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.

NAME: Ann C. Agnew,

Executive Secretary to the Department.

Office for Civil Rights—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
227	HIPAA Privacy Rule: Changing Requirement to Obtain Acknowledgment of Receipt of the Notice of Privacy Practices	0945–AA08

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

Sequence Number	Title	Regulation Identifier Number
228	Health Information Technology: Interoperability and Certification Enhancements **(Reg Plan Seq No. 26)**	0955–AA01

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

Food and Drug Administration—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
229	Sunscreen Drug Products For Over-The-Counter-Human Use; Tentative Final Monograph	0910–AF43
230	Laser Products; Amendment to Performance Standard	0910–AF87
231	Mammography Quality Standards Act; Regulatory Amendments **(Reg Plan Seq No. 29)**	0910–AH04
232	Medication Guides; Patient Medication Information **(Reg Plan Seq No. 32)**	0910–AH68

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

Food and Drug Administration—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
233	Postmarketing Safety Reporting Requirements for Human Drug and Biological Products	0910–AA97
234	Label Requirement for Food That Has Been Refused Admission Into the United States	0910–AF61
235	Human Subject Protection; Acceptance of Data From Clinical Investigations for Medical Devices	0910–AG48
236	Food Labeling; Gluten-Free Labeling of Fermented, Hydrolyzed, or Distilled Foods	0910–AH00
237	Safety and Effectiveness of Healthcare Antiseptics; Topical Antimicrobial Drug Products for Over-the-Counter Human Use	0910–AH40

Food and Drug Administration—Long-Term Actions

Sequence Number	Title	Regulation Identifier Number
238	Over-the-Counter (OTC) Drug Review—Cough/Cold (Antihistamine) Products	0910–AF31
239	Over-the-Counter (OTC) Drug Review—External Analgesic	0910–AF35

	Products	
240	Over-the-Counter (OTC) Drug Review—Internal Analgesic Products	0910–AF36
241	Over-the-Counter (OTC) Drug Review—Laxative Drug Products	0910–AF38
242	Over-the-Counter (OTC) Drug Review—Weight Control Products	0910–AF45
243	Over-the-Counter (OTC) Drug Review—Pediatric Dosing for Cough/Cold Products	0910–AG12
244	Electronic Distribution of Prescribing Information for Human Prescription Drugs Including Biological Products	0910–AG18
245	Investigational New Drug Applications Requirements for Conventional Foods, Dietary Supplements, and Cosmetics	0910–AH07
246	General and Plastic Surgery Devices: Sunlamp Products	0910–AH14
247	Combinations of Bronchodilators With Expectorants; Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use	0910–AH16

Food and Drug Administration—Completed Actions

Sequence Number	Title	Regulation Identifier Number
248	Current Good Manufacturing Practice in Manufacturing, Packing, Labeling, or Holding Operations for Dietary Supplements	0910–AB88

249	Updated Standards for Labeling of Pet Food	0910–AG09
250	Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products	0910–AG94
251	Radiology Devices; Designation of Special Controls for the Computed Tomography X-Ray System	0910–AH03

Centers for Medicare & Medicaid Services—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
252	CY 2019 Notice of Benefit and Payment Parameters (CMS-9930-P) **(Section 610 Review)**	0938–AT12
253	Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction (CMS-3346-P) **(Reg Plan Seq No. 37)**	0938–AT23
254	FY 2019 Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities (SNFs) (CMS-1696-P)	0938–AT24
255	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) (Reg Plan Seq No. 38)**	0938–AT27
256	CY 2019 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy	0938–AT30

	Changes and Payment Rates (CMS-1695-P) **(Section 610 Review)**	
257	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

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

Centers for Medicare & Medicaid Services—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
258	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 Number	Title	Regulation Identifier Number
259	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—Completed Actions

Sequence Number	Title	Regulation Identifier Number
260	Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2018 Rates (CMS-1677-F) **(Completion of a Section 610 Review)**	0938–AS98
261	CY 2018 Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B; Medicare Shared Savings Program Requirements; Medicare Diabetes Prevention Program (CMS-1676-F) **(Completion of a Section 610 Review)**	0938–AT02
262	CY 2018 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates (CMS-1678-FC) **(Completion of a Section 610 Review)**	0938–AT03

