DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

21 CFR Ch. I

25 CFR Ch. V

42 CFR Chs. I-V

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

Regulatory Agenda

AGENCY: Office of the Secretary, HHS.

ACTION: Semiannual Regulatory Agenda.

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

FOR FURTHER INFORMATION CONTACT: Ann C. Agnew, 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 regulatory activities that the Department expects to undertake in the foreseeable future to advance this mission. HHS has an agency-wide effort to support the Agenda's purpose of encouraging more effective public participation in the regulatory process. For example, to encourage public participation, we regularly update our regulatory 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.

Ann C. Agnew,
Executive Secretary to the Department.

Office for Civil Rights—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
64	Nondiscrimination in Health Programs or Activities	0945–AA11

Office of the National Coordinator for Health Information Technology—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number

65	21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program	0955–AA01

Food and Drug Administration—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
66	Over-the-Counter (OTC) Drug Review—Cough/Cold (Antihistamine) Products	0910–AF31
67	Sunscreen Drug Products For Over-The-Counter-Human Use; Tentative Final Monograph	0910–AF43
68	Mammography Quality Standards Act; Amendments to Part 900 Regulations	0910–AH04
69	Medication Guides; Patient Medication Information	0910–AH68
70	Nutrient Content Claims, Definition of Term: Healthy	0910–AI13
71	Revocation of Uses of Partially Hydrogenated Oils in Foods	0910–AI15
72	Required Warnings for Cigarette Packages and Advertisements	0910–AI39

Food and Drug Administration—Final Rule Stage

Sequence Number	Title	Regulation Identifier

		Number
73	Postmarketing Safety Reporting Requirements for Human Drug and Biological Products	0910–AA97
74	Food Labeling; Gluten-Free Labeling of Fermented, Hydrolyzed, or Distilled Foods	0910–AH00
75	Topical Antimicrobial Drug Products for Over-the-Counter Human Use: Final Monograph for Consumer Antiseptic Rub Products	0910–AH97
76	Milk and Cream Product and Yogurt Products, Final Rule to Revoke the Standards for Lowfat Yogurt and Nonfat and to Amend the Standard for Yogurt	0910–AI40

Food and Drug Administration—Long-Term Actions

Sequence Number	Title	Regulation Identifier Number
77	Over-the-Counter (OTC) Drug Review—External Analgesic Products	0910–AF35
78	Over-the-Counter (OTC) Drug Review—Internal Analgesic Products	0910–AF36
79	Over-the-Counter (OTC) Drug Review—Laxative Drug Products	0910–AF38
80	Over-the-Counter (OTC) Drug Review—Weight Control Products	0910–AF45
81	Over-the-Counter (OTC) Drug Review—Pediatric Dosing for	0910–AG12

	Cough/Cold Products	
82	Electronic Distribution of Prescribing Information for Human Prescription Drugs Including Biological Products	0910–AG18
83	Sunlamp Products; Amendment to the Performance Standard	0910–AG30
84	General and Plastic Surgery Devices: Sunlamp Products	0910–AH14
85	Combinations of Bronchodilators With Expectorants; Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use	0910–AH16
86	Acute Nicotine Toxicity Warnings for E-Liquids	0910–AH24
87	Testing Standards for Batteries and Battery Management Systems in Electronic Nicotine Delivery Systems	0910–AH90
88	Administration Detention of Tobacco Products	0910–AI05

Food and Drug Administration—Completed Actions

Sequence Number	Title	Regulation Identifier Number
89	Label Requirement for Food That Has Been Refused Admission Into the United States	0910–AF61
90	Laser Products; Amendment to Performance Standard	0910–AF87

Centers for Medicare & Medicaid Services—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
91	Requirements for Long-Term Care Facilities: Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction (CMS-3347-P) **(Section 610 Review)**	0938–AT36
92	CY 2020 Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Medicare Part B (CMS-1715-P) **(Section 610 Review)**	0938–AT72
93	Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals; the Long-Term Care Hospital Prospective Payment System; and FY 2020 Rates (CMS-1716-F) **(Section 610 Review)**	0938–AT73
94	CY 2020 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates (CMS-1717-P) **(Section 610 Review)**	0938–AT74

Centers for Medicare & Medicaid Services—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
95	Hospital and Critical Access Hospital (CAH) Changes to Promote Innovation, Flexibility, and Improvement in Patient Care (CMS-	0938–AS21

	3295-F) **(Rulemaking Resulting From a Section 610 Review)**	

Centers for Medicare & Medicaid Services—Long-Term Actions

Sequence Number	Title	Regulation Identifier Number
96	Durable Medical Equipment Fee Schedule, Adjustments to Resume the Transitional 50/50 Blended Rates to Provide Relief in Non-Competitive Bidding Areas (CMS-1687-F) **(Section 610 Review)**	0938–AT21

