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Part VII

Department of Health and Human Services

Semiannual Regulatory Agenda

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

21 CFR Ch. I

25 CFR Ch. V

42 CFR Chs. I–V

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

Regulatory Agenda

AGENCY: Office of the Secretary, HHS.

ACTION: Semiannual regulatory agenda.

SUMMARY: The Regulatory Flexibility Act of 1980 and Executive Order (E.O.) 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 web page (*http://www.HHS.gov/regulations*) which includes links to HHS rules currently open for public comment, and also provides a ''regulations toolkit'' with background information on regulations, the commenting process, how public comments influence the development of a rule, and how the public can provide effective comments. HHS also actively encourages meaningful public participation in its retrospective review of regulations through a comment form on the HHS retrospective review web page (*http://www.HHS.gov/RetrospectiveReview*).

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

Ann C. Agnew,

Executive Secretary to the Department.

OFFICE FOR CIVIL RIGHTS—PROPOSED RULE STAGE

Sequence No.	Title	Regulation Identifier No.
83	HIPAA Privacy Rule: Changing Requirement to Obtain Acknowledgment of Receipt of the Notice of Privacy Practices.	0945–AA08
84	Nondiscrimination in Health Programs or Activities	0945–AA11

OFFICE OF THE NATIONAL COORDINATOR FOR HEALTH INFORMATION TECHNOLOGY—PROPOSED RULE STAGE

Sequence No.	Title	Regulation Identifier No.
85	Health Information Technology: Certification and Interoperability Enhancements	0955–AA01

FOOD AND DRUG ADMINISTRATION—PROPOSED RULE STAGE

Sequence No.	Title	Regulation Identifier No.
86	Over-the-Counter (OTC) Drug Review—Cough/Cold (Antihistamine) Products	0910–AF31
87	Sunscreen Drug Products For Over-The-Counter-Human Use; Tentative Final Monograph	0910–AF43
88	Mammography Quality Standards Act; Amendments to Part 900 Regulations	0910–AH04
89	Medication Guides; Patient Medication Information	0910–AH68
90	Testing Standards for Batteries and Battery Management Systems in Electronic Nicotine Delivery Systems.	0910–AH90
91	Administration Detention of Tobacco Products	0910–AI05

FOOD AND DRUG ADMINISTRATION—FINAL RULE STAGE

Sequence No.	Title	Regulation Identifier No.
92	Postmarketing Safety Reporting Requirements for Human Drug and Biological Products	0910–AA97
93	Label Requirement for Food That Has Been Refused Admission Into the United States	0910–AF61
94	Laser Products; Amendment to Performance Standard	0910–AF87
95	Food Labeling; Gluten-Free Labeling of Fermented, Hydrolyzed, or Distilled Foods	0910–AH00

FOOD AND DRUG ADMINISTRATION—LONG-TERM ACTIONS

Sequence No.	Title	Regulation Identifier No.
96	Over-the-Counter (OTC) Drug Review—External Analgesic Products	0910–AF35
97	Over-the-Counter (OTC) Drug Review—Internal Analgesic Products	0910–AF36
98	Over-the-Counter (OTC) Drug Review—Laxative Drug Products	0910–AF38
99	Over-the-Counter (OTC) Drug Review—Weight Control Products	0910–AF45
100	Over-the-Counter (OTC) Drug Review—Pediatric Dosing for Cough/Cold Products	0910–AG12
101	Electronic Distribution of Prescribing Information for Human Prescription Drugs Including Biological Products.	0910–AG18
102	Sunlamp Products; Amendment to the Performance Standard	0910–AG30
103	General and Plastic Surgery Devices: Sunlamp Products	0910–AH14
104	Combinations of Bronchodilators With Expectorants; Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use.	0910–AH16
105	Nicotine Exposure Warning and Child-Resistant Packaging for Liquid Nicotine, Nicotine-Containing E-Liquids, and Other Tobacco Products.	0910–AH24

