DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

21 CFR Ch. I

25 CFR Ch. V

42 CFR Chs. I–V

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

Regulatory Agenda

AGENCY: Office of the Secretary, HHS.

ACTION: Semiannual Regulatory Agenda.

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

FOR FURTHER INFORMATION CONTACT: Elizabeth J. Gramling, 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 Xavier Becerra and the Biden-Harris Administration. Accordingly, this Agenda contains rulemakings aimed at ensuring that the nation is well-prepared to manage the long-term effects of COVID–19 going forward, building and expanding access to affordable, quality health care, addressing health disparities and promoting equity, lowering prescription drug costs, and boosting the mental health and wellbeing of 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.*

Elizabeth J. Gramling,
HHS Executive Secretary.

OFFICE FOR CIVIL RIGHTS—COMPLETED ACTIONS

Sequence No.	Title	Regulation Identifier No.
69	Rulemaking on Discrimination on the Basis of Disability in Health and Human Services Programs or Activities.	0945–AA15

SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION—COMPLETED ACTIONS

Sequence No.	Title	Regulation Identifier No.
70	Medications for the Treatment of Opioid Use Disorder	0930–AA39

CENTERS FOR DISEASE CONTROL AND PREVENTION—FINAL RULE STAGE

Sequence No.	Title	Regulation Identifier No.
71	Control of Communicable Diseases; Foreign Quarantine	0920–AA75

CENTERS FOR DISEASE CONTROL AND PREVENTION—COMPLETED ACTIONS

Sequence No.	Title	Regulation Identifier No.
72	Control of Communicable Diseases; Foreign Quarantine Importation of Dogs and Cats	0920–AA82

FOOD AND DRUG ADMINISTRATION—PROPOSED RULE STAGE

Sequence No.	Title	Regulation Identifier No.
73	Administrative Detention of Tobacco Products	0910–AI05
74	Conduct of Analytical and Clinical Pharmacology, Bioavailability, and Bioequivalence Studies	0910–AI57
75	Amendments to the Final Rule Regarding the List of Bulk Substances That Can Be Used to Compound Drug Products in Accordance With Section 503A of the Federal Food, Drug, and Cosmetic Act **(Section 610 Review)**.	0910–AI70
76	Distribution of Compounded Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act **(Section 610 Review)**.	0910–AI71
77	Front-of-Package Nutrition Labeling	0910–AI80

FOOD AND DRUG ADMINISTRATION—PROPOSED RULE STAGE—Continued

Sequence No.	Title	Regulation Identifier No.
78	Registration of Commercial Importers of Drugs; Good Importing Practice	0910–AI87
79	Amendments to the Current Good Manufacturing Practice Regulations for Drug Products	0910–AI88
80	Pediatric Study Plan Requirements for New Drug and Biologics License Applications	0910–AI89

FOOD AND DRUG ADMINISTRATION—FINAL RULE STAGE

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81	Sunlamp Products; Amendment to the Performance Standard	0910–AG30
82	General and Plastic Surgery Devices: Restricted Sale, Distribution, and Use of Sunlamp Products	0910–AH14
83	Amendments to the List of Bulk Drug Substances That Can Be Used To Compound Drug Products in Accordance With Section 503A of the Federal Food, Drug, and Cosmetic Act.	0910–AH81
84	Requirements for Tobacco Product Manufacturing Practice	0910–AH91
85	Nutrient Content Claims, Definition of Term: Healthy	0910–AI13

FOOD AND DRUG ADMINISTRATION—LONG-TERM ACTIONS

Sequence No.	Title	Regulation Identifier No.
86	National Standards for the Licensure of Wholesale Drug Distributors and Third-Party Logistics Providers	0910–AH11
87	Nicotine Toxicity Warnings	0910–AH24
88	Certain Requirements Regarding Prescription Drug Marketing (203 Amendment)	0910–AH56
89	Medication Guide; Patient Medication Information	0910–AH68
90	Tobacco Product Standard for Characterizing Flavors in Cigars	0910–AI28
91	Tobacco Product Standard for Menthol in Cigarettes	0910–AI60
92	Postmarketing Safety Reporting Requirements, Pharmacovigilance Plans, and Pharmacovigilance Quality Systems for Human Drug and Biological Products.	0910–AI61
93	Tobacco Product Standard for Nicotine Level of Certain Tobacco Products	0910–AI76

FOOD AND DRUG ADMINISTRATION—COMPLETED ACTIONS

Sequence No.	Title	Regulation Identifier No.
94	Direct-to-Consumer Prescription Drug Advertisements: Presentation of the Major Statement in a Clear, Conspicuous, Neutral Manner in Advertisements in Television and Radio Format.	0910–AG27
95	Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water.	0910–AI49
96	Medical Devices; Laboratory Developed Tests	0910–AI85

CENTERS FOR MEDICARE & MEDICAID SERVICES—PROPOSED RULE STAGE

Sequence No.	Title	Regulation Identifier No.
97	CY 2025 Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Medicare Part B (CMS–1807) **(Section 610 Review)**.	0938–AV33
98	CY 2025 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates (CMS–1809) **(Section 610 Review)**.	0938–AV35

CENTERS FOR MEDICARE & MEDICAID SERVICES—FINAL RULE STAGE

Sequence No.	Title	Regulation Identifier No.
99	Mental Health Parity and Addiction Equity Act and the Consolidated Appropriations Act, 2021 (CMS–9902).	0938–AU93
100	Independent Dispute Resolution Operations (CMS–9897)	0938–AV15
101	FY 2025 Hospice Wage Index, Payment Rate Update, and Quality Reporting Requirements (CMS–1810) **(Section 610 Review)**.	0938–AV29
102	FY 2025 Skilled Nursing Facility (SNFs) Prospective Payment System and Consolidated Billing and Updates to the Value-Based Purchasing and Quality Reporting Programs (CMS–1802) **(Section 610 Review)**.	0938–AV30
103	FY 2025 Inpatient Psychiatric Facilities Prospective Payment System Rate and Quality Reporting Updates (CMS–1806) **(Section 610 Review)**.	0938–AV32

