Records and Reports; and Quality Factors	0910–AF27
296	Combinations of Bronchodilators With Nasal Decongestants or Expectorants; Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use	0910–AF33
297	Laser Products; Proposed Amendment to Performance Standard	0910–AF87
298	Food Labeling: Calorie Labeling of Articles of Food Sold in Vending Machines **(Reg Plan Seq No. 57)**	0910–AG56
299	Food Labeling: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments **(Reg Plan Seq No. 58)**	0910–AG57
300	Use of Certain Symbols in Labeling	0910–AG74
301	Requirements for the Submission of Data Needed to Calculate User Fees for Manufacturers and Importers of Tobacco Products	0910–AG81

References in boldface appear in The Regulatory Plan in part II of this issue of the **Federal Register**.

Food and Drug Administration—Long-Term Actions

Sequence Number	Title	Regulation Identifier Number
302	Over-the-Counter (OTC) Drug Review—Topical Antimicrobial Drug Products	0910–AF69
303	Amendment to the Current Good Manufacturing Practice Regulations for Finished Pharmaceuticals—Second Phase	0910–AG20
304	Human Subject Protection; Acceptance of Data From Clinical Studies for Medical Devices	0910–AG48
305	Amendments to the Current Good Manufacturing Practice Regulations for Finished Pharmaceuticals—Components	0910–AG70

Food and Drug Administration—Completed Actions

Sequence Number	Title	Regulation Identifier Number
306	Unique Device Identification	0910–AG31
307	Food Labeling: Serving Sizes; Reference Amount and Serving Size Declaration for Hard Candies and Breath Mints	0910–AG82
308	Food Labeling; Gluten-Free Labeling of Foods	0910–AG84

Centers for Medicare & Medicaid Services—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
309	Emergency Preparedness Requirements for Medicare and	0938–AO91

	Medicaid Participating Providers and Suppliers (CMS-3178-P) **(Section 610 Review)**	
310	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-F) **(Section 610 Review)**	0938–AR62
311	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) **(Reg Plan Seq No. 62)**	0938–AS11
312	CY 2015 Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Medicare Part B (CMS-1612-P) **(Reg Plan Seq No. 63)**	0938–AS12
313	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) **(Reg Plan Seq No. 64)**	0938–AS15

References in boldface appear in The Regulatory Plan in part II of this issue of the **Federal Register**.

Centers for Medicare & Medicaid Services—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
314	Covered Outpatient Drugs (CMS-2345-F) **(Section 610 Review)**	0938–AQ41
315	CY 2014 Changes to the End-Stage Renal Disease (ESRD) Prospective Payment System, ESRD Quality Incentive Program, and Durable Medical Equipment (CMS-1526-F)	0938–AR55

316	Revisions to Payment Policies Under the Physician Fee Schedule and Medicare Part B for CY 2014 (CMS-1600-F)	0938–AR56
317	Adoption of Operating Rules for HIPAA Transactions(CMS-0036-IFC)	0938–AS01

Centers for Medicare & Medicaid Services—Completed Actions

Sequence Number	Title	Regulation Identifier Number
318	Changes to the Hospital Inpatient and Long-Term Care Prospective Payment System for FY 2014 (CMS-1599-F)	0938–AR53
319	Changes to the Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System for CY 2014 (CMS-1601-F)	0938–AR54

Department of Health and Human Services (HHS)	**Prerule Stage**
Food and Drug Administration (FDA)	

274. 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	
ANPRM (Safety)	06/00/14	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: David Eng, Regulatory Project Manager, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 22, Room 5487, 10903 New Hampshire Avenue, Silver Spring, MD 20993

Phone: 301 796–2773

Fax: 301 796–9899

Email: david.eng@fda.hhs.gov

RIN: 0910–AF43

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275. PRESCRIPTION DRUG MARKETING ACT OF 1987; PRESCRIPTION DRUG AMENDMENTS OF 1992; POLICIES, REQUIREMENTS, AND ADMINISTRATIVE PROCEDURES (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 is currently reviewing regulations promulgated under the Prescription Drug Marketing Act (PDMA). FDA is undertaking this review to determine whether the regulations should be changed or rescinded to minimize adverse impacts on a substantial number of small entities. FDA has extended again the completion date by 1 year and will complete the review by November 2013.

Timetable:

Action	Date	FR Cite
Begin Review of Current Regulation	11/24/08	
End Review of Current Regulation	11/00/13	

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

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

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

Regulatory Plan: This entry is Seq. No. 49 in part II of this issue of the **Federal Register**.