Centers for Medicare & Medicaid Services—Completed Actions

Sequence Number	Title	Regulation Identifier Number
97	CY 2019 Changes to the End-Stage Renal Disease (ESRD) Prospective Payment System, Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) (CMS-1691-F) **(Completion of a Section 610 Review)**	0938–AT28
98	CY 2019 Home Health Prospective Payment System Rate Update and CY 2020 Case-Mix Adjustment Methodology Refinements; Value-Based Purchasing Model; Quality Reporting	0938–AT29

	Requirements (CMS-1689-FC) **(Completion of a Section 610 Review)**	
99	CY 2019 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates (CMS-1695-FC) **(Completion of a Section 610 Review)**	0938–AT30
100	CY 2019 Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Medicare Part B and the Quality Payment Program (CMS-1693-F) **(Completion of a Section 610 Review)**	0938–AT31

Department of Health and Human Services (HHS)	**Proposed Rule Stage**
Office for Civil Rights (OCR)	

64. NONDISCRIMINATION IN HEALTH PROGRAMS OR ACTIVITIES

EO 13771 Designation: Deregulatory

Legal Authority: sec. 1557 of the Patient Protection and Affordable Care Act (42 U.S.C. 18116)

Abstract: This proposed rule implements section 1557 of the Patient Protection and Affordable Care Act (PPACA), which prohibits discrimination on the basis of race, color, national origin, sex, age, and disability under any health program or activity, any part of which is receiving Federal financial assistance, including credits, subsidies, or contracts of insurance, or under any program or activity that is administered by an Executive Agency or any entity established under Title l of the PPACA.

Timetable:

Action	Date	FR Cite
NPRM	05/00/19	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Luben Montoya, Section Chief, Civil Rights Division, Department of Health and Human Services, Office for Civil Rights, 200 Independence Avenue, SW, Washington, DC 20201

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RIN: 0945–AA11

Department of Health and Human Services (HHS)	Proposed Rule Stage
Office of the National Coordinator for Health Information Technology (ONC)	

65. 21ST CENTURY CURES ACT: INTEROPERABILITY, INFORMATION BLOCKING, AND THE ONC HEALTH IT CERTIFICATION PROGRAM

EO 13771 Designation: Regulatory

Legal Authority: Pub. L. 114–255

Abstract: The rulemaking would implement certain provisions of the 21st Century Cures Act, including conditions and maintenance of certification requirements for health information technology (IT) developers under the ONC Health IT Certification Program (Program), the voluntary certification of health IT for use by pediatric healthcare providers and reasonable and necessary activities that do not constitute information blocking. The rulemaking would also modify the 2015 Edition health IT certification criteria and Program in additional ways to advance interoperability, enhance health IT certification, and reduce burden and costs.

Timetable:

Action	Date	FR Cite
NPRM	03/04/19	84 FR 7424
NPRM Comment Period Extended	04/23/19	84 FR 16834
NPRM Comment Period End	05/03/19	
NPRM Comment Period Extended End	06/03/19	
Final Action	11/00/19	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Michael Lipinski, Director, Regulatory Affairs Division, Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, Mary E. Switzer Building, 330 C Street SW, Washington, DC 20201

Phone: 202 690–7151

RIN: 0955–AA01

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

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

EO 13771 Designation: Deregulatory

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 on a pilot basis. This proposed rule is the result of collaboration under the U.S.-Canada Regulatory Cooperation Council 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)	06/00/19	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AF31

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67. SUNSCREEN DRUG PRODUCTS FOR OVER–THE–COUNTER–HUMAN USE; TENTATIVE FINAL MONOGRAPH

EO 13771 Designation: Regulatory

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 proposed rule will address the general recognition of safety and effectiveness (GRASE) status of the 16 sunscreen monograph ingredients and describe data gaps that FDA believes need to be filled in order for FDA to permit the continued marketing of these ingredients without submitting new drug applications for premarket review. Consistent with the Sunscreen Innovation Act, we also expect to address sunscreen dosage forms and maximum SPF values.