CENTERS FOR MEDICARE & MEDICAID SERVICES—FINAL RULE STAGE—Continued

Sequence No.	Title	Regulation Identifier No.
104	Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals; the Long-Term Care Hospital Prospective Payment System; and FY 2025 Rates (CMS–1808) **(Section 610 Review)**.	0938–AV34

CENTERS FOR MEDICARE & MEDICAID SERVICES—COMPLETED ACTIONS

Sequence No.	Title	Regulation Identifier No.
105	CY 2024 Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Medicare Part B (CMS–1784) **(Completion of a Section 610 Review)**.	0938–AV07
106	CY 2024 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates (CMS–1786) **(Completion of a Section 610 Review)**.	0938–AV09

ADMINISTRATION FOR CHILDREN AND FAMILIES—PROPOSED RULE STAGE

Sequence No.	Title	Regulation Identifier No.
107	Native American Programs Financial and Administrative Requirements **(Section 610 Review)**	0970–AD05
108	Name Change From Office of Child Support Enforcement to Office of Child Support Services **(Section 610 Review)**.	0970–AD06
109	Temporary Assistance for Needy Families Work Participation Rate Calculation Changes **(Section 610 Review)**.	0970–AD07
110	Unaccompanied Children Program Prevention of Sexual Abuse NPRM **(Section 610 Review)**	0970–AD08

ADMINISTRATION FOR CHILDREN AND FAMILIES—FINAL RULE STAGE

Sequence No.	Title	Regulation Identifier No.
111	Supporting the Head Start Workforce and Other Quality Improvements	0970–AD01
112	Temporary Assistance for Needy Families Work Outcomes Measures **(Section 610 Review)**	0970–AD04
113	Head Start Program CLASS Effective Date Delay Direct Final Rule **(Section 610 Review)**	0970–AD09
114	ORR UC Program Child Abuse and Neglect **(Section 610 Review)**	0970–AD10

ADMINISTRATION FOR CHILDREN AND FAMILIES—COMPLETED ACTIONS

Sequence No.	Title	Regulation Identifier No.
115	Safe and Appropriate, Affirming Foster Care Placement Requirements for Titles IV–E and IV–B **(Completion of a Section 610 Review)**.	0970–AD03

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Office for Civil Rights (OCR)

Completed Actions

69. Rulemaking on Discrimination on the Basis of Disability in Health and Human Services Programs or Activities [0945–AA15]

Legal Authority: sec. 504 of the Rehabilitation Act of 1973; 29 U.S.C. 794

Abstract: This proposed rule would revise regulations under section 504 of the Rehabilitation Act of 1973 to address discrimination on the basis of disability in HHS-funded programs and activities. Covered topics include nondiscrimination in medical treatment; child welfare programs and activities; value assessment methods; accessible medical equipment; accessible web content, mobile apps, and kiosks; and other relevant health and human services activities.

Completed:

Reason	Date	FR Cite
Final Action	05/09/24	89 FR 40066
Final Action Effective.	07/08/24	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Molly Burgdorf, *Phone:* 800 368–1019, *TDD Phone:* 800 537–7697, *Email: 504@hhs.gov.*

RIN: 0945–AA15

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Substance Abuse and Mental Health Services Administration (SAMHSA)

Completed Actions

70. Medications for the Treatment of Opioid Use Disorder [0930–AA39]

Legal Authority: 21 U.S.C. 823(g)(1)

Abstract: The Substance Abuse and Mental Health Services Administration (SAMHSA) will revise 42 CFR part 8 to make permanent some regulatory flexibilities for Opioid Treatment Programs (OTPs) granted under the COVID–19 Public Health Emergency (PHE), and to expand access to care for people with Opioid Use Disorder (OUD). Specifically, SAMHSA will

update criteria pertaining to unsupervised doses of methadone and also initiation of buprenorphine via telemedicine. To expand access to care, SAMHSA will also update admission criteria, particularly those rules that may limit timely access to treatment in an OTP. To achieve this, sections of 42 CFR part 8 will require updating. SAMHSA's changes will impact roughly 1900 opioid treatment programs and state opioid treatment authorities.

In response to the Consolidated Appropriations Act of 2023, which removed the requirement to obtain a waiver in order to prescribe certain schedule III–V medications for the treatment of OUD, SAMHSA issued a supplemental notice of proposed rulemaking on Feb. 13, 2023, (88 FR 9221) calling for additional public comment on SAMHSA's plans to remove reference to the Drug Addiction Treatment Act of 2000 (*DATA* 2000-Waiver) from 42 CFR part 8.

Completed:

Reason	Date	FR Cite
Final Action	02/02/24	89 FR 7528
Final Action Effective.	04/02/24	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Neeraj Gandotra, *Phone:* 202 823–1816, *Email: neeraj.gandotra@samhsa.hhs.gov.*

RIN: 0930–AA39

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Centers for Disease Control and Prevention (CDC)

Final Rule Stage

71. 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	10/00/24	

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: H 16–4, Atlanta, GA 30307, *Phone:* 800 232–4636, *Email: dgmqpolicyoffice@cdc.gov.*

RIN: 0920–AA75

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Centers for Disease Control and Prevention (CDC)

Completed Actions

72. Control of Communicable Diseases; Foreign Quarantine Importation of Dogs and Cats [0920–AA82]

Legal Authority: 42 U.S.C. 264

Abstract: HHS is amending its regulations concerning the importation of dogs from high-risk rabies countries into the United States (U.S.). The final rule will establish requirements regarding an importation system that will reduce fraud and improve the U.S. government's ability to verify U.S. entry requirements and mitigate the introduction of dogs infected with rabies and other communicable diseases of public health concern. Importation requirements for cats will not change.

