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<PARTNO>VII

<AGENCY TYPE='P'>Department of Health and Human Services

<TITLE>Semiannual Regulatory Agenda

<PRORULE>

<PREAMB>

<AGENCY TYPE='S'>DEPARTMENT OF HEALTH AND HUMAN SERVICES

<SUBAGY>Office of the Secretary

<CFR>21 CFR Ch. I

<CFR>25 CFR Ch. V

<CFR>42 CFR Chs. I-V

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

<SUBJECT>Regulatory Agenda

AGENCY: Office of the Secretary, HHS.

ACTION: Semiannual Regulatory Agenda.

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

FOR FURTHER INFORMATION CONTACT: C'Reda J. Weeden, Executive Secretary, Department of Health and Human Services, 200 Independence Avenue SW., Washington, DC 20201; (202) 690-5627.

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

This Agenda presents the rulemaking activities that the Department expects to undertake this year 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.

In the rules outlined for this Agenda, HHS continues its work to build a better, smarter, and stronger health care delivery system. Our aspiration is for patients to receive higher quality of care, for medical information to be easy to understand, and for health care dollars to be spent more

wisely. We welcome the opportunity to build a more transparent health care delivery system and strengthen partnerships with patients, physicians, governments, and businesses. We continue our work by helping more people get and keep health insurance coverage and making health care more affordable for working families.

In addition, HHS strives to lead in the advancement of scientific knowledge and innovation to enable our nation's scientists and researchers to continue making new and improved vaccines, cures, therapies, and rapid diagnostics. The accompanying regulations promote advancements in science, research, and innovation to attract the best experts to accelerate cures; reduce administrative burdens and duplication; and promote data sharing to protect the health of the American people.

HHS has an agency-wide effort to support the Agenda's purpose of encouraging more effective public participation in the regulatory process and promote increase transparency to the public regarding our regulatory activity. 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 also provides a "regulations toolkit" with background information on regulations, the commenting process, how public comments influence the development of a rule, and how the public can provide effective comments. HHS also actively encourages meaningful public participation in its retrospective review of regulations, through a comment form on the HHS retrospective review webpage (http://www.HHS.gov/RetrospectiveReview).

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

<SIG>

<NAME>C'Reda J. Weeden,

<TITLE>Executive Secretary to the Department.</SIG>

Substance Abuse and Mental Health Services Administration—Completed Actions

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

Food and Drug Administration—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
100	Over-the-Counter (OTC) Drug Review—Cough/Cold (Antihistamine) Products	0910–AF31
101	Over-the-Counter (OTC) Drug Review—Topical Antimicrobial Drug Products	0910–AF69
102	Abbreviated New Drug Applications and 505(b)(2)	0910–AF97
103	Updated Standards for Labeling of Pet Food	0910–AG09
104	Electronic Distribution of Prescribing Information for Human Prescription Drugs Including Biological Products	0910–AG18
105	Requirements for the Testing and Reporting of Tobacco Product Constituents, Ingredients, and Additives	0910–AG59
106	Format and Content of Reports Intended to Demonstrate Substantial Equivalence	0910–AG96
107	Food Labeling; Gluten-Free Labeling of Fermented, Hydrolyzed, or Distilled Foods	0910–AH00
108	Radiology Devices; Designation of Special Controls for the	0910–AH03

	Computed Tomography X-Ray System	
109	Mammography Quality Standards Act; Regulatory Amendments	0910–AH04
110	Investigational New Drug Application Annual Reporting	0910–AH07
111	General and Plastic Surgery Devices: Sunlamp Products	0910–AH14
112	Requirements for Tobacco Product Manufacturing Practice	0910–AH22

Food and Drug Administration—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
113	Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs, Including Drugs That Are Regulated Under a Biologics License Application, and Animal Drugs	0910–AA49
114	Food Labeling; Revision of the Nutrition and Supplement Facts Labels	0910–AF22
115	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
116	Laser Products; Amendment to Performance Standard	0910–AF87
117	Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals	0910–AG10
118	Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption	0910–AG35
119	Current Good Manufacturing and Hazard Analysis, and Risk-Based Preventive Controls for Human Food	0910–AG36
120	“Tobacco Products” Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention	0910–AG38

	and Tobacco Control Act	
121	Human Subject Protection; Acceptance of Data From Clinical Investigations for Medical Devices	0910–AG48
122	Foreign Supplier Verification Program	0910–AG64
123	Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products	0910–AG94
124	Veterinary Feed Directive	0910–AG95
125	Sanitary Transportation of Human and Animal Food	0910–AG98