FOOD AND DRUG ADMINISTRATION—COMPLETED ACTIONS

Sequence No.	Title	Regulation Identifier No.
106	Human Subject Protection; Acceptance of Data From Clinical Investigations for Medical Devices	0910–AG48
107	Safety and Effectiveness of Healthcare Antiseptics; Topical Antimicrobial Drug Products for Over-the-Counter Human Use.	0910–AH40

CENTERS FOR MEDICARE & MEDICAID SERVICES—PROPOSED RULE STAGE

Sequence No.	Title	Regulation Identifier No.
108	Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction (CMS–3346–P).	0938–AT23
109	FY 2019 Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities (SNFs) (CMS–1696–P).	0938–AT24
110	Hospital Inpatient Prospective Payment System for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and FY 2019 Rates (CMS–1694–P) **(Section 610 Review)**.	0938–AT27
111	CY 2019 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates (CMS–1695–P) **(Section 610 Review)**.	0938–AT30
112	CY 2019 Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Medicare Part B (CMS–1693–P) **(Section 610 Review)**.	0938–AT31

CENTERS FOR MEDICARE & MEDICAID SERVICES—FINAL RULE STAGE

Sequence No.	Title	Regulation Identifier No.
113	Durable Medical Equipment Fee Schedule, Adjustments to Resume the Transitional 50/50 Blended Rates to Provide Relief in Non-Competitive Bidding Areas (CMS–1687–IFC) **(Section 610 Review)**.	0938–AT21

CENTERS FOR MEDICARE & MEDICAID SERVICES—LONG-TERM ACTIONS

Sequence No.	Title	Regulation Identifier No.
114	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)**.	0938–AS21

CENTERS FOR MEDICARE & MEDICAID SERVICES—COMPLETED ACTIONS

Sequence No.	Title	Regulation Identifier No.
115	CY 2019 Notice of Benefit and Payment Parameters (CMS–9930–F) **(Completion of a Section 610 Review)**.	0938–AT12

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Office for Civil Rights (OCR)

Proposed Rule Stage

83. HIPAA Privacy Rule: Changing Requirement To Obtain Acknowledgment of Receipt of the Notice of Privacy Practices

E.O. 13771 Designation: Deregulatory.

Legal Authority: Health Insurance Portability and Accountability (HIPAA) Act of 1996, Pub. L. 104–191

Abstract: The propsed rule would change the requirement that health care providers make a good faith effort to obtain from individuals a written acknowledgment of receipt of the provider's notice of privacy practices, and if not obtained, to document its good faith efforts and the reason the acknowledgment was not obtained.

Timetable:

Action	Date	FR Cite
NPRM	09/00/18	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Andra Wicks, Health Information Privacy Specialist, Department of Health and Human Services, Office for Civil Rights, 200 Independence Avenue SW, Washington, DC 20201, *Phone:* 202 774–3081, *TDD Phone:* 800 537–7697, *Email: andra.wicks@hhs.gov.*

RIN: 0945–AA08

84. • Nondiscrimination in Health Programs or Activities

E.O. 13771 Designation: Deregulatory.

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

Abstract: The 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, or disability under any health program or activity receiving Federal financial assistance, or under any program or activity that is administered by the Department of Health and Human Services or by an entity established under title I of the PPACA. The proposed rule applies the enforcement mechanisms provided for and available under Title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d *et seq.*), Title IX of the Education Amendments of 1972 (20 U.S.C. 1681 *et seq.*), the Age Discrimination Act of 1975 (42 U.S.C. 6101 *et seq.*), and Section 504 of the Rehabilitation Act (29 U.S.C. 794).

Timetable:

Action	Date	FR Cite
NPRM	07/00/18	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Maya Noronha, Special Advisor, Department of Health and Human Services, Office for Civil Rights, 200 Independence Avenue SW, Room 516E, Washington, DC 20201, *Phone:* 202 568–0028, *Email: maya.noronha@hhs.gov.*

RIN: 0945–AA11

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

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

Proposed Rule Stage

85. Health Information Technology: Certification and Interoperability Enhancements

E.O. 13771 Designation: Regulatory.