Completed:

Reason	Date	FR Cite
Final Rule	05/13/24	89 FR 41726
Final Rule Effective.	08/01/24	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Ashley C. Altenburger, *Phone:* 800 232–4636, *Email: dgmqpolicyoffice@cdc.gov.*

RIN: 0920–AA82

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Food and Drug Administration (FDA)

Proposed Rule Stage

73. 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	12/00/24	

Regulatory Flexibility Analysis Required: Yes.

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

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

RIN: 0910–AI05

74. 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	10/00/24	

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

75. Amendments to the Final Rule Regarding the List of Bulk Substances That Can be Used To Compound Drug Products in Accordance With Section 503A of the Federal Food, Drug, and Cosmetic Act (Section 610 Review) [0910–AI70]

Legal Authority: 21 U.S.C. 353a; 21 U.S.C. 351; 21 U.S.C. 371(a); 21 U.S.C. 352; 21 U.S.C. 355

Abstract: FDA has issued a regulation creating a list of bulk drug substances (active pharmaceutical ingredients) that can be used to compound drug products in accordance with section 503A of the Federal Food, Drug, and Cosmetic Act, although they are neither the subject of an applicable United States Pharmacopeia (USP) or National Formulary (NF) monograph nor components of FDA-approved drug products (the 503A Bulks List). The proposed rule will identify certain bulk drug substances that FDA has considered and is proposing to place on the 503A Bulks List and certain bulk drug substances that FDA has considered and is proposing not to include on the 503A Bulks List.

Timetable:

Action	Date	FR Cite
NPRM	10/00/24	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Rosilend Lawson, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, 10903 New Hampshire Avenue, Building 51, Room 5197, Silver Spring, MD 20993, *Phone:* 240 402–6223, *Email: rosilend.lawson@fda.hhs.gov*.

RIN: 0910–AI70

76. Distribution of Compounded Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act (Section 610 Review) [0910–AI71]

Legal Authority: 21 U.S.C. 351; 21 U.S.C. 352; 21 U.S.C. 353a; 21 U.S.C. 353a–1; 21 U.S.C. 355; 21 U.S.C. 371

Abstract: The Food and Drug Administration is proposing rulemaking regarding statutory requirements under section 503A of the Federal Food, Drug, and Cosmetic Act for certain distributions of compounded human drug products. The proposed rule, if finalized, will include provisions regarding a standard memorandum of understanding (MOU) that describes the responsibilities of a State Board of Pharmacy or other appropriate State agency that chooses to sign the standard MOU in investigating complaints related to drug products compounded in such State and distributed outside such State and in addressing the interstate distribution of inordinate amounts of compounded human drug products. It will also, if finalized, include provisions regarding the statutory 5 percent limit on distribution of compounded human drug products out of the State in which they are compounded in States that do not sign the standard MOU. The rule, will also, if finalized, address communication with State boards of pharmacy.

Timetable:

Action	Date	FR Cite
NPRM	12/00/24	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Dominic Markwordt, 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 5104, Silver Spring, MD 20993, *Phone:* 301 796–9349, *Email: dominic.markwordt@fda.hhs.gov*.

RIN: 0910–AI71

77. 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 proposed 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 proposed rule is being developed as part of a broader, whole-of-government approach to help reduce the burden of chronic disease and advance health equity by helping to improve dietary patterns in the United States. Development of the proposed rule has been informed by, among other things, research findings and extensive public outreach and engagement, including a public meeting conducted by the Reagan-Udall Foundation for the FDA and listening sessions with a range of interested parties.

Timetable:

Action	Date	FR Cite
NPRM	10/00/24	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Mark Kantor, Nutritionist, Department of Health and Human Services, Food and Drug Administration, CPK1 RM 3D034, HFS–830, 5001 Campus Drive, College Park, MD 20740, *Phone:* 240 402–2082, *Email: mark.kantor@fda.hhs.gov.*

RIN: 0910–AI80

78. 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.

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. There would also be cost savings to both FDA and industry from facilitating the review of documentation that ensures compliance with our regulations prior to being allowed to enter the United States. 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	10/00/24	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: James Hanratty, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, WO 75, Rm. 1607A, 10903 New Hampshire Avenue, Silver Spring, MD 20993, *Phone:* 240 402–4718, *Email: james.hanratty@fda.hhs.gov.*

RIN: 0910–AI87

79. • Amendments to the Current Good Manufacturing Practice Regulations for Drug Products [0910–AI88]

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. 355; 21 U.S.C. 360b; 21 U.S.C. 360bbb–7; 21 U.S.C. 371; 21 U.S.C. 374; 42 U.S.C. 262; 42 U.S.C. 264

Abstract: FDA is proposing to amend the Current Good Manufacturing Practice Regulations for Drug Products. The proposed amendment will clarify and modernize the regulations by adding requirements for quality management systems and controls over components and drug product containers and closures.

