DEPARTMEN

Office of the Secretary

21 CFR Ch. I

25 CFR Ch. V

42 CFR Chs. I-V

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

Regulatory Agenda

AGENCY: Office of the Secretary, HHS.

ACTION: Semiannual Regulatory Agenda.

SUMMARY: The Regulatory Flexibility Act of 1980 and Executive Order 12866 require the 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: Wilma M. Robinson, Deputy 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. 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. The purpose of the Agenda is to encourage more effective public participation in the regulatory process. The regulatory actions forecasted in this Agenda reflect the priorities of HHS Secretary Robert F. Kennedy Jr. and the Donald J. Trump Administration. Accordingly, this Agenda contains rulemakings aimed at making America healthy again! To achieve this goal, this Agenda shows a commitment to managing chronic disease; eliminating unnecessary administrative expenses and rent-seeking practices that increase healthcare costs; battling obesity; ensuring the safety and efficacy of our vaccines; protecting the religious liberty of our medical workforce; and standing up for the health and well-being of biological women, children, and families, among other policy priorities.

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: **Wilma M. Robinson,**

HHS Deputy Executive Secretary.

Office for Civil Rights—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
1	Making Technical Changes And Clarifying How OCR Addresses Conscience Authorities In Health Care; Delegation of Authority **(Rulemaking Resulting From a Section 610 Review)**	0945-AA24

Centers for Disease Control and Prevention—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
2	Control of Communicable Diseases; Foreign Quarantine	0920-AA75

Food and Drug Administration—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
3	Conduct of Analytical and Clinical Pharmacology, Bioavailability, and Bioequivalence Studies	0910-AI57

4	Postmarketing Safety Reporting Requirements, Pharmacovigilance Plans, and Pharmacovigilance Quality Systems for Human Drug and Biological Products	0910-AI61
5	Registration of Commercial Importers of Drugs; Good Importing Practice	0910-AI87
6	Pediatric Study Plan Requirements for New Drug and Biologics License Applications	0910-AI89

Food and Drug Administration—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
7	Front-of-Package Nutrition Labeling	0910-AI80

Food and Drug Administration—Long-Term Actions

Sequence Number	Title	Regulation Identifier Number
8	National Standards for the Licensure of Wholesale Drug Distributors and Third-Party Logistics Providers	0910-AH11
9	Certain Requirements Regarding Prescription Drug Marketing (203 Amendment)	0910-AH56
10	Medication Guide; Patient Medication Information	0910-AH68
11	Requirements for Tobacco Product Manufacturing Practice	0910-AH91
12	Administrative Detention of Tobacco Products	0910-AI05
13	Good Laboratory Practice for Nonclinical Laboratory Studies	0910-AJ01

Food and Drug Administration—Completed Actions

Sequence Number	Title	Regulation Identifier Number
14	Nutrient Content Claims, Definition of Term: Healthy	0910-AI13
15	Tobacco Product Standard for Menthol in Cigarettes	0910-AI60
16	Tobacco Product Standard for Nicotine Yield of Cigarettes and Certain Other Combusted Tobacco Products	0910-AI76

Centers for Medicare & Medicaid Services—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
17	CY 2026 Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Medicare Part B (CMS-1832) **(Section 610 Review)**	0938-AV50
18	CY 2026 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates (CMS-1834) **(Section 610 Review)**	0938-AV51

Centers for Medicare & Medicaid Services—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
19	Independent Dispute Resolution Operations (CMS-9897)	0938-AV15
20	Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals; the Long-Term Care Hospital Prospective Payment System; and FY 2026 Rates (CMS-1833) **(Section 610 Review)**	0938-AV45
21	FY 2026 Hospice Wage Index, Payment Rate Update, and Quality Reporting Requirements (CMS-1835) **(Section 610 Review)**	0938-AV49

Centers for Medicare & Medicaid Services—Completed Actions

Sequence Number	Title	Regulation Identifier Number
22	Enhancing Coverage of Preventive Services Under the Affordable Care Act (CMS-9887)	0938-AV57
23	Patient Protection and Affordable Care Act; Marketplace Integrity and Affordability (CMS-9884)	0938-AV61