Food and Drug Administration—Long-Term Actions

Sequence Number	Title	Regulation Identifier Number
126	Focused Mitigation Strategies To Protect Food Against Intentional Adulteration	0910–AG63

Food and Drug Administration—Completed Actions

Sequence Number	Title	Regulation Identifier Number
127	Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Pregnancy and Lactation Labeling	0910–AF11
128	Food Labeling: Calorie Labeling of Articles of Food Sold in Vending Machines	0910–AG56
129	Food Labeling: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments	0910–AG57

Centers for Medicare & Medicaid Services—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
130	Reform of Requirements for Long-Term Care Facilities (CMS-3260-P) **<E T='02'>(Rulemaking Resulting From a Section 610 Review)</E>**	0938–AR61
131	Electronic Health Record (EHR) Incentive Programs—Stage 3 (CMS-3310-F) **<E T='02'>(Section 610 Review)</E>**	0938–AS26
132	Medicare Clinical Diagnostic Laboratory Test Payment System (CMS-1621-P) **<E T='02'>(Section 610 Review)</E>**	0938–AS33
133	CY 2016 Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Medicare Part B (CMS-1631-P)	0938–AS40
134	Hospital Inpatient Prospective Payment System for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and FY 2016 Rates (CMS-1632-F)	0938–AS41
135	CY 2016 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates (CMS-1633-P)	0938–AS42
136	FY 2016 Inpatient Rehabilitation Facility Prospective Payment System (CMS-1624-F) **<E T='02'>(Section 610 Review)</E>**	0938–AS45
137	Electronic Health Record Incentive Program—Modifications to Meaningful Use in 2015 through 2017 (CMS-3311-F) **<E T='02'>(Section 610 Review)</E>**	0938–AS58

Centers for Medicare & Medicaid Services—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number

138	Covered Outpatient Drugs (CMS-2345-F) **<E T='02'>(Section 610 Review)</E>**	0938–AQ41

Centers for Medicare & Medicaid Services—Long-Term Actions

Sequence Number	Title	Regulation Identifier Number
139	Home Health Agency Conditions of Participation (CMS-3819-F) **<E T='02'>(Rulemaking Resulting From a Section 610 Review)</E>**	0938–AG81
140	Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers (CMS-3178-F) **<E T='02'>(Section 610 Review)</E>**	0938–AO91
141	Medicare Shared Savings Program; Accountable Care Organizations (CMS-1461-F) **<E T='02'>(Section 610 Review)</E>**	0938–AS06
142	Hospital and Critical Access Hospital (CAH) Changes to Promote Innovation, Flexibility, and Improvement in Patient Care (CMS-3295-P) **<E T='02'>(Rulemaking Resulting From a Section 610 Review)</E>**	0938–AS21

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<HD1>Department of Health and Human Services (HHS)

<HD2>Substance Abuse and Mental Health Services Administration (SAMHSA)

<HD3>Completed Actions

<HD1>99. SAMHSA USER FEES FOR PUBLICATIONS

Legal Authority: 31 U.S.C. 9701; 31 U.S.C. 1111; E.O. 8284; E.O. 11541; Pub. L. 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
Withdrawn	03/19/15	

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

<Q P='20'>

<HD1>Department of Health and Human Services (HHS)

<HD2>Food and Drug Administration (FDA)

<HD3>Proposed Rule Stage

<HD1>100. OVER–THE–COUNTER (OTC) DRUG REVIEW—COUGH/COLD (ANTIHISTAMINE) PRODUCTS

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

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

Timetable:

Action	Date	FR Cite
Reopening of Administrative Record	08/25/00	65 FR 51780
Comment Period End	11/24/00	
NPRM (Amendment) (Common Cold)	09/00/15	

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–AF31

<HD1>101. OVER–THE–COUNTER (OTC) DRUG REVIEW—TOPICAL ANTIMICROBIAL DRUG PRODUCTS

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

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective, and not misbranded. After a final monograph (i.e., final rule) is issued,

only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action addresses antimicrobial agents in 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)	05/01/15	80 FR 25166
NPRM Comment Period End	10/28/15	