Timetable:

Action	Date	FR Cite
NPRM	02/00/25	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Ashley Boam, Health Science Administrator, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Building 51, Room 4192, 10903 New Hampshire Avenue, Silver Spring, MD 20993, *Phone:* 301 796–6341, *Email: ashley.boam@fda.hhs.gov.*

RIN: 0910–AI88

80. • 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	10/00/24	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Kristiana Brugger, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 51, Room 5252, 10903 New Hampshire Avenue, Silver Spring, MD 20993, *Phone:* 301 796–3600, *Email: kristiana.brugger@fda.hhs.gov.*

RIN: 0910–AI89

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Food and Drug Administration (FDA)

Final Rule Stage

81. Sunlamp Products; Amendment to the Performance Standard [0910–AG30]

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

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

Timetable:

Action	Date	FR Cite
NPRM	12/22/15	80 FR 79505
NPRM Comment Period End.	03/21/16	
Final Rule	12/00/24	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Ian Ostermiller, Regulatory Counsel, Center for Devices and Radiological Health, Department of Health and Human Services, Food and Drug Administration, 10903 New Hampshire Avenue, WO 66, Room 5454, Silver Spring, MD 20993, *Phone:* 301 796–5678, *Email: ian.ostermiller@fda.hhs.gov.*

RIN: 0910–AG30

82. General and Plastic Surgery Devices: Restricted Sale, Distribution, and Use of Sunlamp Products [0910–AH14]

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

Abstract: This rule will apply device restrictions to sunlamp products. Sunlamp products include ultraviolet (UV) lamps and UV tanning beds and booths. A large number of skin cancer cases, including cases of melanoma, are attributable to the use of sunlamp products. Beginning use of sunlamp products at young ages, as well as frequently using sunlamp products, both increases the risk of developing skin cancers and other illnesses, and sustaining other injuries. Even infrequent use, particularly at younger ages, can significantly increase these risks.

Timetable:

Action	Date	FR Cite
NPRM	12/22/15	80 FR 79493
NPRM Comment Period End.	03/21/16	
Final Rule	11/00/24	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Daniel Schieffer, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, 10903 New Hampshire Avenue, WO 66, Silver Spring, MD 20993, *Phone:* 301 796–3350, *Email: daniel.schieffer@fda.hhs.gov.*

RIN: 0910–AH14

83. Amendments to the List of Bulk Drug Substances That Can Be Used To Compound Drug Products in Accordance With Section 503A of the Federal Food, Drug, and Cosmetic Act [0910–AH81]

Legal Authority: 21 U.S.C. 351; 21 U.S.C. 352; 21 U.S.C. 353a; 21 U.S.C. 355; 21 U.S.C. 371

Abstract: FDA has issued a regulation creating a list of bulk drug substances (active pharmaceutical ingredients) that can be used to compound drug products in accordance with section 503A of the Federal Food, Drug, and Cosmetic Act (FD&C Act), although they are neither the subject of an applicable United States Pharmacopeia (USP) or National Formulary (NF) monograph nor components of FDA-approved drugs (the 503A Bulks List). FDA has proposed to amend the 503A Bulks List by placing additional bulk drug substances on the list. FDA has also identified bulk drug substances that FDA has considered and proposed not to include on the 503A Bulks List. Additional substances nominated by the public for inclusion on this list are currently under consideration and will be the subject of future rulemaking.

Timetable:

Action	Date	FR Cite
NPRM	09/05/19	84 FR 46688
NPRM Comment Period End.	12/04/19	
Final Rule	10/00/24	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Oluwaseun ''Kemi'' Asante, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, 10903 New Hampshire Avenue, Silver Spring, MD 20993, *Phone:* 301 796–7425, *Email: kemi.asante@fda.hhs.gov*.

RIN: 0910–AH81

84. 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. This rule provides manufacturers with flexibility in the manner in which they comply with the requirements while giving FDA the ability to enforce regulatory requirements, thus helping to assure the protection of public health. In April 2023, FDA held an all tribes' call to provide an overview of the proposed rule, answer questions, and receive tribal feedback. Additionally, in May 2023, FDA held an open session meeting of the Tobacco Products Scientific Advisory Committee to enable the committee to discuss and provide recommendations on the proposed rule. FDA made background material available to members of the public and interested persons were able to present data, information, and views on issues pending before the committee.

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	04/00/25	

Regulatory Flexibility Analysis Required: Yes.

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

RIN: 0910–AH91

85. 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.

Timetable:

Action	Date	FR Cite
NPRM	09/29/22	87 FR 59168
NPRM Comment Period End.	12/28/22	
NPRM Comment Period Extended.	11/29/22	87 FR 73267
NPRM Comment Period Extended End.	02/16/23	
Final Rule	09/00/24	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Vincent De Jesus, Nutritionist, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition, (HFS–830), Room 3D–031, 5100 Paint Branch Parkway, College Park, MD 20740, *Phone:* 240 402–1774, *Fax:* 301 436–1191, *Email: vincent.dejesus@fda.hhs.gov*.

RIN: 0910–AI13

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Food and Drug Administration (FDA)

Long-Term Actions

86. 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	05/00/26	

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

87. Nicotine Toxicity Warnings [0910–AH24]

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

Abstract: This rule would establish acute nicotine toxicity warning requirements for liquid nicotine and nicotine-containing e-liquid(s) intended for human consumption, and potentially for other tobacco products including, but not limited to, novel tobacco products such as dissolvables, lotions, gels, and drinks. This action is intended to increase consumer awareness and knowledge of the risks of acute toxicity due to accidental nicotine exposure from nicotine-containing e-liquids in tobacco products.

Timetable:

Action	Date	FR Cite
NPRM	10/00/25	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Laura Chilaka, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Tobacco Products, 10903 New Hampshire Avenue, Document Control Center, Building 71, Room G355, Silver Spring, MD 20993, *Phone:* 877 287–1373, *Email: ctpregulations@fda.hhs.gov*.

RIN: 0910–AH24

88. 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	05/00/26	

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

89. 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, namely Patient Medication Information, for submission to and review 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 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	05/00/26	

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

90. Tobacco Product Standard for Characterizing Flavors in Cigars [0910–AI28]

Legal Authority: 21 U.S.C. 331; 21 U.S.C. 333; 21 U.S.C. 371(a); 21 U.S.C. 387b and 387c; 21 U.S.C. 387f(d) and 387g; . . .