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	
NPRM	02/26/19	84 FR 6204
NPRM Comment Period End	05/28/19	
Final Action	11/00/19	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AF43

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68. MAMMOGRAPHY QUALITY STANDARDS ACT; AMENDMENTS TO PART 900 REGULATIONS

EO 13771 Designation: Regulatory

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

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

Timetable:

Action	Date	FR Cite
NPRM	03/28/19	84 FR 11669
NPRM Comment Period End	06/26/19	
Final Action	10/00/20	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AH04

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69. MEDICATION GUIDES; PATIENT MEDICATION INFORMATION

EO 13771 Designation: Regulatory

Legal Authority: 21 U.S.C. 321 et seq.; 42 U.S.C. 262; 42 U.S.C. 264; 21 U.S.C. 371

Abstract: The proposed rule would amend FDA medication guide regulations to require a new form of patient labeling, Patient Medication Information, for submission to and review by the FDA for human prescription drug products and certain blood products used, dispensed, or administered on an outpatient basis. The proposed rule would include requirements for Patient Medication Information development and distribution. The proposed rule would require clear and concisely written prescription drug product information presented in a consistent and easily understood format to help patients use their prescription drug products safely and effectively.

Timetable:

Action	Date	FR Cite
NPRM	11/00/19	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AH68

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70. NUTRIENT CONTENT CLAIMS, DEFINITION OF TERM: HEALTHY

EO 13771 Designation: Regulatory

Legal Authority: 21 U.S.C. 321; 21 U.S.C. 331; 21 U.S.C. 343; 21 U.S.C. 371

Abstract: The proposed rule would update the definition for the implied nutrient content claim "healthy" to be consistent with current nutrition science and federal dietary guidelines. The proposed rule would revise the requirements for when the claim "healthy" can be voluntarily used in the labeling of human food products so that the claim reflects current science and dietary guidelines and help consumers maintain healthy dietary practices.

Timetable:

Action	Date	FR Cite
NPRM	05/00/19	

Regulatory Flexibility Analysis Required: Yes

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

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RIN: 0910–AI13

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71. REVOCATION OF USES OF PARTIALLY HYDROGENATED OILS IN FOODS

EO 13771 Designation: Regulatory

Legal Authority: 21 U.S.C. 321; 21 U.S.C. 341; 21 U.S.C. 343; 21 U.S.C. 348; 21 U.S.C. 371; 21 U.S.C. 379(e)

Abstract: In the Federal Register of June 17, 2015 (80 FR 34650), we published a declaratory order announcing our final determination that there is no longer a consensus among qualified experts that partially hydrogenated oils (PHOs) are generally recognized as safe (GRAS) for any use in human food. In the Federal Register of May 21, 2018 (83 FR 23382), we denied a food additive petition requesting that the food additive regulations be amended to provide for the safe use of PHOs in certain food applications. We are now proposing to update our regulations to remove all mention of partially hydrogenated oils and to revoke all prior sanctioned uses. This rulemaking implements FDA's findings that the available data demonstrate that PHOs used in food may cause the food to be unsafe.

Timetable:

Action	Date	FR Cite
NPRM	11/00/19	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AI15

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72. • REQUIRED WARNINGS FOR CIGARETTE PACKAGES AND ADVERTISEMENTS

EO 13771 Designation: Regulatory

Legal Authority: 15 U.S.C. 1333; 21 U.S.C. 371; 21 U.S.C. 387c; 21 U.S.C. 387i; Secs 201 and 202, Pub. L. 111–31, 123 Stat. 1776; ...

Abstract: This rule would require color graphics depicting the negative health consequences of smoking to accompany textual warning statements on cigarette packages and in cigarette advertisements. As directed by Congress in the Tobacco Control Act, which amends the Federal Cigarette Labeling and Advertising Act, the rule would require these new cigarette health warnings to occupy the top 50 percent of the area of the front and rear panels of cigarette packages and at least 20 percent of the area of cigarette advertisements. The original rule FDA issued in 2011 was vacated by the U.S. Court of Appeals for the District of Columbia Circuit in August 2012 (R.J. Reynolds Tobacco Co. v. United States Food & Drug Admin., 696 F.3d 1205 D.C. Cir. 2012).

Timetable:

Action	Date	FR Cite
NPRM	08/00/19	

Regulatory Flexibility Analysis Required: Yes

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

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RIN: 0910–AI39

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

73. POSTMARKETING SAFETY REPORTING REQUIREMENTS FOR HUMAN DRUG AND BIOLOGICAL PRODUCTS

EO 13771 Designation: Regulatory

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

Abstract: The final rule would amend the postmarketing safety reporting regulations for human drugs and biological products including blood and blood products in order to better align FDA requirements with

guidelines of the International Council on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH); and to update reporting requirements in light of current pharmacovigilance practice and safety information sources and enhance the quality of safety reports received by FDA. These revisions were proposed as part of a single rulemaking (68 FR 12406) to clarify and revise both premarketing and postmarketing safety reporting requirements for human drug and biological products. Premarketing safety reporting requirements were finalized in a separate final rule published on September 29, 2010 (75 FR 59961).