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

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Fax: 301 796–9899

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RIN: 0910–AF69

<HD1>102. ABBREVIATED NEW DRUG APPLICATIONS AND 505(B)(2)

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

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

Timetable:

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

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

<HD1>103. UPDATED STANDARDS FOR LABELING OF PET FOOD

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

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

Timetable:

Action	Date	FR Cite
NPRM	09/00/15	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: William Burkholder, Veterinary Medical Officer, Department of Health and Human Services, Food and Drug Administration, Center for Veterinary Medicine, MPN–4, Room 2642, HFV–228,

7519 Standish Place, Rockville, MD 20855

Phone: 240 402–5900

Email: william.burkholder@fda.hhs.gov

RIN: 0910–AG09

<HD1>104. ELECTRONIC DISTRIBUTION OF PRESCRIBING INFORMATION FOR HUMAN PRESCRIPTION DRUGS INCLUDING BIOLOGICAL PRODUCTS

Legal Authority: 21 U.S.C. 321; 21 U.S.C. 331; 21 U.S.C. 351; 21 U.S.C. 352; 21 U.S.C. 353; 21 U.S.C. 355; 21 U.S.C. 358; 21 U.S.C. 360; 21 U.S.C. 360b; 21 U.S.C. 360gg to 360ss; 21 U.S.C. 371; 21 U.S.C. 374; 21 U.S.C. 379e; 42 U.S.C. 216; 42 U.S.C. 241; 42 U.S.C. 262; 42 U.S.C. 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	12/18/14	79 FR 75506
NPRM Comment Period Extended	03/09/15	80 FR 12364
NPRM Comment Period End	03/18/15	
NPRM Comment Period Extended End	05/18/15	
Final Action	03/00/16	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Emily Gebbia, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, 10903 New Hampshire Avenue, Building 51, Room 6226, Silver Spring, MD 20993

Phone: 240 402–0980

Email: emily.gebbia@fda.hhs.gov

RIN: 0910–AG18

<HD1>105. REQUIREMENTS FOR THE TESTING AND REPORTING OF TOBACCO PRODUCT CONSTITUENTS, INGREDIENTS, AND ADDITIVES

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

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

Timetable:

Action	Date	FR Cite
NPRM	02/00/16	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Laura Rich, Senior Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Tobacco Products, 10903 New Hampshire Avenue, Building 71, G335, Silver Spring, MD 20993

Phone: 877 287–1373

Email: ctpregulations@fda.hhs.gov

RIN: 0910–AG59

<HD1>106. FORMAT AND CONTENT OF REPORTS INTENDED TO DEMONSTRATE SUBSTANTIAL EQUIVALENCE

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

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

and act on these submissions.

Timetable:

Action	Date	FR Cite
NPRM	11/00/15	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Annette L. Marthaler, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Tobacco Products, Document Control Center, Building 71, Room G335, 10903 New Hampshire Avenue, Silver Spring , MD 20993

Phone: 877 287–1373

Fax: 877 287–1426

Email: ctpregulations@fda.hhs.gov

RIN: 0910–AG96

<HD1>107. FOOD LABELING; GLUTEN–FREE LABELING OF FERMENTED, HYDROLYZED, OR DISTILLED FOODS

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

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

Timetable:

Action	Date	FR Cite
NPRM	05/00/15	

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

Phone: 240 402–1803

Fax: 301 436–2636

Email: felicia.billingslea@fda.hhs.gov

RIN: 0910–AH00

<HD1>108. RADIOLOGY DEVICES; DESIGNATION OF SPECIAL CONTROLS FOR THE COMPUTED TOMOGRAPHY X–RAY SYSTEM

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

Abstract: The proposed rule would establish special controls for the computed tomography (CT) X-ray system. A CT X-ray system is a diagnostic X-ray imaging system intended to produce cross-sectional images of the body through use of a computer to reconstruct an image from the same axial plane taken at different angles. High doses of ionizing radiation can cause acute (deterministic) effects such as burns, reddening of the skin, cataracts, hair loss, sterility, and, in extremely high doses, radiation poisoning. The design of a CT X-ray system should balance the benefits of the device (i.e., the ability of the device to produce a diagnostic quality image) with the known risks (e.g., exposure to ionizing radiation). FDA is establishing proposed special controls, which, 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	03/00/16	