Abstract: This rule is a tobacco product standard that would prohibit characterizing flavors (other than tobacco) in all cigars. We are taking this action with the intention of reducing the tobacco-related death and disease associated with cigar use. Evidence shows that flavored tobacco products appeal to youth and also shows that youth may be more likely to initiate tobacco use with such products. Characterizing flavors in cigars, such as strawberry, grape, orange, and cocoa, enhance taste and make these products easier to use. Over a half million youth in the United States use flavored cigars, placing these youth at risk for cigar-related death and disease.

Timetable:

Action	Date	FR Cite
ANPRM	03/21/18	83 FR 12294
ANPRM Comment Period End.	07/19/18	
NPRM	05/04/22	87 FR 26396
NPRM Comment Period Extended.	06/21/22	87 FR 36786
NPRM Comment Period End.	07/05/22	
NPRM Comment Period Extended End.	08/02/22	
Final Action	To Be Determined	

Regulatory Flexibility Analysis Required: Yes.

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

RIN: 0910–AI28

91. 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.

Timetable:

Action	Date	FR Cite
ANPRM	07/24/13	78 FR 44484
ANPRM Comment Period End.	09/23/13	
NPRM	05/04/22	87 FR 26454
NPRM Comment Period Extended.	06/21/22	87 FR 36786
NPRM Comment Period End.	07/05/22	

Action	Date	FR Cite
NPRM Comment Period Extended End.	08/02/22	
Final Action	To Be Determined	

Regulatory Flexibility Analysis Required: Yes.

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

RIN: 0910–AI60

92. 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, including blood and blood components, by capturing important new safety-related information, improving the quality and utility of submitted reports, and supporting enhanced alignment with internationally harmonized reporting guidelines. Among other things, the proposed rule would require the submission of certain nonclinical and clinical data to FDA in a periodic safety report, rather than the annual report. The proposed rule also would require application holders for drug products and certain biological products to establish and maintain a pharmacovigilance quality system that reflects the application holder's unique needs and that may support a more streamlined, flexible approach to satisfying certain postmarketing safety reporting requirements.

Timetable:

Action	Date	FR Cite
NPRM	10/00/25	

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, *Phone:* 301 796–3475, *Fax:* 301 847–8440, *Email: janice.weiner@fda.hhs.gov*.

RIN: 0910–AI61

93. Tobacco Product Standard for Nicotine Level of Certain Tobacco Products [0910–AI76]

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

Abstract: The proposed rule is a tobacco product standard that would establish a maximum nicotine level in cigarettes and certain other finished tobacco products.

Timetable:

Action	Date	FR Cite
NPRM	To Be Determined	

Regulatory Flexibility Analysis Required: Yes.

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

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

RIN: 0910–AI76

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Food and Drug Administration (FDA)

Completed Actions

94. Direct-to-Consumer Prescription Drug Advertisements: Presentation of the Major Statement in a Clear, Conspicuous, Neutral Manner in Advertisements in Television and Radio Format [0910–AG27]

Legal Authority: 21 U.S.C. 321; 21 U.S.C. 331; 21 U.S.C. 352; 21 U.S.C. 355; 21 U.S.C. 360b; 21 U.S.C. 371; . . .

Abstract: The Food and Drug Administration (FDA) is amending its regulations concerning direct-to-consumer (DTC) advertisements of prescription drugs. Prescription drug advertisements presented through media such as TV and radio must disclose the product's major side effects and contraindications in what is sometimes called the major statement. The rule would revise the regulation to reflect the statutory requirement that in DTC advertisements for human prescription drugs presented in television or radio format and stating the name of the drug and its conditions of use, the major statement relating to side effects and contraindications of the advertised drug must be presented in a clear, conspicuous, and neutral manner. This rule also establishes standards for determining whether the major statement in these advertisements is presented in the manner required.

Completed:

Reason	Date	FR Cite
Final Rule	11/21/23	88 FR 80958
Final Rule Effective.	05/20/24	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Suzanna Boyle, *Phone:* 240 402–4723, *Email: suzanna.boyle@fda.hhs.gov*.

RIN: 0910–AG27

95. Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water [0910–AI49]

Legal Authority: 21 U.S.C. 321; 21 U.S.C. 331; 21 U.S.C. 342; 21 U.S.C. 350h; 21 U.S.C. 371; 42 U.S.C. 243; 42 U.S.C. 264; 42 U.S.C. 271; . . .

Abstract: This rulemaking will revise certain requirements for agricultural water for covered produce other than sprouts in the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (produce safety) regulation for covered produce other than sprouts.

Completed:

Reason	Date	FR Cite
Final Rule	05/06/24	89 FR 37448
Final Rule Effective.	07/05/24	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Samir Assar, *Phone:* 240 402–1636, *Email: samir.assar@fda.hhs.gov.*

RIN: 0910–AI49

96. Medical Devices; Laboratory Developed Tests [0910–AI85]

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. 360c; . . .

Abstract: This rule would amend the Food and Drug Administration's regulations to make explicit that laboratory developed tests (LDTs) are devices under the Federal Food, Drug, and Cosmetic Act (FD&C Act.)

Completed:

Reason	Date	FR Cite
NPRM	10/03/23	88 FR 68006
Final Rule	05/06/24	89 FR 37286
Final Rule Effective.	07/05/24	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Eitan Bernstein, *Phone:* 240 402–9812, *Email: eitan.bernstein@fda.hhs.gov.*

RIN: 0910–AI85

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Centers for Medicare & Medicaid Services (CMS)

Proposed Rule Stage

97. CY 2025 Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Medicare Part B (CMS–1807) (Section 610 Review) [0938–AV33]

Legal Authority: 42 U.S.C. 1302; 42 U.S.C. 1395hh; Pub. L. 117–169

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, 2025. Additionally, this rule proposes updates to the Quality Payment Program. This proposed rule would also codify the inflation rebate program for Medicare Part B and Part D drugs established in the Inflation Reduction Act.