Administration for Children and Families—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
24	Native American Programs Financial and Administrative Requirements **(Section 610 Review)**	0970-AD05
25	Temporary Assistance for Needy Families Work Participation Rate Calculation Changes **(Section 610 Review)**	0970-AD07
26	Unaccompanied Children Program Prevention of Sexual Abuse NPRM **(Section 610 Review)**	0970-AD08

Administration for Children and Families—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
27	Office of Refugee Resettlement Child Abuse and Neglect Investigations Rule **(Section 610 Review)**	0970-AD10

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

1. • MAKING TECHNICAL CHANGES AND CLARIFYING HOW OCR ADDRESSES CONSCIENCE AUTHORITIES IN HEALTH CARE; DELEGATION OF AUTHORITY (RULEMAKING RESULTING FROM A SECTION 610 REVIEW) [0945-AA24]

Legal Authority: 5 U.S.C. 301 and other federal authorities

Abstract: In keeping with Executive Orders 14202 and 14188, and HHS' commitment to reevaluate its regulations and guidance pertaining to Federal laws on conscience and religious exercise, the proposed conscience rule would amend the 2024 rule to make technical corrections and clarify how OCR addresses those federal authorities.

Timetable:

Action	Date	FR Cite
NPRM	01/00/26	

Regulatory Flexibility Analysis Required: No

Agency Contact: David Christensen, Supervisory Policy Advisor, Department of Health and Human Services, Office for Civil Rights, 200 Independence Avenue SW, Washington, DC 20201

Phone: 202 795-7830

Email: consciencerule@hhs.gov

RIN: 0945-AA24

Department of Health and Human Services (HHS)	Final Rule Stage
Centers for Disease Control and Prevention (CDC)	

2. CONTROL OF COMMUNICABLE DISEASES; FOREIGN QUARANTINE [0920-AA75]

Legal Authority: 42 U.S.C. 264; 42 U.S.C. 265

Abstract: This rulemaking amends current regulation to enable CDC to require airlines to collect and provide to CDC certain data elements regarding passengers and crew arriving from foreign countries under certain circumstances.

Timetable:

Action	Date	FR Cite
Interim Final Rule Effective	02/07/20	
Interim Final Rule	02/12/20	85 FR 7874
Interim Final Rule Comment Period End	03/13/20	
Final Action	10/00/25	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Ashley C. Altenburger JD, Regulatory Analyst, Department of Health and Human Services, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS: H16-4, Atlanta, GA 30307

Phone: 800 232-4636

Email: dgmqpolicyoffice@cdc.gov

RIN: 0920-AA75

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

3. CONDUCT OF ANALYTICAL AND CLINICAL PHARMACOLOGY, BIOAVAILABILITY, AND BIOEQUIVALENCE STUDIES [0910-AI57]

Legal Authority: 21 U.S.C. 355; 21 U.S.C. 371; 21 U.S.C. 374; 42 U.S.C. 262

Abstract: FDA is proposing to amend 21 CFR 320, in certain parts, and establish a new 21 CFR 321 to clarify FDA's study conduct expectations for clinical pharmacology, and clinical and analytical bioavailability (BA) and bioequivalence (BE) studies that support marketing applications for human drug and biological products. The proposed rule would specify needed basic study conduct requirements to enable FDA to ensure those studies are conducted appropriately and to verify the reliability of study data from those studies. This regulation would align with FDA's other good practice regulations, would also be consistent with current industry best practices, and would harmonize the regulations more closely with related international regulatory expectations.

Timetable:

Action	Date	FR Cite
NPRM	01/00/26	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Brian Joseph Folian, Supervisory Biologist, Department of Health and Human Services, Food and Drug Administration, 10903 New Hampshire Avenue, Building 22, Room 1440, Silver Spring, MD 20993-0002

Phone: 240 402-4089

Email: brian.folian@fda.hhs.gov

RIN: 0910-AI57

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4. POSTMARKETING SAFETY REPORTING REQUIREMENTS, PHARMACOVIGILANCE PLANS, AND PHARMACOVIGILANCE QUALITY SYSTEMS FOR HUMAN DRUG AND BIOLOGICAL PRODUCTS [0910-AI61]

Legal Authority: 42 U.S.C. 262; 42 U.S.C. 264; 42 U.S.C. 300aa-25; 21 U.S.C. 321; 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; ...