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

<HD1>109. MAMMOGRAPHY QUALITY STANDARDS ACT; REGULATORY AMENDMENTS

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

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

Timetable:

Action	Date	FR Cite
NPRM	10/00/15	

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

<HD1>110. INVESTIGATIONAL NEW DRUG APPLICATION ANNUAL REPORTING

Legal Authority: 21 U.S.C. 355(i); 21 U.S.C. 371(a); 42 U.S.C. 262(a)

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

Timetable:

Action	Date	FR Cite
NPRM	12/00/15	

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

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RIN: 0910–AH07

<HD1>111. GENERAL AND PLASTIC SURGERY DEVICES: SUNLAMP PRODUCTS

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

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

Timetable:

Action	Date	FR Cite
NPRM	05/00/15	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Paul Gadiock, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, 10903 New Hampshire Avenue, W0–66, Room 4432, Silver Spring, MD 20993–0002

Phone: 301 796–5736

Fax: 301 847–8145

Email: paul.gadiock@fda.hhs.gov

RIN: 0910–AH14

<HD1>112. • REQUIREMENTS FOR TOBACCO PRODUCT MANUFACTURING PRACTICE

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

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

Timetable:

Action	Date	FR Cite
ANPRM	03/19/13	78 FR 16824
ANPRM Comment Period End	05/20/13	
NPRM	02/00/16	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Darin Achilles, Senior Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, 10903 New Hampshire Avenue, Document Control Center, Building 71, Room G335, Silver Spring , MD 20993

Phone: 877 287–1373

Fax: 301 595–1426

Email: ctpregulations@fda.hhs.gov

RIN: 0910–AH22

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<HD1>Department of Health and Human Services (HHS)

<HD2>Food and Drug Administration (FDA)

<HD3>Final Rule Stage

<HD1>113. REQUIREMENTS FOR FOREIGN AND DOMESTIC ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN DRUGS, INCLUDING DRUGS THAT ARE REGULATED UNDER A BIOLOGICS LICENSE APPLICATION, AND ANIMAL DRUGS

Legal Authority: 21 U.S.C. 321 and 331; 21 U.S.C. 351 to 353; 21 U.S.C. 355 to 356c; 21 U.S.C. 360 and 360b; 21 U.S.C. 360c to 360f; 21 U.S.C. 360h to 360j; 21 U.S.C. 371 and 374; 21 U.S.C. 379e and 381; 21 U.S.C. 393; 15 U.S.C. 1451 to 1561; 42 U.S.C. 262 and 264; 42 U.S.C. 271

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

Timetable:

Action	Date	FR Cite
NPRM	08/29/06	71 FR 51276
NPRM Comment Period End	02/26/07	
Final Action	10/00/15	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: David Joy, Senior Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, WO 51, Room 6254, 10903 New Hampshire Avenue, Silver Spring, MD 20993

Phone: 301 796–2242

Email: david.joy@fda.hhs.gov

RIN: 0910–AA49

<HD1>114. FOOD LABELING; REVISION OF THE NUTRITION AND SUPPLEMENT FACTS LABELS

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

Abstract: FDA is amending the labeling regulations for conventional foods and dietary supplements to provide updated nutrition information on the label to assist consumers in maintaining healthy dietary practices. 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	01/31/08	

Period End		
NPRM	03/03/14	79 FR 11879
NPRM Comment Period End	06/02/14	
Final Action	03/00/16	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Blakeley Fitzpatrick, Interdisciplinary Scientist, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition (HFS–830), HFS–830, 5100 Paint Branch Parkway, College Park, MD 20740

Phone: 240 402–5429

Email: nutritionprogramstaff@fda.hhs.gov

RIN: 0910–AF22

<HD1>115. FOOD LABELING: SERVING SIZES OF FOODS THAT CAN REASONABLY BE CONSUMED AT ONE–EATING OCCASION; DUAL–COLUMN LABELING; UPDATING, MODIFYING, AND ESTABLISHING CERTAIN RACCS