RIN: 0910–AF22

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277. FOOD LABELING: SERVING SIZES OF FOODS THAT CAN REASONABLY BE CONSUMED AT ONE–EATING OCCASION; DUAL–COLUMN LABELING; UPDATING, MODIFYING, AND ESTABLISHING CERTAIN RACCS

Regulatory Plan: This entry is Seq. No. 50 in part II of this issue of the **Federal Register**.

RIN: 0910–AF23

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278. 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)	12/00/13	

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

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RIN: 0910–AF31

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279. 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)	07/00/14	
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

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RIN: 0910–AF36

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280. 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	06/00/14	

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

Regulatory Plan: This entry is Seq. No. 51 in part II of this issue of the **Federal Register**.

RIN: 0910–AG10

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282. 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	06/00/14	

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

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Fax: 301 796–9899

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RIN: 0910–AG12

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283. 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	01/00/14	

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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284. PRODUCE SAFETY REGULATION

Legal Authority: 21 USC 342; 21 USC 350h; 21 USC 371; 42 USC 264; PL 111–353 (signed on Jan. 4, 2011)

Abstract: FDA is proposing to 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 proposed 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 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	03/14/14	

Extended End		

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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285. HAZARD ANALYSIS AND RISK–BASED PREVENTIVE CONTROLS

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

Abstract: This proposed 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	

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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286. "TOBACCO PRODUCTS" SUBJECT TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT, AS AMENDED BY THE FAMILY SMOKING PREVENTION AND TOBACCO CONTROL ACT

Regulatory Plan: This entry is Seq. No. 52 in part II of this issue of the **Federal Register**.

RIN: 0910–AG38

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287. 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	12/00/13	

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

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288. 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: FDA is proposing regulations that describe 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	

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

Regulatory Plan: This entry is Seq. No. 55 in part II of this issue of the **Federal Register**.

RIN: 0910–AG94

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290. VETERINARY FEED DIRECTIVE

Regulatory Plan: This entry is Seq. No. 56 in part II of this issue of the **Federal Register**.

RIN: 0910–AG95

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291. 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	03/00/14	

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

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RIN: 0910–AG96

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

Legal Authority: 21 USC 360

Abstract: The proposed rule would establish special controls for the computed tomography (CT) X-ray system, a class II device as defined in 21 CFR 892.1750. 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, or, in extremely high doses, radiation poisoning. Therefore, the design of a CT X-ray system needs to 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 special controls, combined with the general controls, to provide reasonable assurance of the safety and effectiveness of a class II CT X-ray system.

Timetable:

Action	Date	FR Cite
NPRM	05/00/14	

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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293. 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	12/00/13	

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

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RIN: 0910–AH04

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

294. 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 (21 CFR 201.56 and 201.57) 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	05/00/14	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AF11

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295. 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 in 21 CFR parts 106 and 107 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	
Final Rule	11/00/13	

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

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RIN: 0910–AF27

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296. 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. This action addresses 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	06/00/14	

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

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RIN: 0910–AF33

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297. LASER PRODUCTS; PROPOSED AMENDMENT TO PERFORMANCE STANDARD

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

Abstract: FDA is proposing to 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 proposed 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	06/00/14	

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

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RIN: 0910–AF87

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

Regulatory Plan: This entry is Seq. No. 57 in part II of this issue of the **Federal Register**.

RIN: 0910–AG56

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

Regulatory Plan: This entry is Seq. No. 58 in part II of this issue of the **Federal Register**.

RIN: 0910–AG57

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300. USE OF CERTAIN SYMBOLS IN LABELING

Legal Authority: sec 502(c) of the Food Drug and Cosmetic Act (FD&C Act), 21 USC 352(c); sec 514(c) of FD&C Act, 21 USC 360d(c), enacted by the Food and Drug Modernization Act of 1997 (FDAMA)

Abstract: The purpose of this rule is to allow for the inclusion of certain stand-alone symbols contained in a standard that FDA recognizes, provided that such symbols are explained in a symbols glossary that contemporaneously accompanies the medical device.