Timetable:

Action	**Date**	**FR Cite**
NPRM	03/14/03	68 FR 12406
NPRM Comment Period Extended	06/18/03	
NPRM Comment Period End	07/14/03	
NPRM Comment Period Extension End	10/14/03	
Final Rule	09/00/19	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AA97

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74. FOOD LABELING; GLUTEN–FREE LABELING OF FERMENTED, HYDROLYZED, OR DISTILLED FOODS

EO 13771 Designation: Regulatory

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 final rule would establish requirements concerning ''gluten-free'' labeling for foods that are fermented or hydrolyzed or that contain fermented or hydrolyzed ingredients. These additional requirements for the ''gluten-free'' labeling rule are needed to help ensure that individuals with celiac disease are not misled and receive truthful and accurate information with respect to fermented or hydrolyzed foods labeled as ''gluten-free.''

Timetable:

Action	Date	FR Cite
NPRM	11/18/15	80 FR 71990
NPRM Comment Period Reopened	01/22/16	81 FR 3751
NPRM Comment Period End	02/16/16	
NPRM Comment Period Reopened End	02/22/16	
NPRM Comment Period Reopened	02/23/16	81 FR 8869

NPRM Comment Period Reopened End	04/25/16	
Final Rule	09/00/19	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AH00

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75. TOPICAL ANTIMICROBIAL DRUG PRODUCTS FOR OVER–THE–COUNTER HUMAN USE: FINAL MONOGRAPH FOR CONSUMER ANTISEPTIC RUB PRODUCTS

EO 13771 Designation: Regulatory

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. 360 and 361; 21 U.S.C. 371; 21 U.S.C. 374 and 375; 21 U.S.C. 379; 42 U.S.C. 216; 42 U.S.C. 241 and 242; 42 U.S.C. 262

Abstract: This final rule amends the 1994 tentative final monograph (TFM) for over-the-counter (OTC) antiseptic drug products that published in the Federal Register of June 17, 1994,(the 1994 TFM). The final rule is part of the ongoing review of OTC drug products conducted by FDA. In this final rule, we address whether certain active ingredients used in OTC consumer antiseptic products intended for use

without water (referred to as consumer antiseptic rubs) are for evaluation under the OTC Drug Review for use in consumer antiseptic rub products.

Timetable:

Action	Date	FR Cite
Final Rule	05/00/19	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Anita Kumar, Biologist, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, 10903 New Hampshire Avenue, Building 22, Room 5445, Silver Spring, MD 20993

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RIN: 0910–AH97

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76. • MILK AND CREAM PRODUCT AND YOGURT PRODUCTS, FINAL RULE TO REVOKE THE STANDARDS FOR LOWFAT YOGURT AND NONFAT AND TO AMEND THE STANDARD FOR YOGURT

EO 13771 Designation: Deregulatory

Legal Authority: 21 U.S.C. 321; 21 U.S.C. 336; 21 U.S.C. 341; 21 U.S.C. 343; 21 U.S.C. 348; 21 U.S.C. 371(e); 21 U.S.C. 379e

Abstract: This final rule amends the standard for yogurt and revokes the standards for lowfat and nonfat yogurt. It modernizes the standard to allow for technological advances, to preserve the basic nature and essential characteristics of yogurt, and to promote honesty and fair dealing in the interest of consumers.

Section, 701(e)(1), of the Federal Food, Drug, and Cosmetic Act identifies that specific decisions such as the definitions and standards of identity for dairy products are to be promulgated under formal rulemaking provisions of 5 U.S.C. 556 and 557. Section 3(d) of Executive Order 12866 defines regulation to exclude regulations or rules issued in accordance with the formal rulemaking provisions of 5 U.S.C. 556 and 557; accordingly, this final rule is not subject to the requirements of Executive Order 12866. Notwithstanding this exclusion, and our standard practice not to include formal rulemaking in the Unified Agenda, we have decided to include this particular rule in the Unified Agenda in order to highlight our de-regulatory work in this space.

Timetable:

Action	**Date**	**FR Cite**
ANPRM	07/03/03	68 FR 39873
ANPRM Comment Period End	10/01/03	
NPRM	01/15/09	74 FR 2443
NPRM Comment Period End	04/29/09	
Final Action	09/00/19	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AI40

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

77. OVER–THE–COUNTER (OTC) DRUG REVIEW—EXTERNAL ANALGESIC PRODUCTS

EO 13771 Designation: Regulatory

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. The final action addresses the 2003 proposed rule on patches, plasters, and poultices. The proposed rule will address issues not addressed in previous rulemakings.