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

Office for Civil Rights (OCR)	

227. • HIPAA PRIVACY RULE: CHANGING REQUIREMENT TO OBTAIN ACKNOWLEDGMENT OF RECEIPT OF THE NOTICE OF PRIVACY PRACTICES

EO 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

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RIN: 0945–AA08

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

228. • HEALTH INFORMATION TECHNOLOGY: INTEROPERABILITY AND CERTIFICATION ENHANCEMENTS

Regulatory Plan: This entry is Seq. No. 26 in part II of this issue of the **Federal Register.**

RIN: 0955–AA01

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

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

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:

The proposed rule will address the general recognition of safety and effectiveness (GRASE) status of the 16 sunscreen mo

and describe data gaps that FDA believes need to be filled in order for FDA to permit the continued marketing of these ingr
submitting new drug applications for premarket review. Consistent with the Sunscreen Innovation Act, we also expect to ad
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	08/00/18	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Sharon Colemsn, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 22, Room 6212, 10903 New Hampshire Avenue, Silver Spring, MD 20993

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RIN: 0910–AF43

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230. LASER PRODUCTS; AMENDMENT TO PERFORMANCE STANDARD

EO 13771 Designation: Regulatory

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 (Reproposal)	10/00/18	

Final Action	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Erica Blake–Payne, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, WO 66, Room 5522, 10903 New Hampshire Avenue, Silver Spring, MD 20993

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RIN: 0910–AF87

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231. MAMMOGRAPHY QUALITY STANDARDS ACT; REGULATORY AMENDMENTS

Regulatory Plan: This entry is Seq. No. 29 in part II of this issue of the **Federal Register.**

RIN: 0910–AH04

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232. • MEDICATION GUIDES; PATIENT MEDICATION INFORMATION

Regulatory Plan: This entry is Seq. No. 32 in part II of this issue of the **Federal Register.**

RIN: 0910–AH68

Department of Health and Human Services	**Final Rule Stage**

(HHS)	
Food and Drug Administration (FDA)	

233. 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). This final rule applies to postmarketing safety reporting requirements.

Timetable:

Action	Date	FR Cite
NPRM	03/14/03	68 FR 12406
NPRM Comment Period	06/18/03	

Extended		
NPRM Comment Period End	07/14/03	
NPRM Comment Period Extension End	10/14/03	
Final Rule	10/00/18	

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

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RIN: 0910–AA97

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

EO 13771 Designation: Fully or Partially Exempt

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	
Final Action	07/00/18	

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

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RIN: 0910–AF61

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235. HUMAN SUBJECT PROTECTION; ACCEPTANCE OF DATA FROM CLINICAL INVESTIGATIONS FOR MEDICAL DEVICES

EO 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 generally 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.

Timetable:

Action	Date	FR Cite
NPRM	02/25/13	78 FR 12664
NPRM Comment Period End	05/28/13	
Final Action	03/00/18	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Soma Kalb, Biomedical Engineer, Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Heath, Building 66, Room 1534, 10903 New Hampshire Avenue, Silver Spring, MD 20993

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RIN: 0910–AG48

236. 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:

FDA was required by statute to establish criteria for the voluntary labeling of food as "gluten-free" to assist consumers with celiac disease who must avoid gluten in their diet. In 2013, FDA issued a final rule on gluten-free" labeling that established criteria for when food may be labeled "gluten-free." The final rule included methods that FDA would use for testing for the presence of gluten, which are appropriate for many food types, but not for fermented and hydrolyzed foods. FDA then issued a proposed rule entitled "Gluten-Free Labeling of Fermented or Hydrolyzed Foods" to propose requirements for maintenance of certain records that provide alternative means for the agency to verify that manufacturers of fermented and hydrolyzed foods have complied with the federal criteria for foods voluntarily labeled "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	10/00/18	

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

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RIN: 0910–AH00

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237. SAFETY AND EFFECTIVENESS OF HEALTHCARE ANTISEPTICS; TOPICAL ANTIMICROBIAL DRUG PRODUCTS FOR OVER–THE–COUNTER HUMAN USE

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

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.