Legal Authority: Pub. L. 114–255

Abstract: The rulemaking would update the ONC Health IT Certification Program (Program) by implementing certain provisions of the 21st Century Cures Act, including conditions and maintenance of certification requirements for health information technology (IT) developers, the voluntary certification of health IT for use by pediatric healthcare providers, health information network voluntary attestation to the adoption of a trusted exchange framework and common agreement in support of network-to-network exchange, and reasonable and necessary activities that do not constitute information blocking. The rulemaking would also modify the Program through other complementary means to advance health IT certification and interoperability.

Timetable:

Action	Date	FR Cite
NPRM	09/00/18	

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)

Food and Drug Administration (FDA)

Proposed Rule Stage

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

E.O. 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. 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).	11/00/18	

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

87. Sunscreen Drug Products for Over-the-Counter-Human Use; Tentative Final Monograph

E.O. 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: 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	12/00/18	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Kristen Hardin, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, 10903 New Hampshire Ave., WO 22, Room 5491, Silver Spring, MD 20993, *Phone:* 240 402–4246, *Fax:* 301 796–9841, *Email: kristen.hardin@fda.hhs.gov.*

RIN: 0910–AF43

88. Mammography Quality Standards Act; Amendments to Part 900 Regulations

E.O. 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	08/00/18	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Erica Payne, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, 10903 New Hampshire Avenue, WO 66, Room 5522, Silver Spring, MD 20993, *Phone:* 301 796–3999, *Fax:* 301 847–8145, *Email: erica.payne@fda.hhs.gov.*

RIN: 0910–AH04

89. Medication Guides; Patient Medication Information

E.O. 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	02/00/19	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Chris Wheeler, Supervisory Project Manager, Department of Health and Human Services, Food and Drug Administration, 10903 New Hampshire Avenue, Building 51, Room 3330, Silver Spring, MD 20993, *Phone:* 301 796–0151, *Email: chris.wheeler@fda.hhs.gov.*

RIN: 0910–AH68

90. Testing Standards for Batteries and Battery Management Systems in Electronic Nicotine Delivery Systems

E.O. 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 through a battery management system for ENDS using 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	12/00/18	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Colleen Lee, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, 10903 New Hampshire Avenue, WO 71, Room G335, Silver Spring, MD 20993, *Phone:* 877 287–1373, *Email: ctpregulations@fda.hhs.gov.*

RIN: 0910–AH90

91. • Administration Detention of Tobacco Products

E.O. 13771 Designation: Other.

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

Abstract: The Food and Drug Administration 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	11/00/18	

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–AI05

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Food and Drug Administration (FDA)

Final Rule Stage

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

E.O. 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). This final rule applies to postmarketing safety reporting requirements.
Timetable:

Action	Date	FR Cite
NPRM	03/14/03	68 FR 12406
NPRM Comment Period Extended.	06/18/03	
NPRM Comment Period End.	07/14/03	
NPRM Comment Period Extension End.	10/14/03	
Final Rule	12/00/18	

Regulatory Flexibility Analysis Required: Yes.
Agency Contact: Jane E. Baluss, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 51, Room 6278, 10903 New Hampshire Avenue, Silver Spring, MD 20993–0002, *Phone:* 301 796–3469, *Fax:* 301 847–8440, *Email: jane.baluss@fda.hhs.gov.*
RIN: 0910–AA97

93. Label Requirement for Food That Has Been Refused Admission Into the United States

E.O. 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: The final rule will require owners or consignees to label imported food that is refused entry into the United States. The label will read, ''UNITED STATES: REFUSED ENTRY.'' The proposal describes the label's characteristics (such as its size) and processes for verifying that the label has been affixed properly. We are taking this action to prevent the introduction of unsafe food into the United States, to facilitate the examination of imported food, and to implement section 308 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) (Pub. L. 107–188).
Timetable:

Action	Date	FR Cite
NPRM	09/18/08	73 FR 54106
NPRM Comment Period End.	12/02/08	
NPRM; Withdrawal.	08/00/18	