Abstract: The proposed rule would modernize FDA's regulations on postmarketing safety reporting and pharmacovigilance for human drug and biological products by capturing important new safety-related information, improving the quality and utility of submitted reports, and supporting enhanced efficiency and alignment with internationally harmonized reporting guidelines. The proposed rule also would require application holders for drug products and biological products (other than blood or blood components) to establish and maintain a pharmacovigilance quality system that reflects the application holder's unique needs and that would support the more streamlined, flexible approach to fulfilling certain postmarketing safety reporting requirements

Timetable:

Action	Date	FR Cite
NPRM	03/00/26	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Janice L. Weiner, Principal Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, 10903 New Hampshire Avenue, Building 51, Room 6270, Silver Spring, MD 20993-0002

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Email: janice.weiner@fda.hhs.gov

RIN: 0910-AI61

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5. REGISTRATION OF COMMERCIAL IMPORTERS OF DRUGS; GOOD IMPORTING PRACTICE

[0910-AI87]

Legal Authority: sec. 714 of the Food and Drug Administrative Safety and Innovation Act (FDASIA) of July 2012

Abstract: This proposed rulemaking meets the mandate of section 714 of the Food and Drug Administration Safety and Innovation Act and will establish registration and good importing practice requirements for commercial importers of drugs. Although manufacturers are subject to regulatory requirements to ensure such quality standards are met, there are few clear responsibilities for commercial importers of drugs to do the same.

Cost estimates of the rule include reading and understanding the rule, registering as a commercial importer through the Food and Drug Administration's (FDA) electronic importer registration system, annual updating of registration, establishing a quality management system, conducting risk evaluations of drugs and suppliers, shipment verifications, investigations, corrective actions, and records maintenance. These incremental costs would be more than offset by cost savings to FDA and industry from facilitating the review of documentation that ensures compliance with our regulations prior to being allowed to enter the United States.

The unquantified benefits of the proposed rule include improvement in the safety of finished drugs allowed to enter the United States from the commercial drug importer's requirement to register with FDA and for increased due diligence required by the importer regarding the safety of the drugs. This proposed rulemaking will also enhance FDA's ability to collect and analyze data to enable risk-informed decision-making while focusing on protecting the integrity of the global drug supply chain and ensuring safety, effectiveness, and quality of imported drugs.

Timetable:

Action	Date	FR Cite
NPRM	09/00/25	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: James Hanratty, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, 12420 Parklawn Dr, Room 4045, Rockville, MD 20852

Phone: 240 402-4718

Email: james.hanratty@fda.hhs.gov

RIN: 0910-AI87

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6. PEDIATRIC STUDY PLAN REQUIREMENTS FOR NEW DRUG AND BIOLOGICS LICENSE APPLICATIONS [0910-AI89]

Legal Authority: 21 U.S.C. 355c(e)(7); 21 U.S.C. 355c(k)(1); 21 U.S.C. 371(a)

Abstract: FDA is proposing to amend its existing regulations and add new regulations pertaining to submission of required initial pediatric study plans (iPSPs) under the Federal Food, Drug, and Cosmetic Act (FD&C Act). This proposed rule, if finalized, would implement the pediatric study plans provisions of the FD&C Act, and exercise the authority granted to the Secretary in the provisions of the FD&C Act governing exemptions from pediatric study requirements.

Timetable:

Action	Date	FR Cite
NPRM	02/00/26	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Reena Raman, Senior Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO Bldg. 51, Room 6284, 10903 New Hampshire Avenue, Silver Spring, MD 20993-0002

Phone: 301 796-7577

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Email: reena.raman@fda.hhs.gov

RIN: 0910-AI89

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

Food and Drug Administration (FDA)	

7. FRONT-OF-PACKAGE NUTRITION LABELING [0910-AI80]

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

Abstract: This rule, if finalized, would require the front of food labels to display certain nutrition information to help consumers, including those who are busy and those with lower nutrition knowledge, make more informed dietary choices. Front-of-package nutrition labeling is intended to complement the Nutrition Facts label on packaged foods by giving consumers additional context to help them quickly and easily identify foods that can help them build a healthy eating pattern. This rule would also amend certain nutrient content claim regulations to align with current nutrition science and ensure consistency in labeling.