Timetable:

Action	Date	FR Cite
NPRM	04/19/13	78 FR 23508
NPRM Comment Period End	06/18/13	
Final Action	04/00/14	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Mary Follette Story, Human Factors and Accessible Medical Technology Specialist, Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, Room 2553, 10903 New Hampshire Avenue, Silver Spring, MD 20993

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Email: molly.story@fda.hhs.gov

RIN: 0910–AG74

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

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

Abstract: FDA is proposing to 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

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RIN: 0910–AG81

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

302. 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 consumer hand wash 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)	12/00/14	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: David Eng, Regulatory Project Manager, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 22, Room 5487, 10903 New Hampshire Avenue, Silver Spring, MD 20993

Phone: 301 796–2773

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Email: david.eng@fda.hhs.gov

RIN: 0910–AF69

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303. AMENDMENT TO THE CURRENT GOOD MANUFACTURING PRACTICE REGULATIONS FOR FINISHED PHARMACEUTICALS—SECOND PHASE

Legal Authority: 21 USC 321; 21 USC 351; 21 USC 352; 21 USC 355; 21 USC 360b; 21 USC 371; 21 USC 374; 42 USC 262; 42 USC 264

Abstract: FDA will revise regulations for "current good manufacturing practice" for oversight and controls over the manufacture of drugs to ensure quality, including managing the risk of and establishing the safety of raw materials, materials used in the manufacturing of drugs, and finished drug products. This revision will update and harmonize requirements and improve detection and response to emerging product safety and quality signals.

Timetable:

Action	Date	FR Cite
NPRM	11/00/14	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Paula Katz, Regulatory Counsel, Office of Compliance, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 51, Room 4314, 10903 New Hampshire Avenue, Silver Spring, MD 20993

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RIN: 0910–AG20

304. 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 conducted in support of a premarket approval application, humanitarian device exemption application, an investigational device exemption application, or a premarket notification submission for a medical device.

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

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RIN: 0910–AG48

305. AMENDMENTS TO THE CURRENT GOOD MANUFACTURING PRACTICE REGULATIONS FOR FINISHED PHARMACEUTICALS—COMPONENTS

Legal Authority: 21 USC 321; 21 USC 351; 21 USC 352; 21 USC 355; 21 USC 360b; 21 USC 360bbb–7; 21 USC 371; 21 USC 374; 42 USC 262; 42 USC 264

Abstract: FDA will revise regulations for "current good manufacturing practice" with regard to the control over components used in manufacturing finished pharmaceuticals.

Timetable:

Action	Date	FR Cite
NPRM	11/00/14	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Brian Hasselbalch, Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 51, Room 4364, 10903 New Hampshire Avenue, Silver Spring, MD 20993

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RIN: 0910–AG70

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

306. UNIQUE DEVICE IDENTIFICATION

Legal Authority: 21 USC 351; 21 USC 352; 21 USC 360; 21 USC 360h; 21 USC 360i; 21 USC 360j; 21 USC 360l; 21 USC 371

Abstract: FDA is issuing a final rule establishing a unique device identification system for medical devices. A unique device identification system would allow healthcare professionals and others to rapidly

and precisely identify a device and obtain important information concerning the device and would reduce medical errors.

Timetable:

Action	Date	FR Cite
NPRM	07/10/12	77 FR 40735
NPRM Comment Period End	11/07/12	
Second NPRM	11/19/12	77 FR 69393
Second NPRM Comment Period End	12/19/13	
Final Action	09/24/13	78 FR 58786

Regulatory Flexibility Analysis Required: Yes

Agency Contact: John J. Crowley, Senior Advisor for Patient Safety, Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, WO 66, Room 2315, 10903 New Hampshire Avenue, Silver Spring, MD 20993

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Email: jay.crowley@fda.hhs.gov

RIN: 0910–AG31

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307. FOOD LABELING: SERVING SIZES; REFERENCE AMOUNT AND SERVING SIZE DECLARATION FOR HARD CANDIES AND BREATH MINTS

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

Abstract: FDA is proposing to change the nutrition label serving size for breath mints to one unit. FDA is taking this action in response to a citizen petition that requested a serving size for breath mints that more accurately reflects the amount customarily consumed per eating occasion and comments received on an advance notice of proposed rulemaking published in 2005.

Timetable:

Action	Date	FR Cite

NPRM	12/30/97	62 FR 67775
NPRM Comment Period End	03/16/98	
ANPRM	04/05/05	70 FR 17010
ANPRM Comment Period End	06/20/05	
Withdrawn and Merged with 0910–AF23	08/14/13	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Mark Kantor, Nutritionist, Department of Health and Human Services, Food and Drug Administration, HFS–830, 5100 Paint Branch Parkway, College Park, MD 20740

Phone: 240 402–1450

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Email: mark.kantor@fda.hhs.gov

RIN: 0910–AG82

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308. FOOD LABELING; GLUTEN–FREE LABELING OF FOODS

Legal Authority: title II of PL 108–282; 21 USC 321; 21 USC 331; 21 USC 342; 21 USC 343; 21 USC 348; 21 USC 371

Abstract: FDA is amending its regulations to define the term “gluten-free” for voluntary use in the labeling of foods. FDA is taking this action to assist persons who have celiac disease to more easily identify foods that they can eat while following a “gluten-free” diet.