Regulatory Flexibility Analysis Required: Yes.
Agency Contact: Anthony C. Taube, Branch Chief, Department of Health and Human Services, Food and Drug Administration, Office of Regulatory Affairs, Office of Regional Operations, 12420 Parklawn Drive, ELEM–4051, Rockville, MD 20857, *Phone:* 240 420–4565, *Fax:* 703 261–8625, *Email: anthony.taube@fda.hhs.gov.*
RIN: 0910–AF61

94. Laser Products; Amendment to Performance Standard

E.O. 13771 Designation: Deregulatory.
Legal Authority: 21 U.S.C. 360hh to 360ss; 21 U.S.C. 371; 21 U.S.C. 393
Abstract: FDA is proposing to amend the 2013 proposed rule for the performance standard for laser products, which will amend the performance standard for laser products to achieve closer harmonization between the current standard and the recently amended International Electrotechnical Commission (IEC) standard for laser products and medical laser products. The amendment is intended to update FDA's performance standard to reflect advancements in technology.
Timetable:

Action	Date	FR Cite
NPRM	06/24/13	78 FR 37723
NPRM Comment Period End.	09/23/13	
NPRM; Withdrawal.	08/00/18	

Regulatory Flexibility Analysis Required: Yes.
Agency Contact: Erica Payne, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, 10903 New Hampshire Avenue, WO 66, Room 5522, Silver Spring, MD 20993, *Phone:* 301 796–3999, *Fax:* 301 847–8145, *Email: erica.payne@fda.hhs.gov.*
RIN: 0910–AF87

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

E.O. 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.	02/22/16	81 FR 8869
NPRM Comment Period Reopened End.	04/25/16	
Final Rule	12/00/18	

Regulatory Flexibility Analysis Required: Yes.
Agency Contact: Carol D'Lima, Staff Fellow, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition, Room 4D022,

HFS 820, 5100 Paint Branch Parkway, College Park, MD 20740, *Phone:* 240 402–2371, *Fax:* 301 436–2636, *Email: carol.dlima@fda.hhs.gov.*

RIN: 0910–AH00

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Food and Drug Administration (FDA)

Long-Term Actions

96. Over-the-Counter (OTC) Drug Review—External Analgesic Products

E.O. 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, *Phone:* 301 796–3713, *Email: janice.adams-king@fda.hhs.gov.*

RIN: 0910–AF35

97. Over-the-Counter (OTC) Drug Review—Internal Analgesic Products

E.O. 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, *Phone:* 301 796–3713, *Fax:* 301 796–9899, *Email: janice.adams-king@fda.hhs.gov.*

RIN: 0910–AF36

98. Over-the-Counter (OTC) Drug Review—Laxative Drug Products

E.O. 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
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, *Phone:* 301 796–3713, *Fax:* 301 796–9899, *Email: janice.adams-king@fda.hhs.gov.*

RIN: 0910–AF38

99. Over-the-Counter (OTC) Drug Review—Weight Control Products

E.O. 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, *Phone:* 301 796–3713, *Email: janice.adams-king@fda.hhs.gov.*

RIN: 0910–AF45

100. Over-the-Counter (OTC) Drug Review—Pediatric Dosing for Cough/Cold Products

E.O. 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, *Phone:* 301 796–3713, *Fax:* 301 796–9899, *Email: janice.adams-king@fda.hhs.gov.*

RIN: 0910–AG12

101. Electronic Distribution of Prescribing Information for Human Prescription Drugs Including Biological Products

E.O. 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, *Email: michael.bernstein@fda.hhs.gov.*

RIN: 0910–AG18

102. Sunlamp Products; Amendment to the Performance Standard

E.O. 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	12/00/19	

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 5515, Silver Spring, MD 20993, *Phone:* 301 796–5678, *Email: ian.ostermiller@fda.hhs.gov.*

RIN: 0910–AG30

103. General and Plastic Surgery Devices: Sunlamp Products

E.O. 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	12/00/19	

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 5515, Silver Spring, MD 20993, *Phone:* 301 796–5678, *Email: ian.ostermiller@fda.hhs.gov.*

RIN: 0910–AH14

104. Combinations of Bronchodilators With Expectorants; Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use

E.O. 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.