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

Abstract: FDA is amending its labeling regulations for foods to provide updated Reference Amounts Customarily Consumed (RACCs) for certain food categories. This rule would provide consumers with nutrition information based on the amount of food that is customarily consumed, which would assist consumers in maintaining healthy dietary practices. In addition to updating certain RACCs, FDA is also amending the definition of single-serving containers; amending the label serving size for breath mints; and providing for dual-column labeling, which would provide nutrition information per serving and per container or unit, 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	
Final Action	03/00/16	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AF23

<HD1>116. LASER PRODUCTS; AMENDMENT TO PERFORMANCE STANDARD

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

Abstract: 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	04/00/16	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AF87

<HD1>117. CURRENT GOOD MANUFACTURING PRACTICE AND HAZARD ANALYSIS AND RISK–BASED PREVENTIVE CONTROLS FOR FOOD FOR ANIMALS

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

Abstract: This rule establishes requirements for good manufacturing practice, and requires 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 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 Extension End	03/31/14	
Supplemental NPRM	09/29/14	79 FR 58475
Supplemental NPRM Comment Period End	12/15/14	
Final Rule	08/00/15	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AG10

<HD1>118. STANDARDS FOR THE GROWING, HARVESTING, PACKING, AND HOLDING OF PRODUCE FOR HUMAN CONSUMPTION

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

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

Timetable:

Action	**Date**	**FR Cite**
NPRM	01/16/13	78 FR 3503
NPRM Comment Period End	05/16/13	
NPRM Comment Period Extended	04/26/13	78 FR 24692
NPRM Comment Period Extended End	09/16/13	
NPRM Comment Period Extended	08/09/13	78 FR 48637
NPRM Comment Period Extended End	11/15/13	
Notice of Intent To Prepare an Environmental Impact Statement for the Proposed Rule	08/19/13	78 FR 50358
Notice of Intent To Prepare Environmental Impact	11/15/13	

Statement for the Proposed Rule Comment Period End		
NPRM Comment Period Extended	11/20/13	78 FR 69605
NPRM Comment Period Extended End	11/22/13	
Environmental Impact Statement for the Proposed Rule; Comment Period Extended	03/11/14	79 FR 13593
Environmental Impact Statement for the Proposed Rule; Comment Period Extended End	04/18/14	
Supplemental NPRM	09/29/14	79 FR 58433
Supplemental NPRM Comment Period End	12/15/14	
Draft Environmental Impact Statement	01/14/15	80 FR 1852
Draft Environmental Impact Statement Comment Period End	03/13/15	
Final Rule	10/00/15	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AG35

<HD1>119. CURRENT GOOD MANUFACTURING AND HAZARD ANALYSIS, AND RISK–BASED PREVENTIVE CONTROLS FOR HUMAN FOOD

Legal Authority: 21 U.S.C. 342; 21 U.S.C. 371; 42 U.S.C. 264; Pub. L. 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	09/29/14	79 FR 58523
Supplemental NPRM Comment Period End	12/15/14	

Final Rule	08/00/15	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AG36

<HD1>120. "TOBACCO PRODUCTS" SUBJECT TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT, AS AMENDED BY THE FAMILY SMOKING PREVENTION AND TOBACCO CONTROL ACT

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

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

Timetable:

Action	Date	FR Cite
NPRM	04/25/14	79 FR 23142
NPRM Comment Period End	07/09/14	
NPRM Comment Period Extended	06/24/14	79 FR 35711
NPRM Comment Period End	08/08/14	
Final Action	06/00/15	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AG38

<HD1>121. HUMAN SUBJECT PROTECTION; ACCEPTANCE OF DATA FROM CLINICAL INVESTIGATIONS FOR MEDICAL DEVICES

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

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

Timetable:

Action	Date	FR Cite
NPRM	02/25/13	78 FR 12664
NPRM Comment Period End	05/28/13	
Final Action	12/00/15	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AG48

<HD1>122. FOREIGN SUPPLIER VERIFICATION PROGRAM

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

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

Timetable:

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

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RIN: 0910–AG64

<HD1>123. SUPPLEMENTAL APPLICATIONS PROPOSING LABELING CHANGES FOR APPROVED DRUGS AND BIOLOGICAL PRODUCTS

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

Abstract: This rule would amend the regulations regarding new drug applications (NDAs), abbreviated new drug applications (ANDAs), and biologics license 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.