Timetable:

Action	Date	FR Cite
NPRM	01/16/25	90 FR 5426
NPRM Comment Period End	05/16/25	
Final Rule	05/00/26	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Claudine Kavanaugh, Director, Office of Nutrition and Food Labeling, Department of Health and Human Services, Food and Drug Administration, Humans Foods Program, CPK1 RM 4C096, 5001 Campus Drive, College Park, MD 20740

Phone: 240 402-1450

Email: claudine.kavanaugh@fda.hhs.gov

RIN: 0910-AI80

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

8. NATIONAL STANDARDS FOR THE LICENSURE OF WHOLESALE DRUG DISTRIBUTORS AND THIRD-PARTY LOGISTICS PROVIDERS [0910-AH11]

Legal Authority: secs. 583 and 584 of the FD&C Act, as added by the DSCSA under Pub. L. 113-54, together with related FD&C Act authority added by the DSCSA.

Abstract: The final rule establishes national standards for State licensing of prescription drug wholesale distributors and third-party logistics providers. The rulemaking also establishes a Federal system for wholesale drug distributor and third-party logistics provider licensing for use in the absence of a State licensure program.

Timetable:

Action	Date	FR Cite
NPRM	02/04/22	87 FR 6708
NPRM Comment Period End	06/06/22	
NPRM Comment Period Extended	05/24/22	87 FR 31439
NPRM Comment Period Extended End	09/06/22	
Final Rule	05/00/27	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Aaron Weisbuch, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Building 51, Room 4261, 10903 New Hampshire Avenue, Silver Spring, MD 20993

Phone: 301 796-9362

Email: aaron.weisbuch@fda.hhs.gov

RIN: 0910-AH11

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9. CERTAIN REQUIREMENTS REGARDING PRESCRIPTION DRUG MARKETING (203 AMENDMENT) [0910-AH56]

Legal Authority: Section 503 and related provisions of the FD&C Act, as amended by Pub. L. 113-54

Abstract: The final rule amends Food and Drug Administration (FDA) regulations at 21 CFR 203 to remove provisions no longer in effect and incorporate conforming changes following enactment of the Drug Supply Chain Security Act (DSCSA). The final rule amends the regulations to clarify provisions and avoid causing confusion with the new standards for wholesale distribution established by DSCSA.

Timetable:

Action	Date	FR Cite
NPRM	02/04/22	87 FR 6443
NPRM Comment Period End	04/05/22	
Final Rule	05/00/27	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Aaron Weisbuch, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Building 51, Room 4261, 10903 New Hampshire Avenue, Silver Spring, MD 20993

Phone: 301 796-9362

Email: aaron.weisbuch@fda.hhs.gov

RIN: 0910-AH56

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10. MEDICATION GUIDE; PATIENT MEDICATION INFORMATION [0910-AH68]

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

Timetable:

Action	Date	FR Cite
NPRM	05/31/23	88 FR 35694
NPRM Comment Period End	11/27/23	
Final Rule	07/00/26	

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: cderomp@fda.hhs.gov

RIN: 0910-AH68

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11. REQUIREMENTS FOR TOBACCO PRODUCT MANUFACTURING PRACTICE [0910-AH91]

Legal Authority: 21 U.S.C. 371; 21 U.S.C. 374; 21 U.S.C. 381(a); 21 U.S.C. 387b; 21 U.S.C. 387c; 21 U.S.C. 387f; 21 U.S.C. 387i; ...

Abstract: The rule would establish tobacco product manufacturing practice (TPMP) requirements for manufacturers of finished and bulk tobacco products. This rule, if finalized, would set forth requirements for the manufacture, pre-production design validation, packing, and storage of a tobacco product. This rule would help prevent the manufacture and distribution of contaminated and otherwise nonconforming tobacco products.

Timetable:

Action	Date	FR Cite
NPRM	03/10/23	88 FR 15174
NPRM Comment Period End	09/06/23	
NPRM Comment Period Extension to Oct. 06, 2023	08/29/23	88 FR 59481
Final Rule	05/00/27	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: May Nelson, Department of Health and Human Services, Food and Drug Administration, Center for Tobacco Products, 10903 New Hampshire Avenue, Document Control Center, Bldg. 71, Room G335, Silver Spring, MD 20993

Phone: 877 287-1373

Email: askctp@fda.hhs.gov

RIN: 0910-AH91

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12. ADMINISTRATIVE DETENTION OF TOBACCO PRODUCTS [0910-AI05]

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

Abstract: FDA is proposing a regulation to establish requirements for the administrative detention of tobacco products. This proposed rule, when finalized, would allow FDA to administratively detain tobacco

products encountered during inspections of manufacturers or other establishments that manufacture, process, pack, or hold tobacco products that an authorized FDA representative 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 tobacco products encountered during inspections that are believed to be adulterated or misbranded until FDA has had time to consider the appropriate action to take and, where appropriate, to initiate legal action.