Timetable:

Action	Date	FR Cite
NPRM	01/23/07	72 FR 2795
NPRM Comment Period End	04/23/07	
NPRM Comment Period Reopened	08/03/11	76 FR 46671

NPRM Comment Period Reopened End	10/03/11	
Final Action	08/05/13	78 FR 47154

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Felicia Billingslea, Director, Food Labeling and Standard Staff, Department of Health and Human Services, Food and Drug Administration, Room 4D045, HFS 820, 5100 Paint Branch Parkway, College Park, MD 20740

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RIN: 0910–AG84

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

309. EMERGENCY PREPAREDNESS REQUIREMENTS FOR MEDICARE AND MEDICAID PARTICIPATING PROVIDERS AND SUPPLIERS (CMS–3178–P) (SECTION 610 REVIEW)

Legal Authority: 42 USC 1821; 42 USC 1861 (ff) (3)(B)(i)(ii); 42 USC 1913 (c)(1) et al

Abstract: This rule proposes 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 would ensure 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	11/00/13	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Janice Graham, Health Insurance Specialist, Clincal Standards Group, 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

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RIN: 0938–AO91

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310. 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–F) (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 Action	08/00/14	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Sarah Harding, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mail Stop C4–01–26, 7500 Security Boulevard, Windsor Mill, MD 21244

Phone: 410 786–4001

Email: sarah.harding@cms.hhs.gov

RIN: 0938–AR62

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311. • 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)

Regulatory Plan: This entry is Seq. No. 62 in part II of this issue of the **Federal Register**.

RIN: 0938–AS11

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312. • CY 2015 REVISIONS TO PAYMENT POLICIES UNDER THE PHYSICIAN FEE SCHEDULE AND OTHER REVISIONS TO MEDICARE PART B (CMS–1612–P)

Regulatory Plan: This entry is Seq. No. 63 in part II of this issue of the **Federal Register**.

RIN: 0938–AS12

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313. • 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)

Regulatory Plan: This entry is Seq. No. 64 in part II of this issue of the **Federal Register**.

RIN: 0938–AS15

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

Centers for Medicare & Medicaid Services (CMS)	

314. 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	05/00/14	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AQ41

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315. CY 2014 CHANGES TO THE END–STAGE RENAL DISEASE (ESRD) PROSPECTIVE PAYMENT SYSTEM, ESRD QUALITY INCENTIVE PROGRAM, AND DURABLE MEDICAL EQUIPMENT (CMS–1526–F)

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	11/00/13	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AR55

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316. REVISIONS TO PAYMENT POLICIES UNDER THE PHYSICIAN FEE SCHEDULE AND MEDICARE PART B FOR CY 2014 (CMS–1600–F)

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	11/00/13	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Kathy Bryant, Deputy 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

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RIN: 0938–AR56

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317. • 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	06/00/14	

Regulatory Flexibility Analysis Required: Yes

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

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RIN: 0938–AS01

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

(CMS)	

318. CHANGES TO THE HOSPITAL INPATIENT AND LONG–TERM CARE PROSPECTIVE PAYMENT SYSTEM FOR FY 2014 (CMS–1599–F)

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

Abstract: This annual 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	05/10/13	78 FR 27485
NPRM Comment Period End	06/25/13	
Final Action	08/19/13	78 FR 50419

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AR53

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319. CHANGES TO THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM AND AMBULATORY SURGICAL CENTER PAYMENT SYSTEM FOR CY 2014 (CMS–1601–F)

Legal Authority: sec 1833 of the Social Security Act

Abstract: This final rule revises the Medicare hospital outpatient prospective payment system to implement applicable statutory requirements and changes arising from our continuing experience with this system. The rule also describes changes to the amounts and factors used to determine payment rates for services. In addition, the rule finalizes changes to the Ambulatory Surgical Center Payment System list of services and rates.

Timetable:

Action	Date	FR Cite
NPRM	07/19/13	78 FR 43534
NPRM Comment Period End	09/06/13	
Final Action	09/06/13	78 FR 54842

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AR54

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