Timetable:

Action	Date	FR Cite
NPRM	07/00/24	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Gift Tee, Director, Division of Physician Services, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, 7500 Security Boulevard, MS: C1–09–07, Baltimore, MD 21244, *Phone:* 410 786–9316, *Email: gift.tee@cms.hhs.gov.*

RIN: 0938–AV33

98. CY 2025 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates (CMS–1809) (Section 610 Review) [0938–AV35]

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

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

Timetable:

Action	Date	FR Cite
NPRM	07/00/24	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Elise Barringer, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, MS: C4–03–06, 7500 Security Boulevard, Baltimore, MD 21244, *Phone:* 410 786–9222, *Email: elise.barringer@cms.hhs.gov.*

RIN: 0938–AV35

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Centers for Medicare & Medicaid Services (CMS)

Final Rule Stage

99. Mental Health Parity and Addiction Equity Act and the Consolidated Appropriations Act, 2021 (CMS–9902) [0938–AU93]

Legal Authority: Pub. L. 116–260, Division BB, title II; Pub. L. 110–343, secs. 511 and 512

Abstract: This rule would finalize proposed amendments to the final rules implementing the Mental Health Parity and Addiction Equity Act (MHPAEA). The amendments clarify plans' and issuers' obligations under the law, promote compliance with MHPAEA, and update requirements taking into account experience with MHPAEA in the years since the rules were finalized. The rule would also finalize new regulations implementing amendments to MHPAEA recently enacted as part of the Consolidated Appropriations Act, 2021 (CAA, 2021).

Timetable:

Action	Date	FR Cite
NPRM	08/03/23	88 FR 51552
NPRM Comment Period Extended.	09/28/23	88 FR 66728
NPRM Comment Period End.	10/02/23	
NPRM Comment Period Extended End.	10/17/23	
Final Action	07/00/24	

Regulatory Flexibility Analysis Required: Yes.

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

RIN: 0938–AU93

100. Independent Dispute Resolution Operations (CMS–9897) [0938–AV15]

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

Abstract: This final rule amends the Requirements Related to Surprise Billing; Part I (July 2021 interim final rules), Requirements Related to Surprise Billing Interim Final Rules; Part II (October 2021 interim final rules), and Requirements Related to Surprise Billing Final Rules (August 2022 final rules), which set forth requirements related to Title I (No Surprises Act (NSA)) and Title II (Transparency) of Division BB of the Consolidated Appropriations Act, 2021.

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	11/00/24	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Deborah Bryant, Senior Advisor, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center

for Consumer Information and Insurance Oversight, MS: W08–134, 7500 Security Boulevard, Baltimore, MD 21244, *Phone:* 301 492–4293, *Email: deborah.bryant@cms.hhs.gov.*

RIN: 0938–AV15

101. FY 2025 Hospice Wage Index, Payment Rate Update, and Quality Reporting Requirements (CMS–1810) (Section 610 Review) [0938–AV29]

Legal Authority: 42 U.S.C. 1302

Abstract: This annual proposed rule would update the hospice payment rates and the wage index for fiscal year 2025. The rule also proposes changes to the Hospice Quality Reporting program.

Timetable:

Action	Date	FR Cite
NPRM	04/04/24	89 FR 23778
NPRM Comment Period End.	05/28/24	
Final Action	10/00/24	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Brian Slater, Director, Division of Home Health and Hospice, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, MS: C4–07–07, 7500 Security Boulevard, Baltimore, MD 21244, *Phone:* 410 786–5229, *Email: brian.slater@cms.hhs.gov.*

RIN: 0938–AV29

102. FY 2025 Skilled Nursing Facility (SNFS) Prospective Payment System and Consolidated Billing and Updates to the Value-Based Purchasing and Quality Reporting Programs (CMS–1802) (Section 610 Review) [0938–AV30]

Legal Authority: 42 U.S.C. 1302; 42 U.S.C. 1395d(d); 42 U.S.C. 1395f(b); 42 U.S.C. 1395g; 42 U.S.C. 1395l(a); 42 U.S.C. 1395l(i); 42 U.S.C. 13951(n); 42 U.S.C. 1395m; 42 U.S.C. 1395x(v); 42 U.S.C. 1395x(kkk); 42 U.S.C. 1395hh; 42 U.S.C. 1395rr; 42 U.S.C. 1395tt; 42 U.S.C. 1395ww

Abstract: This annual rule updates the payment rates used under the prospective payment system for SNFs for fiscal year 2025. The rule also includes updates to the SNF Quality Reporting Program (QRP) and the Skilled Nursing Facility Value-Based Purchasing (VBP) Program that will affect Medicare payment to SNFs.

Timetable:

Action	Date	FR Cite
NPRM	04/03/24	89 FR 23424
NPRM Comment Period End.	05/28/24	
Final Action	10/00/24	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Tammy Luo, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, MS: C5–06–17, 7500 Security Boulevard, Baltimore, MD 21244, *Phone:* 410 786–4325, *Email: tammy.luo@cms.hhs.gov.*

RIN: 0938–AV30

103. FY 2025 Inpatient Psychiatric Facilities Prospective Payment System Rate and Quality Reporting Updates (CMS–1806) (Section 610 Review) [0938–AV32]

Legal Authority: 42 U.S.C. 1302; 42 U.S.C. 1395f; 42 U.S.C. 1395g; 42 U.S.C. 1395hh; 42 U.S.C. 1395ww(s)

Abstract: This annual rule updates the prospective payment system for inpatient psychiatric facilities (IPF) with discharges beginning on October 1, 2024. The rule also includes updates to the IPF Quality Reporting Program.