Timetable:

Action	Date	FR Cite
NPRM	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Janice Adams–King, Regulatory 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–AF35

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

EO 13771 Designation: Regulatory

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; 21 U.S.C. 374; 21 U.S.C. 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) (Acetaminophen)	To Be	Determined

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

EO 13771 Designation: Regulatory

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

Timetable:

Action	Date	FR Cite
Final Action (Granular Psyllium)	03/29/07	72 FR 14669
Final Action Effective (Granular Psyllium)	10/01/07	
NPRM (Professional Labeling—Sodium Phosphate)	02/11/11	76 FR 7743
NPRM Comment Period End	03/14/11	
Final Rule	To Be	Determined

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–AF38

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80. OVER–THE–COUNTER (OTC) DRUG REVIEW—WEIGHT CONTROL PRODUCTS

EO 13771 Designation: Regulatory

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. The final action finalizes the 2005 proposed rule for weight control products containing phenylpropanolamine.

Timetable:

Action	Date	FR Cite
NPRM (Phenylpropanolamine)	12/22/05	70 FR 75988
NPRM Comment Period End	03/22/06	
NPRM (Benzocaine)	03/09/11	76 FR 12916
NPRM Comment Period End	06/07/11	
Final Action (Phenylpropanolamine)	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Janice Adams–King, Regulatory 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–AF45

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

EO 13771 Designation: Regulatory

Legal Authority: 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 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	To Be	Determined

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–AG12

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

EO 13771 Designation: Other

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 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 Rule	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Michael Bernstein, Supervisory Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 51, Room 6240, 10903 New Hampshire Avenue, Silver Spring, MD 20993–0002

Phone: 301 796–3478

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RIN: 0910–AG18

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83. SUNLAMP PRODUCTS; AMENDMENT TO THE PERFORMANCE STANDARD

EO 13771 Designation: Fully or Partially Exempt

Legal Authority: 21 U.S.C. 360ii; 21 U.S.C. 360kk; 21 U.S.C. 393; 21 U.S.C. 371

Abstract: FDA is updating the performance standard for sunlamp products to improve safety, reflect new scientific information, and work towards harmonization with international standards. By harmonizing with the International Electrotechnical Commission, this rule will decrease the regulatory burden on industry and allow the Agency to take advantage of the expertise of the international committees, thereby also saving resources.

Timetable:

Action	Date	FR Cite
NPRM	12/22/15	80 FR 79505
NPRM Comment Period End	03/21/16	
Final Rule	06/00/20	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Ian Ostermiller, Regulatory Counsel, Center for Devices and Radiological Health, Department of Health and Human Services, Food and Drug Administration, 10903 New Hampshire Avenue, WO 66, Room 5454, Silver Spring, MD 20993

Phone: 301 796–5678

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RIN: 0910–AG30

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84. GENERAL AND PLASTIC SURGERY DEVICES: SUNLAMP PRODUCTS

EO 13771 Designation: Regulatory

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

Abstract: This rule would apply device restrictions to sunlamp products. Sunlamp products include ultraviolet (UV) lamps and UV tanning beds and booths. The incidence of skin cancer, including melanoma, has been increasing, and a large number of skin cancer cases are attributable to the use of sunlamp products. The devices may cause about 400,000 cases of skin cancer per year, and 6,000 of which are melanoma. Beginning use of sunlamp products at young ages, as well as frequently using sunlamp products, both increases the risk of developing skin cancers and other illnesses, and sustaining other injuries. Even infrequent use, particularly at younger ages, can significantly increase these risks.This rule would apply device restrictions to sunlamp products.

Timetable:

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

Final Rule	06/00/20	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Ian Ostermiller, Regulatory Counsel, Center for Devices and Radiological Health, Department of Health and Human Services, Food and Drug Administration, 10903 New Hampshire Avenue, WO 66, Room 5454, Silver Spring, MD 20993

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RIN: 0910–AH14

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

EO 13771 Designation: Regulatory

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. These actions address cough/cold drug products containing an oral bronchodilator (ephedrine and its salts) in combination with any expectorant.

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 Rule	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AH16

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86. ACUTE NICOTINE TOXICITY WARNINGS FOR E–LIQUIDS

EO 13771 Designation: Regulatory

Legal Authority: 21 U.S.C. 301 et seq.; 21 U.S.C. 331; 21 U.S.C. 371; 21 U.S.C. 374; 21 U.S.C. 387

Abstract: This rule would establish nicotine exposure warning requirements for liquid nicotine and nicotine-containing e-liquid(s) that are made or derived from tobacco and intended for human consumption, and potentially for other tobacco products including, but not limited to, novel tobacco products such as dissolvables, lotions, gels, and drinks. This action is intended to protect users and non-users from accidental exposures to nicotine-containing e-liquids in tobacco products.