Timetable:

Action	Date	FR Cite
NPRM	05/00/27	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: May Nelson, Department of Health and Human Services, Food and Drug Administration, Center for Tobacco Products, 10903 New Hampshire Avenue, Document Control Center, Bldg. 71, Room G335, Silver Spring, MD 20993

Phone: 877 287-1373

Email: askctp@fda.hhs.gov

RIN: 0910-AI05

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13. GOOD LABORATORY PRACTICE FOR NONCLINICAL LABORATORY STUDIES [0910-AJ01]

Legal Authority: 21 U.S.C. 371

Abstract: The Food and Drug Administration (FDA) is proposing to: (1) Amend the regulations for Good Laboratory Practice (21 CFR part 58) to require a modern quality system for conducting nonclinical laboratory studies when safety and toxicity studies support or are intended to support applications or submissions for products regulated by FDA; (2) to provide an opportunity for a hearing prior to disqualification of certain persons involved in the conduct of a nonclinical laboratory study (21 CFR part 16); and (3) to simultaneously withdraw the 2016 proposed rule.

Timetable:

Action	Date	FR Cite
NPRM	08/00/26	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Ann Marie Metayer, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, 10903 New Hampshire Avenue, Building 32, Room 4375, Silver Spring, MD 20993

Phone: 301 796-3324

Email: ann.metayer@fda.hhs.gov

RIN: 0910-AJ01

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

14. NUTRIENT CONTENT CLAIMS, DEFINITION OF TERM: HEALTHY [0910-AI13]

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

Abstract: The rule would update the definition for the implied nutrient content claim "healthy" to be consistent with current nutrition science and federal dietary guidelines. The rule would revise the requirements for when the claim "healthy" can be voluntarily used in the labeling of human food products to indicate that a food, because of its nutrient content, may be useful in achieving a total diet that conforms to current dietary recommendations and helps consumers maintain healthy dietary practices.

Completed:

Reason	Date	FR Cite
Final Rule	12/27/24	89 FR 106064
Final Rule Effective Delay	02/25/25	90 FR 10592
Final Rule Effective	04/28/25	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Vincent De Jesus

Phone: 240 402-1774

Fax: 301 436-1191

Email: vincent.dejesus@fda.hhs.gov

RIN: 0910-AI13

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15. TOBACCO PRODUCT STANDARD FOR MENTHOL IN CIGARETTES [0910-AI60]

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

Abstract: This rule is a tobacco product standard to prohibit the use of menthol as a characterizing flavor in cigarettes.

Completed:

Reason	Date	FR Cite
Withdrawn	07/25/25	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: May Nelson

Phone: 877 287-1373

Email: askctp@fda.hhs.gov

RIN: 0910-AI60

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16. TOBACCO PRODUCT STANDARD FOR NICOTINE YIELD OF CIGARETTES AND CERTAIN OTHER COMBUSTED TOBACCO PRODUCTS [0910-AI76]

Legal Authority: 21 U.S.C. 387g

Abstract: The rule is a tobacco product standard that would regulate nicotine yield by establishing a maximum nicotine level in cigarettes and certain other combusted tobacco products.

Completed:

Reason	Date	FR Cite
NPRM	01/16/25	90 FR 5032
Withdrawn	04/21/25	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: May Nelson

Phone: 877 287-1373

Email: askctp@fda.hhs.gov

RIN: 0910-AI76

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

17. CY 2026 REVISIONS TO PAYMENT POLICIES UNDER THE PHYSICIAN FEE SCHEDULE AND OTHER REVISIONS TO MEDICARE PART B (CMS-1832) (SECTION 610 REVIEW) [0938-AV50]

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

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, 2026. Additionally, this rule proposes updates to the Quality Payment Program.