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–AH16

105. Nicotine Exposure Warning and Child-Resistant Packaging for Liquid Nicotine, Nicotine-Containing E-Liquids, and Other Tobacco Products

E.O. 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 and child-resistant packaging 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	03/00/20	

Regulatory Flexibility Analysis Required: Yes.

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

RIN: 0910–AH24

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Food and Drug Administration (FDA)

Completed Actions

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

E.O. 13771 Designation: Deregulatory.

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 updates FDA's requirements for accepting clinical data used to bring new medical devices to market as part of fulfilling FDA's mission. While helping to ensure the quality and integrity of clinical trial data and the protection of study participants, this rule should reduce burden on industry by avoiding the need for on-site inspections. This rule parallels the drug regulation, which should further reduce burden by having a harmonized approach. Under this new rule, a device applicant would provide FDA with information about the conduct of their study such as, the research sites where the study was conducted, the investigators who conducted the study, a summary of the protocol, information about how informed consent from the study participants was obtained, and information about the ethics committee that reviewed the study. (If such information is not available, the sponsor may explain why and request a waiver.)

Completed:

Reason	Date	FR Cite
Final Action	02/21/18	83 FR 7366
Final Action Effective.	02/21/19	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Soma Kalb, *Phone:* 301 796–6359, *Email: soma.kalb@fda.hhs.gov.*

RIN: 0910–AG48

107. Safety and Effectiveness of Healthcare Antiseptics; Topical Antimicrobial Drug Products for Over-the-Counter Human Use

E.O. 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. 360b to 360f; 21 U.S.C. 360j; 21 U.S.C. 360hh to 360ss; 21 U.S.C. 371; 21 U.S.C. 374 to 375; 21 U.S.C. 379e; 42 U.S.C. 241; 42 U.S.C. 262; . . .

Abstract: This rulemaking addresses whether FDA considers certain active ingredients in over-the-counter (OTC) healthcare antiseptic hand wash and healthcare antiseptic products to be generally recognized as safe and effective. If FDA determines that the ingredient is not generally recognized as safe and effective, a manufacturer will not be able to market the product unless it submits and receives approval of a new drug application.

Completed:

Reason	Date	FR Cite
Final Action	12/20/17	82 FR 60474
Final Action Effective.	12/20/18	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Michelle Jackson, *Phone:* 301 796–0923, *Email: michelle.jackon@fda.hhs.gov.*

RIN: 0910–AH40

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Centers for Medicare & Medicaid Services (CMS)

Proposed Rule Stage

108. Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction (CMS–3346–P)

E.O. 13771 Designation: Deregulatory.

Legal Authority: 42 U.S.C. 263a; 42 U.S.C. 273; 42 U.S.C. 1302; 42 U.S.C. 1320a–7; . . .

Abstract: This proposed rule would reform Medicare regulations that are unnecessary, obsolete, or excessively burdensome on healthcare providers and suppliers. This rule would increase the ability of healthcare professionals to devote resources to improving patient care by eliminating or reducing requirements that impede quality patient care or that divert resources away from furnishing high quality patient care.

Timetable:

Action	Date	FR Cite
NPRM	05/00/18	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Alpha-Banu Huq, 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: 410 786–8687, *Email: alpha.huq@cms.hhs.gov.*

RIN: 0938–AT23

109. FY 2019 Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities (SNFS) (CMS–1696–P)

E.O. 13771 Designation: Deregulatory.

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

Abstract: This annual proposed rule would update the payment rates used under the prospective payment system for SNFs for fiscal year 2019. The rule also includes proposals for the SNF Quality Reporting Program (QRP) and for the Skilled Nursing Facility Value-Based Purchasing (VBP) Program that will affect Medicare payment to SNFs.