Timetable:

Action	Date	FR Cite
NPRM	03/00/21	

Regulatory Flexibility Analysis Required: Yes

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

Phone: 301 796–3894

Fax: 301 595–1426

Email: ctpregulations@fda.hhs.gov

RIN: 0910–AH24

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87. TESTING STANDARDS FOR BATTERIES AND BATTERY MANAGEMENT SYSTEMS IN ELECTRONIC NICOTINE DELIVERY SYSTEMS

EO 13771 Designation: Regulatory

Legal Authority: 21 U.S.C. 301 et. seq.; 21 U.S.C. 371; 21 U.S.C. 387(b); 21 U.S.C. 387(g); 21 U.S.C. 387i

Abstract: This rule would propose to establish a product standard to require testing standards for batteries used in electronic nicotine delivery systems (ENDS) and require design protections including a battery management system for ENDS using batteries and protective housing for replaceable batteries. This product standard would protect the safety of users of battery-powered tobacco products and will help to streamline the FDA premarket review process, ultimately reducing the burden on both manufacturers

and the Agency. The proposed rule would be applicable to tobacco products that include a non-user replaceable battery as well as products that include a user replaceable battery.

Timetable:

Action	Date	FR Cite
NPRM	05/00/20	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Darin Achilles, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Tobacco Products, 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–AH90

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88. ADMINISTRATION DETENTION OF TOBACCO PRODUCTS

EO 13771 Designation: Other

Legal Authority: 21 U.S.C. 334; 21 U.S.C. 371

Abstract: The Food and Drug Administration (FDA) is proposing regulations to establish requirements for the administrative detention of tobacco products. This action, if finalized, would allow FDA to administratively detain tobacco products encountered during inspections that an officer or employee conducting the inspection has reason to believe are adulterated or misbranded. The intent of administrative detention is to protect public health by preventing the distribution or use of violative

tobacco products until FDA has had time to consider the appropriate action to take and, where appropriate, to initiate a regulatory action.

Timetable:

Action	Date	FR Cite
NPRM	08/00/20	

Regulatory Flexibility Analysis Required: Yes

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

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RIN: 0910–AI05

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

89. LABEL REQUIREMENT FOR FOOD THAT HAS BEEN REFUSED ADMISSION INTO THE UNITED STATES

EO 13771 Designation: Deregulatory

Legal Authority: 15 U.S.C. 1453 to 1455; 21 U.S.C. 321; 21 U.S.C. 342 and 343; 21 U.S.C. 371; 21 U.S.C. 374; 21 U.S.C. 381; 42 U.S.C. 216; 42 U.S.C. 264

Abstract: On September 18, 2008, FDA issued a proposed rule that would have required owners or consignees to label imported food that was refused entry into the United States. FDA does not plan to finalize the rule.

Completed:

Reason	Date	FR Cite
NPRM; Withdrawal	09/28/18	83 FR 49022

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Anthony C. Taube

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Fax: 703 261–8625

Email: anthony.taube@fda.hhs.gov

RIN: 0910–AF61

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90. LASER PRODUCTS; AMENDMENT TO PERFORMANCE STANDARD

EO 13771 Designation: Deregulatory

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

Abstract: On June 24, 2013, FDA issued a proposed rule that would have amended the performance standard for laser products to achieve closer harmonization between the current standard and the

amended International Electrotechnical Commission (IEC) standard for laser products and medical laser products. FDA does not plan to finalize the 2013 proposal.

Completed:

Reason	Date	FR Cite
NPRM; Withdrawal	11/01/18	83 FR 54891

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Erica Payne

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RIN: 0910–AF87

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

91. REQUIREMENTS FOR LONG–TERM CARE FACILITIES: REGULATORY PROVISIONS TO PROMOTE PROGRAM EFFICIENCY, TRANSPARENCY, AND BURDEN REDUCTION (CMS–3347–P) (SECTION 610 REVIEW)

EO 13771 Designation: Deregulatory

Legal Authority: secs.1819 and 1919 of the Social Security Act; sec.1819(d)(4)(B) and 1919(d)(4)(B) of the Social Security Act; sec. 1819(b)(1)(A) and 1919 (b)(1)(A) of the Social Security Act

Abstract: This proposed rule would reform the requirements that long-term care facilities must meet to participate in the Medicare and Medicaid programs, that CMS has identified as unnecessary, obsolete, or excessively burdensome on facilities. This rule would increase the ability of healthcare professionals to devote resources to improving resident care by eliminating or reducing requirements that impede quality care or that divert resources away from providing high quality care.

