DEPARTMEN

Office of the Secretary

21 CFR Ch. I

25 CFR Ch. V a

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: Regulatory Agenda.

SUMMARY: The Regulatory Flexibility Act of 1980 and Executive Order 12866 require the 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: Liesl I. Fowler, 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: **Liesl l. Fowler,**

HHS Executive Secretary.

Billing Code: 4150-03

Office for Civil Rights—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
223	Making Technical Changes and Clarifying How OCR Addresses Conscience Authorities in Health Care; Delegation of Authority **(Rulemaking Resulting From a Section 610 Review) (Reg Plan Seq No. 40)**	0945–AA24

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

Office for Civil Rights—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
224	Rescinding Portions of Department of Health and Human Services Title VI Regulations to Conform More Closely with the Statutory Text and to Implement Executive Order 14281 **(Section 610 Review)**	0945–AA29
225	Nondiscrimination on the Basis of Disability by Recipients of Department of Health and Human Services Financial Assistance **(Section 610 Review)**	0945–AA30

226	Rescinding Guidelines for Eliminating Discrimination and Denial of Services on the Basis of Race, Color, National Origin, Sex, and Handicap in Vocational Education Programs **(Section 610 Review)**	0945–AA31

Substance Abuse and Mental Health Services Administration—Completed Actions

Sequence Number	Title	Regulation Identifier Number
227	Medications for the Treatment of Opioid Use Disorder	0930–AA39

Centers for Disease Control and Prevention—Completed Actions

Sequence Number	Title	Regulation Identifier Number
228	Control of Communicable Diseases; Foreign Quarantine	0920–AA75

Food and Drug Administration—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
229	Conduct of Analytical and Clinical Pharmacology, Bioavailability, and Bioequivalence Studies	0910–AI57
230	Postmarketing Safety Reporting Requirements, Pharmacovigilance Plans, and Pharmacovigilance Quality Systems for Human Drug and Biological Products	0910–AI61
231	Registration of Commercial Importers of Drugs; Good Importing Practice	0910–AI87

232	Pediatric Study Plan Requirements for New Drug and Biologics License Applications	0910–AI89
233	Good Laboratory Practice for Nonclinical Laboratory Studies	0910–AJ01
234	Transparency in Direct-to-Consumer Advertising **(Reg Plan Seq No. 48)**	0910–AJ14

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

Food and Drug Administration—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
235	Medication Guide; Patient Medication Information	0910–AH68
236	Front-of-Package Nutrition Labeling	0910–AI80

Food and Drug Administration—Long-Term Actions

Sequence Number	Title	Regulation Identifier Number
237	National Standards for the Licensure of Wholesale Drug Distributors and Third-Party Logistics Providers	0910–AH11
238	Certain Requirements Regarding Prescription Drug Marketing (203 Amendment)	0910–AH56
239	Requirements for Tobacco Product Manufacturing Practice	0910–AH91

Centers for Medicare & Medicaid Services—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number

240	Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals; the Long-Term Care Hospital Prospective Payment System; and FY 2027 Rates (CMS-1849) **(Section 610 Review)**	0938–AV79
241	CY 2027 Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Medicare Part B (CMS-1848) **(Section 610 Review) (Reg Plan Seq No. 58)**	0938–AV82
242	CY 2027 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates (CMS-1850) **(Section 610 Review)**	0938–AV83
243	Medicare Drug Price Negotiation Program (CMS-4215) **(Section 610 Review)**	0938–AV90
244	Exchange Pre-Enrollment Eligibility Verification (CMS-9873) **(Section 610 Review)**	0938–AW03
245	Cutting Administrative Requirements for Excellence in Patient Care (CMS-3484) **(Section 610 Review)**	0938–AW04

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

Centers for Medicare & Medicaid Services—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
246	Independent Dispute Resolution Operations (CMS-9897)	0938–AV15

Centers for Medicare & Medicaid Services—Completed Actions

Sequence Number	Title	Regulation Identifier Number
247	Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals; the Long-Term Care Hospital Prospective Payment	0938–AV45