Timetable:

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

Final Rule	02/00/16	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AG94

<HD1>124. VETERINARY FEED DIRECTIVE

Legal Authority: 21 U.S.C. 354; 21 U.S.C. 360b; 21 U.S.C. 360ccc; 21 U.S.C. 360ccc –1; 21 U.S.C. 371

Abstract: The Animal Drug Availability Act created a new category of products called veterinary feed directive (VFD) drugs. 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	05/00/15	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AG95

<HD1>125. SANITARY TRANSPORTATION OF HUMAN AND ANIMAL FOOD

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

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

Timetable:

Action	Date	FR Cite
ANPRM	04/30/10	75 FR 22713
ANPRM Comment Period End	08/30/10	
NPRM	02/05/14	79 FR 7005
NPRM Comment Period Extended	05/23/14	79 FR 29699
NPRM Comment Period End	05/31/14	
NPRM Comment Period Extended End	07/30/14	
Final Rule	03/00/16	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AG98

<Q P='20'>

<HD1>Department of Health and Human Services (HHS)

<HD2>Food and Drug Administration (FDA)

<HD3>Long-Term Actions

<HD1>126. FOCUSED MITIGATION STRATEGIES TO PROTECT FOOD AGAINST INTENTIONAL ADULTERATION

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

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

Timetable:

Action	Date	FR Cite
NPRM	12/24/13	78 FR 78014
NPRM Comment Period Extended	03/25/14	79 FR 16251
NPRM Comment Period End	03/31/14	
NPRM Comment Period Extended End	06/30/14	
Final Rule	05/00/16	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AG63

<Q P='20'>

<HD1>Department of Health and Human Services (HHS)

<HD2>Food and Drug Administration (FDA)

<HD3>Completed Actions

<HD1>127. CONTENT AND FORMAT OF LABELING FOR HUMAN PRESCRIPTION DRUGS AND BIOLOGICS; REQUIREMENTS FOR PREGNANCY AND LACTATION LABELING

Legal Authority: 21 U.S.C. 321; 21 U.S.C. 331; 21 U.S.C. 351 to 353; 21 U.S.C. 355; 21 U.S.C. 358; 21 U.S.C. 360; 21 U.S.C. 360b; 21 U.S.C. 360gg to 360ss; 21 U.S.C. 371; 21 U.S.C. 374; 21 U.S.C. 379e; 42 U.S.C. 216; 42 U.S.C. 241; 42 U.S.C. 262; 42 U.S.C. 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	12/04/14	79 FR 72064

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AF11

<HD1>128. FOOD LABELING: CALORIE LABELING OF ARTICLES OF FOOD SOLD IN VENDING MACHINES

Legal Authority: 21 U.S.C. 321; 21 U.S.C. 343; 21 U.S.C. 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	12/01/14	79 FR 71259

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AG56

<HD1>129. FOOD LABELING: NUTRITION LABELING OF STANDARD MENU ITEMS IN RESTAURANTS AND SIMILAR RETAIL FOOD ESTABLISHMENTS

Legal Authority: 21 U.S.C. 321; 21 U.S.C. 343; 21 U.S.C. 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	12/01/14	79 FR 71156

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AG57

<Q P='20'>

<HD1>Department of Health and Human Services (HHS)

<HD2>Centers for Medicare & Medicaid Services (CMS)

<HD3>Proposed Rule Stage

<HD1>130. REFORM OF REQUIREMENTS FOR LONG–TERM CARE FACILITIES (CMS–3260–P) (RULEMAKING RESULTING FROM A SECTION 610 REVIEW)

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

Abstract: This proposed rule would revise the requirements that Long-Term Care facilities must meet to participate in the Medicare and Medicaid programs. These proposed changes are necessary to reflect the substantial advances that have been made over the past several years in the theory and practice of service

delivery and safety. These proposals are also an integral part of our efforts to achieve broad-based improvements both in the quality of health care furnished through Federal programs, and in patient safety, while at the same time reducing procedural burdens on providers.