Timetable:

Action	Date	FR Cite
NPRM	05/01/15	80 FR 25166
NPRM Comment Period End	10/28/15	
Final Action	01/00/18	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Michelle Jackson, Department of Health and Human Services, Food and Drug Administration, 10903 New Hampshire Avenue, Silver Spring, MD 20993

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RIN: 0910–AH40

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

238. 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. 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

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RIN: 0910–AF31

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239. 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.

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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240. 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 action addresses acetaminophen safety.

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

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RIN: 0910–AF36

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241. 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
NPRM (Professional Labeling—Sodium	02/11/11	76 FR 7743

Phosphate)		
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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242. 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 first final rule finalizes the 2005 proposed rule for weight control products containing phenylpropanolamine. The second final rule will finalize the proposed rule for weight control products containing benzocaine.

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

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RIN: 0910–AF45

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243. 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

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244. 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; 21 U.S.C. 352; 21 U.S.C. 353; 21 U.S.C. 355; 21 U.S.C. 358; 21 U.S.C. 360; 21 U.S.C. 360b; 21 U.S.C. 360gg to 360ss; 21 U.S.C. 371; 21 U.S.C. 374; 21 U.S.C. 379e; 42 U.S.C. 216; 42 U.S.C. 241; 42 U.S.C. 262; 42 U.S.C. 264

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

Timetable:

Action	Date	FR Cite
NPRM	12/18/14	79 FR 75506
NPRM Comment Period Extended	03/09/15	80 FR 12364
NPRM Comment Period End	03/18/15	
NPRM Comment Period Extended End	05/18/15	
Final Rule	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AG18

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245. INVESTIGATIONAL NEW DRUG APPLICATIONS REQUIREMENTS FOR CONVENTIONAL FOODS, DIETARY SUPPLEMENTS, AND COSMETICS

EO 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. 353; 21 U.S.C. 355(i); 21 U.S.C. 371(a); 42 U.S.C. 262(a)

Abstract: Researchers conducting studies of FDA-regulated products involving human subjects must, in some circumstances, meet requirements set out in FDA's Investigational New Drug (IND) Application regulations. The proposed rule would exempt sponsors of certain studies that evaluate a drug use of a product that is lawfully marketed as a conventional food, dietary supplement, or cosmetic from being required to submit an IND application under circumstances when the study does not present a potential for significant risk to the health, safety, or welfare of the human subjects. The proposed rule is intended to broaden the regulatory criteria for studies exempt from IND requirements and provide clarity and consistency regarding when studies evaluating drug uses of products that are lawfully marketed as conventional foods, dietary supplements, or cosmetics are subject to IND review. The proposed rule would also streamline some IND application requirements for certain studies that do not qualify for the new exemption.

Timetable:

Action	Date	FR Cite

NPRM	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Ebla Ali Ibrahim, Project Manager, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Building 51, Room 6302, 10903 New Hampshire Avenue, Silver Spring, MD 20993

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RIN: 0910–AH07

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246. 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. 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 sunlamp product use at young ages, as well as frequently using sunlamp products, both increase 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.

Sunlamp products incorporate ultraviolet (UV) lamps and include devices such as UV tanning beds and booths. People who use sunlamp products are at increased risk of developing skin cancer and other illnesses, and sustaining injuries.

Timetable:

Action	Date	FR Cite
NPRM	12/22/15	80 FR 79493
NPRM Comment Period End	03/21/16	
Final Rule	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AH14

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247. 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

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

248. CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKING, LABELING, OR HOLDING OPERATIONS FOR DIETARY SUPPLEMENTS

EO 13771 Designation: Deregulatory

Legal Authority: 21 U.S.C. 321; 21 U.S.C. 342; 21 U.S.C. 343; 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

Abstract: The Food and Drug Administration published a final rule in the Federal Register of June 25, 2007 (72 FR 34752), on current good manufacturing practice (CGMP) regulations for dietary supplements. FDA also published an Interim Final Rule in the same Federal Register (72 FR 34959) that provided a procedure for requesting an exemption from the final rule requirement that the manufacturer conduct at least one appropriate test or examination to verify the identity of any component that is a dietary ingredient. This IFR allows for submission to, and review by, FDA of an alternative to the required 100 percent identity testing of components that are dietary ingredients, provided certain conditions are met. This IFR also establishes a requirement for retention of records relating to the FDA's response to an exemption request.