	System; and FY 2026 Rates (CMS-1833) **(Completion of a Section 610 Review)**	
248	FY 2026 Hospice Wage Index, Payment Rate Update, and Quality Reporting Requirements (CMS-1835) **(Completion of a Section 610 Review)**	0938–AV49
249	CY 2026 Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Medicare Part B (CMS-1832) **(Completion of a Section 610 Review)**	0938–AV50
250	CY 2026 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates (CMS-1834) **(Completion of a Section 610 Review)**	0938–AV51
251	CY 2026 Changes to the End-Stage Renal Disease (ESRD) Prospective Payment System and Quality Incentive Program (CMS-1830) **(Completion of a Section 610 Review)**	0938–AV52
252	CY 2026 Home Health Prospective Payment System Rate and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Competitive Bidding Program Updates (CMS-1828) **(Completion of a Section 610 Review)**	0938–AV53

Administration for Children and Families—Proposed Rule Stage

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

Sequence Number	Title	Regulation Identifier Number
256	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)	

223. MAKING TECHNICAL CHANGES AND CLARIFYING HOW OCR ADDRESSES CONSCIENCE AUTHORITIES IN HEALTH CARE; DELEGATION OF AUTHORITY (RULEMAKING RESULTING FROM A SECTION 610 REVIEW)

Regulatory Plan: This entry is Seq. No. 40 in part II of this issue of the **Federal Register.**

RIN: 0945–AA24

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

224. • RESCINDING PORTIONS OF DEPARTMENT OF HEALTH AND HUMAN SERVICES TITLE VI REGULATIONS TO CONFORM MORE CLOSELY WITH THE STATUTORY TEXT AND TO IMPLEMENT EXECUTIVE ORDER 14281 (SECTION 610 REVIEW)

Legal Authority: 42 U.S.C. 2000d–1; EO 14281

Relevant Executive Orders: 14281; 12250; 13563

Abstract: By this rulemaking, the Department of Health and Human Services would amend its regulations implementing Title VI of the Civil Rights Act of 1964 (Title VI) to align the conduct prohibited by its

regulations more closely to the conduct Congress intended to prohibit when enacting Title VI, and relatedly to implement changes required by Executive Order 14281.

Timetable:

Action	Date	FR Cite
Direct Final Rule	07/00/26	

Regulatory Flexibility Analysis Required: No

Agency Contact: Conner O'Brien, Senior Advisor, Department of Health and Human Services, Office for Civil Rights, 200 Independence Avenue SW, Washington, DC 20201

Phone: 800 537–7697

Email: conner.obrien@hhs.gov

RIN: 0945–AA29

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225. • NONDISCRIMINATION ON THE BASIS OF DISABILITY BY RECIPIENTS OF DEPARTMENT OF HEALTH AND HUMAN SERVICES FINANCIAL ASSISTANCE

(SECTION 610 REVIEW)

Legal Authority: 29 U.S.C. 794

Relevant Executive Orders: 13563; 14179; 14303

Abstract: Section 504 of the Rehabilitation Act states, "No otherwise qualified individual with a disability in the United States, as defined in section 705 (20) of this title, shall, solely by reason of his or her disability, be excluded from the participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance or under any program or activity conducted by any Executive agency or by the United States Postal Service." 29 U.S.C. 794(a). However, some recipients' websites and mobile apps do not fully enable users with disabilities to access the recipients' programs and activities. Accordingly, on May 9, 2024, the Department published a final rule that, among other things, revised its regulations implementing Section 504, Part 84, to provide technical standards to assist recipients in complying with their existing obligations to make their websites and mobile apps accessible to individuals with disabilities. (89 FR 40066). The compliance date for these requirements for recipients with fifteen or more employees is May 11, 2026.

By interim final rule, the Department would extend the deadlines for implementation of this provision of the final rule. The Department contemplates later publishing a Notice of Proposed Rulemaking (NPRM) to reconsider whether some of the regulatory provisions imposed by the May 9, 2024 rule could be made less burdensome.