Timetable:

Action	Date	FR Cite
NPRM	04/03/24	89 FR 23146
NPRM Comment Period End.	05/28/24	
Final Action	10/00/24	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Marissa Kellam, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, MS: C5–04–23, 7500 Security Boulevard, Baltimore, MD 21244, *Phone:* 410 786–3012, *Email: marissa.kellam@cms.hhs.gov.*

RIN: 0938–AV32

104. Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals; the Long-Term Care Hospital Prospective Payment System; and FY 2025 Rates (CMS–1808) (Section 610 Review) [0938–AV34]

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

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

Timetable:

Action	Date	FR Cite
NPRM	05/02/24	89 FR 35934
NPRM Comment Period End.	06/10/24	
Final Action	10/00/24	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Donald Thompson, Director, Division of Acute Care, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, MS: C4–01–26, 7500 Security Boulevard, Baltimore, MD 21244, *Phone:* 410 786–6504, *Email: donald.thompson@cms.hhs.gov.*

RIN: 0938–AV34

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Centers for Medicare & Medicaid Services (CMS)

Completed Actions

105. CY 2024 Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Medicare Part B (CMS–1784) (Completion of a Section 610 Review) [0938–AV07]

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

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 including, but not limited to, establishing payment policies for dental services prior to the initiation of immunotherapy services. These changes apply to services furnished beginning January 1, 2024. Additionally, this rule updates the Quality Payment Program.

Timetable:

Action	Date	FR Cite
NPRM	08/07/23	88 FR 52262
NPRM Comment Period End.	09/11/23	
Final Action	11/16/23	88 FR 78818
Final Action Effective.	01/01/24	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Gift Tee, Director, Division of Physician Services, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, 7500 Security Boulevard, MS: C1–09–

07, Baltimore, MD 21244, *Phone:* 410 786–9316, *Email: gift.tee@cms.hhs.gov.*

RIN: 0938–AV07

106. CY 2024 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates (CMS–1786) (Completion of a Section 610 Review) [0938–AV09]

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

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

Timetable:

Action	Date	FR Cite
NPRM	07/31/23	88 FR 49552
NPRM Comment Period End.	09/11/23	
Final Action	11/22/23	88 FR 81540
Final Action Effective.	01/01/24	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Elise Barringer, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, MS: C4–03–06, 7500 Security Boulevard, Baltimore, MD 21244, *Phone:* 410 786–9222, *Email: elise.barringer@cms.hhs.gov.*

RIN: 0938–AV09

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Administration for Children and Families (ACF)

Proposed Rule Stage

107. • 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). This is in response to Executive Order 14112 *Reforming Federal Funding and Support for Tribal Nations to Better Embrace Our Trust Responsibilities and Promote the Next Era of Tribal Self-Determination* which in part recognizes that federal programs were administered in unduly burdensome ways that left Tribal Nations unduly burdened and frustrated with bureaucracy. Elimination of the 20 percent non-federal match for all ANA projects would have profound impact on tribal communities with respect to improving equity and access to federal programs intended for their benefit. Tribal leaders across Indian Country have testified that nonfederal share requirement is a significant barrier for applying and administering grant funds especially for the smaller tribes that lack the resources to meet the non-federal share.

Timetable:

Action	Date	FR Cite
NPRM	11/00/24	

Regulatory Flexibility Analysis Required: No.

Agency Contact: Amy Zukowski, Acting 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, *Phone:* 202 205–5606, *Email: amy.zukowski@acf.hhs.gov.*

RIN: 0970–AD05

108. • Name Change From Office of Child Support Enforcement to Office of Child Support Services (Section 610 Review) [0970–AD06]

Legal Authority: Not Yet Determined

Abstract: This Notice of Proposed Rulemaking would update 45 CFR Chapter III to reflect that on June 5, 2023, the Office of Child Support Enforcement became the Office of Child Support Services. This name change reflects the program's commitment to serve the whole family and provide services that promote family self-sufficiency so children receive reliable support from both parents.

Timetable:

Action	Date	FR Cite
NPRM	12/00/24	

Regulatory Flexibility Analysis Required: No.

Agency Contact: Tavaughn McKenny, Program Specialist, Department of Health and Human Services, Administration for Children and Families, Office of Child Support Services, 330 C Street SW, Washington, DC 20201, *Phone:* 202 565–0129, *Email: tavaughn.mckenny@acf.hhs.gov.*

RIN: 0970–AD06

109. • 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: To comply with requirements from the Fiscal Responsibility Act of 2023 (FRA), this NPRM will propose changes to the how Temporary Assistance for Needy Families (TANF) regulations describe the federal work participation rate (WPR) calculation. As required by Section 301 of the FRA, this NPRM will propose a recalibration of the base year for the caseload reduction credit component of the WPR calculation. The base year will change from 2005 to 2015. As required by Section 303 of the FRA, this NPRM will propose that ACF only count a case in a state's work participation rate calculation if the assistance level for that case is at least $35 a month. Both changes will be effective October 1, 2025.

Timetable:

Action	Date	FR Cite
NPRM	11/00/24	

Regulatory Flexibility Analysis Required: No.

Agency Contact: La Sherra Ayala, Deputy Director, Department of Health and Human Services, Administration for Children and Families, Office of Family Assistance, 330 C Street SW, Washington, DC 20201, *Phone:* 202 478–0714, *Email: lasherra.ayala@acf.hhs.gov.*

RIN: 0970–AD07

110. • 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 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 Children (UC) Program. The Violence Against Women Reauthorization Act of 2013 (VAWA 2013), Public Law 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	12/00/24	

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, *Phone:* 202 555–4440, *Email: ucpolicy-regulatoryaffairs@acf.hhs.gov*.