Timetable:

Action	Date	FR Cite
NPRM	06/00/15	

Regulatory Flexibility Analysis Required: Yes

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

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RIN: 0938–AR61

<HD1>131. ELECTRONIC HEALTH RECORD (EHR) INCENTIVE PROGRAMS—STAGE 3 (CMS–3310–F) (SECTION 610 REVIEW)

Legal Authority: Pub. L. 111–5, title IV of Division B

Abstract: This final rule specifies the meaningful use criteria that eligible professionals (EPs), eligible hospitals, and critical access hospitals (CAHs) must meet in order to qualify for Medicare and/or Medicaid electronic health record (EHR) incentive payments and avoid downward payment adjustments under Medicare for Stage 3 of the EHR Incentive Programs. This rule also establishes an EHR reporting period for all providers under a calendar year timeline except for providers in the first year of the Medicaid EHR Incentive Program where states may continue to allow an introductory 90 day period; requires the electronic submission of clinical quality measures (CQMs); creates a single set of meaningful use requirements for Stage 3 which will be optional for providers in 2017 and applicable for all providers beginning in 2018; and ensure privacy and security requirements continue to protect patient health information (PHI).

Timetable:

Action	Date	FR Cite
NPRM	03/30/15	80 FR 16732
NPRM Comment Period End	05/29/15	
Final Action	03/00/18	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Elizabeth S. Holland, Director, Division of HIT Initiatives, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Clinical Standards and Quality, Mail Stop S2–26–17, 7500 Security Boulevard, Baltimore, MD 21244

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RIN: 0938–AS26

<HD1>132. MEDICARE CLINICAL DIAGNOSTIC LABORATORY TEST PAYMENT SYSTEM (CMS–1621–P) (SECTION 610 REVIEW)

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

Abstract: This proposed rule would require Medicare payment for clinical laboratory tests to be based on private payor rates beginning January 1, 2017, as required by section 216(a) of the Protecting Access to Medicare Act of 2014.

Timetable:

Action	Date	FR Cite
NPRM	06/00/15	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Valerie Miller, Deputy Director, Division of Ambulatory Services, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, Mail Stop C4–01–26, 7500 Security Boulevard, Baltimore, MD 21244

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RIN: 0938–AS33

<HD1>133. CY 2016 REVISIONS TO PAYMENT POLICIES UNDER THE PHYSICIAN FEE SCHEDULE AND OTHER REVISIONS TO MEDICARE PART B (CMS–1631–P)

Legal Authority: Social Security Act, secs 1102, 1871, 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, 2016.

Timetable:

Action	Date	FR Cite
NPRM	06/00/15	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: John McInnes, Acting Director, Division of Practitioner Services, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, MS: C4–01–15, 7500 Security Boulevard, Baltimore, MD 21244

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RIN: 0938–AS40

<HD1>134. HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEM FOR ACUTE CARE HOSPITALS AND THE LONG–TERM CARE HOSPITAL PROSPECTIVE PAYMENT SYSTEM AND FY 2016 RATES (CMS–1632–F)

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

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

Timetable:

Action	Date	FR Cite
NPRM	04/30/15	80 FR 24323
NPRM Comment Period End	06/16/15	
Final Action	08/00/15	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Donald Thompson, Deputy Director, Division of Acute Care, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, MS: C4–01–26, 7500 Security Boulevard, Baltimore, MD 21244

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RIN: 0938–AS41

<HD1>135. CY 2016 HOSPITAL OUTPATIENT PPS POLICY CHANGES AND PAYMENT RATES AND AMBULATORY SURGICAL CENTER PAYMENT SYSTEM POLICY CHANGES AND PAYMENT RATES (CMS–1633–P)

Legal Authority: sec 1833 of the Social Security Act

Abstract: This annual proposed rule would revise the Medicare hospital outpatient prospective payment system to implement statutory requirements and changes arising from our continuing experience with this system. The 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	06/00/15	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Marjorie Baldo, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, MS: C4–03–06, 7500 Security Boulevard, Baltimore, MD 21244

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RIN: 0938–AS42

<HD1>136. FY 2016 INPATIENT REHABILITATION FACILITY PROSPECTIVE PAYMENT SYSTEM (CMS–1624–F) (SECTION 610 REVIEW)

Legal Authority: Social Security Act, sec 1886(j); Pub. L. 106–554; Pub. L. 106–113

Abstract: This annual final rule updates the prospective payment rates for inpatient rehabilitation facilities (IRFs) for fiscal year 2016.