Timetable:

Action	Date	FR Cite
NPRM	07/00/25	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Lindsey Baldwin, Director, Division of Practitioner Services, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-1694

Email: lindsey.baldwin@cms.hhs.gov

RIN: 0938-AV50

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18. CY 2026 HOSPITAL OUTPATIENT PPS POLICY CHANGES AND PAYMENT RATES AND AMBULATORY SURGICAL CENTER PAYMENT SYSTEM POLICY CHANGES AND PAYMENT RATES (CMS-1834) (SECTION 610 REVIEW) [0938-AV51]

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

Abstract: This annual proposed rule would revise the Medicare hospital outpatient prospective payment system to implement statutory requirements and changes arising from our continuing experience with this system. The proposed rule describes changes to the amounts and factors used to determine payment

rates for services. In addition, the rule proposes changes to the ambulatory surgical center payment system list of services and rates. This proposed rule would also update and refine the requirements for the Hospital Outpatient Quality Reporting (OQR) Program and the ASC Quality Reporting (ASCQR) Program.

Timetable:

Action	Date	FR Cite
NPRM	07/00/25	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: David Rice, Director, Division of Outpatient Care, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-6004

Email: david.rice1@cms.hhs.gov

RIN: 0938-AV51

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

19. INDEPENDENT DISPUTE RESOLUTION OPERATIONS (CMS-9897) [0938-AV15]

Legal Authority: Pub. L. 116-260, Division BB, title I & title II

Abstract: This document finalizes rules related to certain provisions of the No Surprises Act regarding the Federal independent dispute resolution (IDR) process, which was established as part of the Consolidated Appropriations Act, 2021 (CAA). This rule sets forth new requirements relating to the disclosure of information that group health plans and health insurance issuers offering group or individual health insurance coverage must include along with the initial payment or notice of denial of payment for certain items and services subject to the surprise billing protections in the No Surprises Act. This rule also requires plans and issuers to communicate information by using claim adjustment reason codes (CARCs) and remittance advice remark codes (RARCs), as specified in guidance, when providing any paper or electronic remittance advice to an entity that does not have a contractual relationship with the plan or

issuer. This document also amends certain requirements related to the open negotiation period preceding the Federal IDR process, the initiation of the Federal IDR process, the Federal IDR dispute eligibility review, and the payment and collection of administrative fees and certified IDR entity fees. This document also defines bundled payment arrangements, amends requirements related to batched items and services, and amends the rules for extensions of timeframes due to extenuating circumstances. Additionally, this document requires plans and issuers to register in the Federal IDR portal.

Timetable:

Action	Date	FR Cite
NPRM	11/03/23	88 FR 75744
NPRM Comment Period End	01/02/24	
NPRM Comment Period Reopened	01/22/24	89 FR 3896
NPRM Comment Period Reopened End	02/05/24	
Final Action	11/00/25	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Bryan Kirk, Deputy Director, Division of Independent Dispute Resolution, 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: 301 492-4122

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RIN: 0938-AV15

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20. HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEMS FOR ACUTE CARE HOSPITALS; THE LONG-TERM CARE HOSPITAL PROSPECTIVE PAYMENT SYSTEM; AND FY 2026 RATES (CMS-1833) (SECTION 610 REVIEW) [0938-AV45]

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

Abstract: This annual final rule revises the Medicare hospital inpatient and long-term care hospital prospective payment systems for operating and capital-related costs. This rule implements changes arising from our continuing experience with these systems. In addition, the rule establishes new requirements or revises existing requirements for quality reporting by specific Medicare providers.

Timetable:

Action	Date	FR Cite
NPRM	04/30/25	90 FR 18002
NPRM Comment Period End	06/10/25	
Final Action	10/00/25	

Regulatory Flexibility Analysis Required: Yes

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

Phone: 410 786-6504

Email: donald.thompson@cms.hhs.gov

RIN: 0938-AV45

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21. FY 2026 HOSPICE WAGE INDEX, PAYMENT RATE UPDATE, AND QUALITY REPORTING REQUIREMENTS (CMS-1835) (SECTION 610 REVIEW) [0938-AV49]

Legal Authority: 42 U.S.C. 1302

Abstract: This annual final rule updates the hospice payment rates, the wage index, and the hospice aggrgate cap for fiscal year 2026. The rule also finalizes changes to the Hospice Quality Reporting program.