RIN: 0970–AD08

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Administration for Children and Families (ACF)

Final Rule Stage

111. Supporting the Head Start Workforce and Other Quality Improvements [0970–AD01]

Legal Authority: 42 U.S.C. 9801; 42 U.S.C. 9836a; 42 U.S.C. 9839

Abstract: This NPRM will propose changes to the Head Start Program Performance Standards to better support the Head Start workforce and to maintain the quality of comprehensive Head Start services. During the public comment period, ACF engaged with the Head Start community through listening sessions in multiple locations around the country and virtually on the proposed rule to generate interest in submitting public comments.

Timetable:

Action	Date	FR Cite
NPRM	11/20/23	88 FR 80818
NPRM Comment Period End.	01/19/24	
Final Action	07/00/24	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Jessica Bialecki, Policy and Planning Director, Department of Health and Human Services, Administration for Children and Families, Office of Head Start, 330 C Street SW, Washington, DC 20201, *Phone:* 202 283–1004, *Email: jessica.bialecki@acf.hhs.gov*.

RIN: 0970–AD01

112. • Temporary Assistance for Needy Families Work Outcomes Measures (Section 610 Review) [0970–AD04]

Legal Authority: Section 304 of the Fiscal Responsibility Act of 2023 (FRA, Pub. L. 118–5)

Abstract: This interim final rule modifies 45 CFR part 265 in order to implement the statutory changes enacted by section 304 of the Fiscal Responsibility Act of 2023 (FRA, Public Law 118–5) related to the reporting of work outcomes under the Temporary Assistance for Needy Families (TANF) program. ACF is promulgating this rule as an interim final rule to ensure states and territories have sufficient time to comply with data collection for fiscal year 2025.

Timetable:

Action	Date	FR Cite
Interim Final Rule	07/00/24	

Regulatory Flexibility Analysis Required: No.

Agency Contact: La Sherra Ayala, Deputy Director, Department of Health and Human Services, Administration for Children and Families, Office of Family Assistance, 330 C Street SW, Washington, DC 20201, *Phone:* 202 478–0714, *Email: lasherra.ayala@acf.hhs.gov*.

RIN: 0970–AD04

113. • Head Start Program Class Effective Date Delay Direct Final Rule (Section 610 Review) [0970–AD09]

Legal Authority: sec. 641 of the Act (42 U.S.C. 9836) as amended by the Improving Head Start for School Readiness Act of 2007 (Pub. L. 110–134)

Abstract: This Direct Final Rule describes how the Office of Head Start officially delays the compliance date for programs to meet the new competitive threshold for the Instructional Support domain of the Classroom Assessment Scoring System (CLASS®) used to determine whether a Head Start agency will be subject to an open competition under the Designation Renewal System. The effective date in the Head Start Program Performance Standards that raises the CLASS Instructional Support competitive threshold from 2.3 to 2.5 was August 1, 2025. ACF is pursuing this as a Direct Final Rule due to the time constraints of when the threshold increase was scheduled to go into effect. This Direct Final Rule officially delays this effective date to August 1, 2027.

Timetable:

Action	Date	FR Cite
Final Action	09/00/24	

Regulatory Flexibility Analysis Required: No.

Agency Contact: Jessica Bialecki, Policy and Planning Director, Department of Health and Human Services, Administration for Children and Families, Office of Head Start, 330 C Street SW, Washington, DC 20201, *Phone:* 202 283–1004, *Email: jessica.bialecki@acf.hhs.gov*.

RIN: 0970–AD09

114. • ORR UC Program Child Abuse and Neglect (Section 610 Review) [0970–AD10]

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

Abstract: This Interim Final Rule on ORR child abuse and neglect investigations describes how ORR shall investigate and substantiate allegations of child abuse or neglect occurring in certain ORR care facilities and maintain a registry of perpetrators relating to those facilities where a State agency that would otherwise be responsible for such investigations will not investigate allegations arising at facilities housing unaccompanied children (*e.g.,* because the State does not license facilities on the basis that they serve unaccompanied children). This interim final rule describes the obligations of care provider facilities in the course of an investigation of allegations of child abuse or neglect.

Timetable:

Action	Date	FR Cite
Interim Final Rule	08/00/24	

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, *Phone:* 202 555–4440, *Email: ucpolicy-regulatoryaffairs@acf.hhs.gov*.

RIN: 0970–AD10

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Administration for Children and Families (ACF)

Completed Actions

115. Safe and Appropriate, Affirming Foster Care Placement Requirements for Titles IV–E and IV–B (Completion of a Section 610 Review) [0970–AD03]

Legal Authority: 42 U.S.C. 671(a)(16); 42 U.S.C. 622(b)(8)(A)(ii); 42 U.S.C. 675(1)(B); 42 U.S.C. 675(5))

Abstract: This rule clarifies that title IV–E/IV–B agencies are required to offer safe and appropriate foster care placements, including processes to ensure children can request such placements and agencies must respond to concerns about those placements, for children in foster care who identify as lesbian, gay, bisexual, transgender, queer or questioning, intersex (LGBTQI+). The rule will not interfere with faith-based child welfare providers that continue to partner with title IV–E/IV–B agencies in a way that does not interfere with those providers' sincerely held religious beliefs.

Timetable:

Action	Date	FR Cite
NPRM	09/28/23	88 FR 66752
NPRM Comment Period End.	11/27/23	
Final Action	04/30/24	89 FR 34818
Final Action Effective.	07/01/24	

Regulatory Flexibility Analysis Required: No.

Agency Contact: Kathleen McHugh, Director, Department of Health and Human Services, Administration for Children and Families, Children's Bureau, Division of Policy, 330 C Street SW, Washington, DC 20201, *Phone:* 202 401–5789, *Fax:* 202 205–8221, *Email: kmchugh@acf.hhs.gov*.

RIN: 0970–AD03

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