Timetable:

Action	Date	FR Cite
NPRM	04/27/15	80 FR 23332
NPRM Comment Period End	06/22/15	
Final Action	08/00/15	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AS45

<HD1>137. • ELECTRONIC HEALTH RECORD INCENTIVE PROGRAM—MODIFICATIONS TO MEANINGFUL USE IN 2015 THROUGH 2017 (CMS–3311–F) (SECTION 610 REVIEW)

Legal Authority: 42 U.S.C. 1302 and 1395hh; Pub. L. 111–5

Abstract: This final rule changes the Medicare and Medicaid Electronic Health Record (EHR) Incentive Program EHR reporting period in 2015 to a 90-day period aligned with the calendar year, and also aligns the reporting period in 2016 with the calendar year. In addition, this rule modifies the patient action measures in the Stage 2 objectives related to patient engagement. Finally, it streamlines the program by removing reporting requirements on measures which have become redundant, duplicative, or topped out through advancements in EHR function and provider performance for Stage 1 and Stage 2 of the Medicare and Medicaid EHR Incentive Programs.

Timetable:

Action	Date	FR Cite
NPRM	04/15/15	80 FR 20346
NPRM Comment Period End	06/15/15	
Final Action	04/00/18	

Regulatory Flexibility Analysis Required: Yes

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<Q P='20'>

<HD1>Department of Health and Human Services (HHS)

<HD2>Centers for Medicare & Medicaid Services (CMS)

<HD3>Final Rule Stage

<HD1>138. COVERED OUTPATIENT DRUGS (CMS–2345–F) (SECTION 610 REVIEW)

Legal Authority: Pub. L. 111– 48, secs 2501; Pub. L. 111– 48, 2503; Pub. L. 111– 48, 3301(d)(2); Pub. L.

111–152, sec 1206; Pub. L. 111–8, sec 221

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

Timetable:

Action	Date	FR Cite
NPRM	02/02/12	77 FR 5318
NPRM Comment Period End	04/02/12	
Final Action	08/00/15	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AQ41

<Q P='20'>

<HD1>Department of Health and Human Services (HHS)

<HD2>Centers for Medicare & Medicaid Services (CMS)

<HD3>Long-Term Actions

<HD1>139. HOME HEALTH AGENCY CONDITIONS OF PARTICIPATION (CMS–3819–F)

(RULEMAKING RESULTING FROM A SECTION 610 REVIEW)

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

Abstract: This final rule revises the existing Conditions of Participation that Home Health Agencies (HHA) must meet to participate in the Medicare program. The new requirements 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	10/09/14	79 FR 61163
NPRM Comment Period Extended	12/01/14	79 FR 71081
Second NPRM Comment Period End	01/07/15	
Final Action	10/00/17	

Regulatory Flexibility Analysis Required: No

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RIN: 0938–AG81

<HD1>140. EMERGENCY PREPAREDNESS REQUIREMENTS FOR MEDICARE AND MEDICAID PARTICIPATING PROVIDERS AND SUPPLIERS (CMS–3178–F) (SECTION 610 REVIEW)

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

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

Timetable:

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

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AO91

<HD1>141. MEDICARE SHARED SAVINGS PROGRAM; ACCOUNTABLE CARE ORGANIZATIONS (CMS–1461–F) (SECTION 610 REVIEW)

Legal Authority: Pub. L. 111–148, sec 3022

Abstract: This rule finalizes changes to the Medicare Shared Savings Program (Shared Savings Program), including provisions relating to the payment of Accountable Care Organizations (ACOs) participating in the Shared Savings Program. Under the Shared Savings Program, providers of services and suppliers that participate in an ACO continue to receive traditional Medicare fee for service (FFS) payments under Parts

A and B and are eligible for additional payments from the ACO if they meet specified quality and savings requirements.

Timetable:

Action	Date	FR Cite
NPRM	12/08/14	79 FR 72760
NPRM Comment Period End	02/06/15	
Final Action	12/00/17	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AS06

<HD1>142. HOSPITAL AND CRITICAL ACCESS HOSPITAL (CAH) CHANGES TO PROMOTE INNOVATION, FLEXIBILITY, AND IMPROVEMENT IN PATIENT CARE (CMS–3295–P) (RULEMAKING RESULTING FROM A SECTION 610 REVIEW)

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

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

Timetable:

Action	Date	FR Cite
NPRM	12/00/16	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AS21

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