Timetable:

Action	Date	FR Cite
NPRM	04/30/25	90 FR 18568
NPRM Comment Period End	06/10/25	
Final Action	10/00/25	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Kelly Vontran, Deputy Director, Division of Home Health and Hospice, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, 7500 Security Boulevard, Baltimore, MD 21244

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RIN: 0938-AV49

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

22. ENHANCING COVERAGE OF PREVENTIVE SERVICES UNDER THE AFFORDABLE CARE ACT (CMS-9887) [0938-AV57]

Legal Authority: Public Health Service Act, Sec. 2713

Abstract: The proposed rule was formally withdrawn on January 15, 2025. This rule would amend the regulations implementing the Affordable Care Act's requirement that non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage cover recommended preventive services without cost sharing. Among other actions, the rule would take steps to expand access to certain recommended preventive items and services that are available over-the-counter; require coverage of certain preventive drugs and drug-led devices in a manner that minimizes barriers to accessing the drug or drug-led device of one's choice; reduce the likelihood that individuals face unexpected out-of-pocket costs when they receive preventive services; and ensure medical management techniques are reasonable and do not unduly prevent individuals from accessing certain preventive services. Together, these actions would make it easier for covered individuals to access certain preventive services and improve health outcomes.

Completed:

Reason	Date	FR Cite
NPRM	10/28/24	89 FR 85750

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Lindsey Murtagh

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RIN: 0938-AV57

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23. • PATIENT PROTECTION AND AFFORDABLE CARE ACT; MARKETPLACE INTEGRITY AND AFFORDABILITY (CMS-9884) [0938-AV61]

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

Abstract: This final rule revises certain standards relevant to American Health Benefits Exchanges, including standards relating to past-due premium payments for qualified health plans; the impact of an Exchange enrollee's failure to file and reconcile advance premium tax credits received during a tax year; income eligibility verifications for premium tax credits and cost-sharing reductions; annual eligibility redeterminations; the automatic reenrollment hierarchy; the annual open enrollment period; verifications of eligibility for special enrollment periods; and, the premium adjustment percentage methodology.

Timetable:

Action	Date	FR Cite
NPRM	03/19/25	90 FR 12942
NPRM Comment Period End	04/11/25	
Final Action	06/25/25	90 FR 27074

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Rogelyn McLean, 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

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RIN: 0938-AV61

Department of Health and Human Services (HHS)	Proposed Rule Stage
Administration for Children and Families (ACF)	

24. NATIVE AMERICAN PROGRAMS FINANCIAL AND ADMINISTRATIVE REQUIREMENTS (SECTION 610 REVIEW) [0970-AD05]

Legal Authority: 42 U.S.C. 2991b (b)

Abstract: This rule would remove the 20 percent non-federal contribution requirement for all grant awards under the Native American Programs Act (NAPA). The proposed rule is informed by extensive tribal consultation in which applicants shared experiences that the 20 percent cost share waiver process

is extensive and discouragingly burdensome; particularly for tribes that have limited capacity and are otherwise resource constrained. The NPRM will seek to additionally eliminate 20 percent non-federal match which should have a positive impact on tribal communities by increasing access to critical federal programs intended to improve overall health and well-being through the promotion of physical, social, and economic self-sufficiency. This change is also in fulfillment of the Administration's commitment to uphold the federal government's trust and treaty obligations to American Indian and Alaska Native tribes and responsive to Executive Order 14192 *Unleashing Prosperity Through Deregulation.*

Timetable:

Action	Date	FR Cite
NPRM	05/00/26	

Regulatory Flexibility Analysis Required: No

Agency Contact: Michelle Sauve, Director Policy, Department of Health and Human Services, Administration for Children and Families, Administration for Native Americans, 330 C Street SW, Mail Stop 4126, Washington, DC 20201

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Email: michelle.sauve@acf.hhs.gov

RIN: 0970-AD05

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25. TEMPORARY ASSISTANCE FOR NEEDY FAMILIES WORK PARTICIPATION RATE CALCULATION CHANGES (SECTION 610 REVIEW) [0970-AD07]

Legal Authority: secs. 301 and 303 of the Fiscal Responsibility Act of 2023 (FRA, Public Law 118-5)

Abstract: This NPRM will propose changes to how the Temporary Assistance for Needy Families (TANF) regulations describe the Federal work participation rate (WPR) calculation, consistent with requirements in the Fiscal Responsibility Act of 2023 (FRA). Section 301 of the FRA recalibrates the base year for the caseload reduction credit component of the WPR calculation, changing it from 2005 to 2015. Section 303 of the FRA requires that ACF only include in a state's work participation rate calculation a case with a work-eligible individual if the assistance level for that case is at least $35 a month. The FRA requires states to make these changes starting October 1, 2025.