Timetable:

Action	Date	FR Cite
NPRM	05/00/19	

Regulatory Flexibility Analysis Required: Yes

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

Phone: 410 786–6882

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RIN: 0938–AT36

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92. CY 2020 REVISIONS TO PAYMENT POLICIES UNDER THE PHYSICIAN FEE SCHEDULE AND OTHER REVISIONS TO MEDICARE PART B (CMS–1715–P) (SECTION 610 REVIEW)

EO 13771 Designation: Other

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

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, 2020. Additionally, this rule proposes updates to the Quality Payment Program.

Timetable:

Action	Date	FR Cite
NPRM	06/00/19	

Regulatory Flexibility Analysis Required: Yes

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

Phone: 410 786–4361

Email: marge.watchorn@cms.hhs.gov

RIN: 0938–AT72

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93. HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEMS FOR ACUTE CARE HOSPITALS; THE LONG–TERM CARE HOSPITAL PROSPECTIVE PAYMENT SYSTEM; AND FY 2020 RATES (CMS–1716–F) (SECTION 610 REVIEW)

EO 13771 Designation: Other

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

Abstract: This annual final rule revises the Medicare hospital inpatient and long-term care hospital prospective payment systems for operating and capital-related costs. This rule would implements

changes arising from our continuing experience with these systems. In addition, the rule establishes new requirements or revises existing requirements for quality reporting by specific Medicare providers.

Timetable:

Action	Date	FR Cite
NPRM	05/03/19	84 FR 19158
NPRM Comment Period End	06/24/19	
Final Action	08/00/19	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Donald Thompson, Director, Division of Acute Care, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, MS: C4–08–06, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786–6504

Email: donald.thompson@cms.hhs.gov

RIN: 0938–AT73

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94. CY 2020 HOSPITAL OUTPATIENT PPS POLICY CHANGES AND PAYMENT RATES AND AMBULATORY SURGICAL CENTER PAYMENT SYSTEM POLICY CHANGES AND PAYMENT RATES (CMS–1717–P) (SECTION 610 REVIEW)

EO 13771 Designation: Other

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

Abstract: This annual proposed rule would revise the Medicare hospital outpatient prospective payment system to implement statutory requirements and changes arising from our continuing experience with this system. The 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. This proposed rule would also update and refine the requirements for the Hospital Outpatient Quality Reporting (OQR) Program and the ASC Quality Reporting (ASCQR) Program.

Timetable:

Action	Date	FR Cite
NPRM	06/00/19	

Regulatory Flexibility Analysis Required: Yes

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

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RIN: 0938–AT74

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

(CMS)	

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

EO 13771 Designation: Regulatory

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

Abstract: This final rule updates the requirements that hospitals and critical access hospitals (CAHs) must meet to participate in the Medicare and Medicaid programs. These final requirements 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	06/16/16	81 FR 39447
NPRM Comment Period End	08/15/16	
Final Action—To Be Merged With 0938-AS59 and 0938-AT23	06/00/19	

Regulatory Flexibility Analysis Required: No

Agency Contact: CAPT Scott Cooper, Senior Technical Advisor, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Clinical Standards and Quality, Mail Stop S3–01–02, 7500 Security Boulevard, Baltimore, MD 21244

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RIN: 0938–AS21

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

96. DURABLE MEDICAL EQUIPMENT FEE SCHEDULE, ADJUSTMENTS TO RESUME THE TRANSITIONAL 50/50 BLENDED RATES TO PROVIDE RELIEF IN NON–COMPETITIVE BIDDING AREAS (CMS–1687–F) (SECTION 610 REVIEW)

EO 13771 Designation: Fully or Partially Exempt

Legal Authority: 42 U.S.C. 1302, 1395hh, and 1395rr(b)(l)); Pub. L. 114–255, sec. 5004(b), 16007(a) and 16008

Abstract: This final rule follows the interim final rule that published May 11, 2018, and extended the end of the transition period from June 30, 2016, to December 31, 2016 for phasing in adjustments to the fee schedule amounts for certain durable medical equipment (DME) and enteral nutrition paid in areas not subject to the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP). In addition, the interim rule amended the regulation to resume the transition period for items furnished from August 1, 2017, through December 31, 2018. The interim rule also made technical amendments to existing regulations for DMEPOS items and services to exclude infusion drugs used with DME from the DMEPOS CBP.