Timetable:

Action	Date	FR Cite
NPRM	05/00/18	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Bill Ullman, Technical Advisor, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, MS: C5–06–27, 7500 Security Boulevard, Baltimore, MD 21244, *Phone:* 410 786–5667, *Fax:* 410 786–0765, *Email: william.ullman@cms.hhs.gov.*

RIN: 0938–AT24

110. Hospital Inpatient Prospective Payment System for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and FY 2019 Rates (CMS–1694–P) (Section 610 Review)

E.O. 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 inpatient and long-term care hospital prospective payment systems for operating and capital-related costs. This proposed rule would implement changes arising from our continuing experience with these systems. In addition, the rule proposes to establish new requirements or revise existing requirements for quality reporting by specific Medicare providers.

Timetable:

Action	Date	FR Cite
NPRM	05/00/18	

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: C4–08–06, 7500 Security Boulevard, Baltimore, MD 21244, *Phone:* 410 786–6504, *Email: donald.thompson@cms.hhs.gov.*

RIN: 0938–AT27

111. CY 2019 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates (CMS–1695–P) (Section 610 Review)

E.O. 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 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	06/00/18	

Regulatory Flexibility Analysis Required: Yes.

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

RIN: 0938–AT30

112. CY 2019 Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Medicare Part B (CMS–1693–P) (Section 610 Review)

E.O. 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, 2019. Additionally, this rule proposes updates to the third and future years of the Quality Payment Program.

Timetable:

Action	Date	FR Cite
NPRM	06/00/18	

Regulatory Flexibility Analysis Required: Yes.

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

RIN: 0938–AT31

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Centers for Medicare & Medicaid Services (CMS)

Final Rule Stage

113. Durable Medical Equipment Fee Schedule, Adjustments To Resume the Transitional 50/50 Blended Rates To Provide Relief in Non-Competitive Bidding Areas (CMS–1687–IFC) (Section 610 Review)

E.O. 13771 Designation: Other.

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 interim final rule with comment period extends the end of the transition period 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) from June 30, 2016, to December 31, 2016. In addition, this interim final rule with comment period amends the regulation to resume the transition period for items furnished from August 1, 2017, through December 31, 2018. This interim final rule with comment period also makes technical amendments to existing regulations for DMEPOS items and services to exclude infusion drugs used with DME from the DMEPOS CBP. Finally, this interim final rule with comment period also requests information on issues related to adjustments to DMEPOS fee schedules, alternatives for ensuring budget neutrality of oxygen payment classes, and current rules under the DMEPOS CBP.

Timetable:

Action	Date	FR Cite
Interim Final Rule	05/00/18	

Regulatory Flexibility Analysis Required: Undetermined.

Agency Contact: Alexander Ullman, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, MS: C5–07–26, 7500 Security Boulevard, Baltimore, MD 21244, *Phone:* 410 786–9671, *Email: alexander.ullman@cms.hhs.gov.*

RIN: 0938–AT21

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Centers for Medicare & Medicaid Services (CMS)

Long-Term Actions

114. 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)

E.O. 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	06/00/19	

Regulatory Flexibility Analysis Required: No.

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

RIN: 0938–AS21

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Centers for Medicare & Medicaid Services (CMS)

Completed Actions

115. CY 2019 Notice of Benefit and Payment Parameters (CMS–9930–F) (Completion of a Section 610 Review)

E.O. 13771 Designation: Deregulatory.

Legal Authority: Pub. L. 111–148, title I

Abstract: This final rule sets forth payment parameters and provisions related to the risk adjustment and risk adjustment data validation programs; cost-sharing parameters; and user fees for Federally-facilitated Exchanges and State-based Exchanges on the Federal platform.

Timetable:

Action	Date	FR Cite
NPRM	11/02/17	82 FR 51052
NPRM Comment Period End.	11/27/17	
Final Action	04/17/18	83 FR 16930
Final Action Effective.	06/18/18	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Lindsey Murtagh, Senior Policy Advisor, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Consumer Information and Insurance Oversight, 7500 Security Boulevard, Baltimore, MD 21244, *Phone:* 301 492–4106, *Email: lindsey.murtagh@cms.hhs.gov.*

RIN: 0938–AT12

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