Timetable:

Action	Date	FR Cite
NPRM	10/00/25	

Regulatory Flexibility Analysis Required: No

Agency Contact: Deborah List, Associate Deputy Director, Department of Health and Human Services, Administration for Children and Families, Office of Family Assistance, 330 C Street SW, Washington, DC 20201

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RIN: 0970-AD07

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26. UNACCOMPANIED CHILDREN PROGRAM PREVENTION OF SEXUAL ABUSE NPRM (SECTION 610 REVIEW) [0970-AD08]

Legal Authority: sec. 1101(c) of the Violence Against Women Reauthorization Act of 2013, Pub. L. 113–4 (VAWA 2013); Amendment to the Prison Rape Elimination Act (PREA) Pub. L. 108–79

Abstract: This Notice of Proposed Rulemaking would update the Standards To Prevent, Detect, and Respond to Sexual Abuse and Sexual Harassment Involving Unaccompanied Children Interim Final Rule published on December 24, 2014, to incorporate more up to date public feedback and ensure that the practices established in the IFR are effectively tailored to the operational realities of the Office of Refugee Resettlement's (ORR) Unaccompanied Alien Children (UAC) Program. The Violence Against Women Reauthorization Act of 2013 (VAWA 2013), Pub. L. 1134, contained a provision applying PREA to custodial facilities operated by HHS. VAWA 2013 requires HHS to publish a final rule adopting national standards to prevent, detect, and respond to rape and sexual assault. These national standards are to apply to all care provider facilities that maintain custody of UCs as defined in the Homeland Security Act of 2002 (6 U.S.C. 279(g)) and give due consideration to the recommended national standards provided by the NPREC report. Additionally, HHS is required to regularly assess compliance with the standards adopted and include the results of the assessments in performance evaluations of care provider facilities. As a result, HHS published the IFR to establish standards for the prevention, detection, and response to sexual abuse and sexual harassment of unaccompanied children in all ORR care provider facilities, except secure care providers and traditional foster care homes as described in the rule.

Timetable:

Action	Date	FR Cite
NPRM	01/00/26	

Regulatory Flexibility Analysis Required: No

Agency Contact: Toby Robert McFarren Biswas, Director of Policy, Department of Health and Human Services, Administration for Children and Families, Office of Refugee Resettlement, Unaccompanied Children Bureau, 330 C Street SW, Washington, DC 20201

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RIN: 0970-AD08

Department of Health and Human Services (HHS)	Final Rule Stage
Administration for Children and Families (ACF)	

27. OFFICE OF REFUGEE RESETTLEMENT CHILD ABUSE AND NEGLECT INVESTIGATIONS RULE (SECTION 610 REVIEW) [0970-AD10]

Legal Authority: 6 U.S.C. 279; 8 U.S.C. 1232(b)-(c)

Abstract: This Final Rule converts the previously issued Investigations of Child Abuse and Neglect IFR, that was published on November 27, 2024, with an effective date of December 27, 2024, and public comment concluding on January 27, 2025. The purpose of the Investigations rule is to outline ACF's procedures, in certain applicable states, to investigate and substantiate child abuse and neglect (CA/N) allegations involving staff employed by the Unaccompanied Alien Children Bureau affiliated grantees and contractors, and implement actions responsive to such investigations (e.g., related to staff employment). The Final Rule would apply only to situations in states that do not conduct CA/N investigations of individuals who may be working in such facilities.

Timetable:

Action	Date	FR Cite

Interim Final Rule With Comment Period	11/27/24	89 FR 93498
Interim Final Rule; Correction	12/27/24	89 FR 104890
Interim Final Rule Effective; Correction	12/27/24	
Interim Final Rule With Comment Period Effective	12/27/24	
Interim Final Rule Comment Period End	01/27/25	
Final Action	09/00/25	

Regulatory Flexibility Analysis Required: No

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RIN: 0970-AD10

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