Completed:

Reason	Date	FR Cite
Withdrawn	10/18/17	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Linda Kahl

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RIN: 0910–AB88

249. UPDATED STANDARDS FOR LABELING OF PET FOOD

EO 13771 Designation: Other

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

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

Completed:

Reason	Date	FR Cite
Withdrawn	11/22/17	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: William Burkholder

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RIN: 0910–AG09

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

EO 13771 Designation: Other

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

Abstract: This rule would amend the regulations regarding new drug applications (NDAs), abbreviated new drug applications (ANDAs), and biologics license application (BLAs) to revise and clarify procedures for changes to the labeling of an approved drug to reflect certain types of newly acquired information in advance of FDA's review of such change.

Completed:

Reason	Date	FR Cite
Withdrawn	09/29/17	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Janice L. Weiner

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RIN: 0910–AG94

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

EO 13771 Designation: Other

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

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

Completed:

Reason	Date	FR Cite
Withdrawn	09/29/17	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AH03

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

Centers for Medicare & Medicaid Services (CMS)	

252. CY 2019 NOTICE OF BENEFIT AND PAYMENT PARAMETERS (CMS–9930–P) (SECTION 610 REVIEW)

EO 13771 Designation: Deregulatory

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

Abstract: This proposed rule sets forth payment parameters and provisions related to the risk adjustment and risk adjustment data validation programs; cost-sharing parameters and cost-sharing reductions; and user fees for Federally-facilitated Exchanges and State-based Exchanges on the Federal platform. It proposes changes that would enhance the role of States related to essential health benefits and qualified health plan (QHP) certification; and would provide States with additional flexibility in the operation and establishment of Exchanges, including the Small Business Health Options Program (SHOP) Exchanges. It includes proposed changes to the required functions of the Small Business Health Options Programs; actuarial value for stand-alone dental plans; the rate review program; the medical loss ratio program; eligibility and enrollment; exemptions; and other related topics.

Timetable:

Action	Date	FR Cite
NPRM	11/00/17	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AT12

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253. • REGULATORY PROVISIONS TO PROMOTE PROGRAM EFFICIENCY, TRANSPARENCY, AND BURDEN REDUCTION (CMS–3346–P)

Regulatory Plan: This entry is Seq. No. 37 in part II of this issue of the **Federal Register.**

RIN: 0938–AT23

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254. • FY 2019 PROSPECTIVE PAYMENT SYSTEM AND CONSOLIDATED BILLING FOR SKILLED NURSING FACILITIES (SNFS) (CMS–1696–P)

EO 13771 Designation: Fully or Partially Exempt

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.

Timetable:

Action	Date	FR Cite
NPRM	04/00/18	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AT24

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255. • 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)

Regulatory Plan: This entry is Seq. No. 38 in part II of this issue of the **Federal Register.**

RIN: 0938–AT27

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256. • 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)

EO 13771 Designation: Fully or Partially Exempt

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.

Timetable:

Action	Date	FR Cite
NPRM	06/00/18	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Lela Strong, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, MS: C4–05–13, 7500 Security Boulevard, Baltimore, MD 21244

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RIN: 0938–AT30

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257. • CY 2019 REVISIONS TO PAYMENT POLICIES UNDER THE PHYSICIAN FEE SCHEDULE AND OTHER REVISIONS TO MEDICARE PART B (CMS–1693–P) (SECTION 610 REVIEW)

EO 13771 Designation: Fully or Partially Exempt

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.

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

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RIN: 0938–AT31

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

258. • 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)

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), 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	11/00/17	

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

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RIN: 0938–AT21

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

259. 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	06/00/19	

Regulatory Flexibility Analysis Required: No

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RIN: 0938–AS21

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

260. HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEMS FOR ACUTE CARE HOSPITALS AND THE LONG–TERM CARE HOSPITAL PROSPECTIVE PAYMENT SYSTEM AND POLICY CHANGES AND FISCAL YEAR 2018 RATES (CMS–1677–F) (COMPLETION OF A SECTION 610 REVIEW)

EO 13771 Designation: Regulatory

Legal Authority: 42 U.S.C. 1302; 42 U.S.C. 1395hh; Pub. L. 114–255; ...