Timetable:

Action	Date	FR Cite
Interim Final Rule	05/11/18	83 FR 21912
Interim Final Rule Comment Period End	07/09/18	
Final Action	05/00/21	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AT21

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

97. CY 2019 CHANGES TO THE END–STAGE RENAL DISEASE (ESRD) PROSPECTIVE PAYMENT SYSTEM, QUALITY INCENTIVE PROGRAM, DURABLE MEDICAL EQUIPMENT, PROSTHETICS, ORTHOTICS, AND SUPPLIES (DMEPOS) (CMS–1691–F) (COMPLETION OF A SECTION 610 REVIEW)

EO 13771 Designation: Regulatory

Legal Authority: 42 U.S.C. 1302; 42 U.S.C. 1395d(d); 42 U.S.C. 1395f(b); 42 U.S.C 1395g

Abstract: This annual final rule updates the bundled payment system for ESRD facilities by January 1, 2019. The rule also updates the quality incentives in the ESRD program and implements changes to the DMEPOS competitive bidding program.

Timetable:

Action	Date	FR Cite
NPRM	07/19/18	83 FR 34304
NPRM Comment Period End	09/10/18	
Final Action	11/14/18	83 FR 56922
Final Action Effective	01/01/19	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Janae James, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, MS: C5–05–27, 7500 Security Boulevard, Baltimore, MD 21244

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RIN: 0938–AT28

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98. CY 2019 HOME HEALTH PROSPECTIVE PAYMENT SYSTEM RATE UPDATE AND CY 2020 CASE–MIX ADJUSTMENT METHODOLOGY REFINEMENTS; VALUE–BASED PURCHASING

MODEL; QUALITY REPORTING REQUIREMENTS (CMS–1689–FC) (COMPLETION OF A SECTION 610 REVIEW)

EO 13771 Designation: Deregulatory

Legal Authority: 42 U.S.C. 1302; 42 U.S.C. 1315a; 42 U.S.C. 1395(hh)

Abstract: This annual final rule updates the payment rates under the Medicare prospective payment system for home health agencies. In addition, this rule finalizes changes to the Home Health Value-Based Purchasing (HHVBP) Model and to the Home Health Quality Reporting Program (HH QRP).

Timetable:

Action	Date	FR Cite
NPRM	07/12/18	83 FR 32340
NPRM Comment Period End	08/31/18	
Final Action	11/13/18	83 FR 56406
Comment Period End	12/31/18	
Final Action Effective	01/01/19	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Hillary Loeffler, Director, Division of Home Health and Hospice, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, MS: C5–08–28, 7500 Security Boulevard, Baltimore, MD 21244

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RIN: 0938–AT29

99. CY 2019 HOSPITAL OUTPATIENT PPS POLICY CHANGES AND PAYMENT RATES AND AMBULATORY SURGICAL CENTER PAYMENT SYSTEM POLICY CHANGES AND PAYMENT RATES (CMS–1695–FC) (COMPLETION OF A SECTION 610 REVIEW)

EO 13771 Designation: Deregulatory

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

Abstract: This annual final rule revises the Medicare hospital outpatient prospective payment system to implement statutory requirements and changes arising from our continuing experience with this system. The rule describes changes to the amounts and factors used to determine payment rates for services. In addition, the rule finalizes changes to the ambulatory surgical center payment system list of services and rates. This rule updates and refines the requirements for the Hospital Outpatient Quality Reporting (OQR) Program and the ASC Quality Reporting (ASCQR) Program.

Timetable:

Action	Date	FR Cite
NPRM	07/31/18	83 FR 37046
NPRM Comment Period End	09/24/18	
Final Action	11/21/18	83 FR 58818
Final Action Effective	01/01/19	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AT30

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100. CY 2019 REVISIONS TO PAYMENT POLICIES UNDER THE PHYSICIAN FEE SCHEDULE AND OTHER REVISIONS TO MEDICARE PART B AND THE QUALITY PAYMENT PROGRAM (CMS–1693–F) (COMPLETION OF A SECTION 610 REVIEW)

EO 13771 Designation: Deregulatory

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

Abstract: This annual final rule revises payment polices under the Medicare physician fee schedule, and makes other policy changes to payment under Medicare Part B. These changes apply to services furnished beginning January 1, 2019. Additionally, this rule updates the Quality Payment Program.

Timetable:

Action	Date	FR Cite
NPRM	07/27/18	83 FR 35704
NPRM Comment Period End	09/10/18	
Final Action	11/23/18	83 FR 59836
Final Action Effective	01/01/19	

Regulatory Flexibility Analysis Required: Yes

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