Abstract: We are revising the Medicare hospital inpatient prospective payment systems (IPPS) for operating and capital-related costs of acute care hospitals to implement changes arising from our continuing experience with these systems for FY 2018. Some of these changes implement certain statutory provisions contained in the Pathway for Sustainable Growth Rate (SGR) Reform Act of 2013, the Improving Medicare Post-Acute Care Transformation Act of 2014, the Medicare Access and CHIP Reauthorization Act of 2015, the 21st Century Cures Act, and other legislation. We also are making changes relating to the provider-based status of Indian Health Service (IHS) and Tribal facilities and organizations and to the low-volume hospital payment adjustment for hospitals operated by the IHS or a Tribe. In addition, we are providing the market basket update that will apply to the rate-of-increase limits for certain hospitals excluded from the IPPS that are paid on a reasonable cost basis subject to these limits for FY 2018. We are updating the payment policies and the annual payment rates for the Medicare prospective payment system (PPS) for inpatient hospital services provided by long-term care hospitals (LTCHs) for FY 2018.

In addition, we are establishing new requirements or revising existing requirements for quality reporting by specific Medicare providers (acute care hospitals, PPS-exempt cancer hospitals, LTCHs, and inpatient psychiatric facilities). We also are establishing new requirements or revising existing requirements for eligible professionals (EPs), eligible hospitals, and critical access hospitals (CAHs) participating in the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs. We are updating policies relating to the Hospital Value-Based Purchasing (VBP) Program, the Hospital Readmissions Reduction Program, and the Hospital-Acquired Condition (HAC) Reduction Program.

We also are making changes relating to transparency of accrediting organization survey reports and plans of correction of providers and suppliers; electronic signature and electronic submission of the Certification and Settlement Summary page of the Medicare cost reports; and clarification of provider disposal of assets.

Timetable:

Action	**Date**	**FR Cite**
NPRM	04/28/17	82 FR 19796
NPRM Comment Period End	06/13/17	
Final Action	08/14/17	82 FR 37990
Final Action Effective	10/01/17	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AS98

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261. CY 2018 REVISIONS TO PAYMENT POLICIES UNDER THE PHYSICIAN FEE SCHEDULE AND OTHER REVISIONS TO PART B; MEDICARE SHARED SAVINGS PROGRAM REQUIREMENTS; MEDICARE DIABETES PREVENTION PROGRAM (CMS–1676–F) (COMPLETION OF A SECTION 610 REVIEW)

EO 13771 Designation: Regulatory

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, 2018.

Timetable:

Action	Date	FR Cite
NPRM	07/21/17	82 FR 33950
NPRM Comment Period End	09/11/17	
Final Action	11/15/17	82 FR 52976
Final Action Effective	01/01/18	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AT02

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262. CY 2018 HOSPITAL OUTPATIENT PPS POLICY CHANGES AND PAYMENT RATES AND AMBULATORY SURGICAL CENTER PAYMENT SYSTEM POLICY CHANGES AND PAYMENT RATES (CMS–1678–FC) (COMPLETION OF A SECTION 610 REVIEW)

EO 13771 Designation: Fully or Partially Exempt

Legal Authority: 42 U.S.C. 1302; 42 U.S.C. 1395hh; Pub. L. 114–255

Abstract: This annual final rule revises the Medicare hospital outpatient prospective payment system (OPPS) and the Medicare ambulatory surgical center (ASC) payment system for CY 2018 to implement changes arising from our continuing experience with these systems and certain provisions under the 21st Century Cures Act. In this rule, we describe the changes to the amounts and factors used to determine the payment rates for Medicare services paid under the OPPS and those paid under the ASC payment system. In addition, 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	07/20/17	82 FR 33558
NPRM Comment Period End	09/11/17	
Final Action	11/13/17	82 FR 52356
Final Action Effective	01/01/18	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AT03

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