Timetable:

Action	Date	FR Cite
Interim Final Rule	05/11/26	91 FR 25496

Regulatory Flexibility Analysis Required: Undetermined

Agency Contact: Conner O'Brien, Senior Advisor, Department of Health and Human Services, Office for Civil Rights, 200 Independence Avenue SW, Washington, DC 20201

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RIN: 0945–AA30

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226. • RESCINDING GUIDELINES FOR ELIMINATING DISCRIMINATION AND DENIAL OF SERVICES ON THE BASIS OF RACE, COLOR, NATIONAL ORIGIN, SEX, AND HANDICAP IN VOCATIONAL EDUCATION PROGRAMS (SECTION 610 REVIEW)

Legal Authority: 42 U.S.C. 2000d–1

Relevant Executive Orders: 14281; 14192; 14219

Abstract: By this rule, the Department of Health and Human Services rescinds Appendix B to 45 CFR Part 80 (the Guidelines for Eliminating Discrimination and Denial of Services on the Basis of Race, Color, National Origin, Sex, and Handicap in Vocational Education Programs) (Guidelines) and removes related cross-references to the Guidelines in Appendix B to 45 CFR Part 84 (implementing Section 504 of the Rehabilitation Act) and Appendix A to 45 CFR Part 86 (implementing Title IX of the Education Amendments).

Timetable:

Action	Date	FR Cite
Final Action	07/00/26	

Regulatory Flexibility Analysis Required: No

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

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Email: david.hyams@hhs.gov

RIN: 0945–AA31

Department of Health and Human Services (HHS)	**Completed Actions**
Substance Abuse and Mental Health Services Administration (SAMHSA)	

227. MEDICATIONS FOR THE TREATMENT OF OPIOID USE DISORDER

Legal Authority: 21 U.S.C. sec. 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 - Correction	02/23/26	91 FR 8381

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)	Completed Actions
Centers for Disease Control and Prevention (CDC)	

228. CONTROL OF COMMUNICABLE DISEASES; FOREIGN QUARANTINE

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

Relevant Executive Orders: 14243; 13563; 14239

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.

Completed:

Reason	Date	FR Cite
Final Rule - Notice of Expiration	12/04/25	90 FR 55813
Final Rule Effective	12/04/25	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Ashley C. Altenburger

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)	

229. CONDUCT OF ANALYTICAL AND CLINICAL PHARMACOLOGY, BIOAVAILABILITY, AND BIOEQUIVALENCE STUDIES

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

Relevant Executive Orders: 14303; 14293; 14212

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 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	09/00/26	

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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230. POSTMARKETING SAFETY REPORTING REQUIREMENTS, PHARMACOVIGILANCE PLANS, AND PHARMACOVIGILANCE QUALITY SYSTEMS FOR HUMAN DRUG AND BIOLOGICAL PRODUCTS

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; ...

Relevant Executive Orders: 14303; 14212; 14219

Abstract: The 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 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	07/00/26	

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

Phone: 301 796–3475

Fax: 301 847–8440

Email: janice.weiner@fda.hhs.gov

RIN: 0910–AI61

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

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

Relevant Executive Orders: 14293; 14336; 14273

Abstract: This 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 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 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	12/00/26	

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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232. PEDIATRIC STUDY PLAN REQUIREMENTS FOR NEW DRUG AND BIOLOGICS LICENSE APPLICATIONS

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

Relevant Executive Orders: 14303; 14212; 14273

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 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	11/00/26	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Kristiana Brugger Roche, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 51, Room 6262, 10903 New Hampshire Avenue, Silver Spring, MD 20993

Phone: 301 796–3601

Email: kristiana.brugger@fda.hhs.gov

RIN: 0910–AI89

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233. GOOD LABORATORY PRACTICE FOR NONCLINICAL LABORATORY STUDIES

Legal Authority: 21 U.S.C. 371

Relevant Executive Orders: 14212; 14303; 13563

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

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234. • TRANSPARENCY IN DIRECT–TO–CONSUMER ADVERTISING

Regulatory Plan: This entry is Seq. No. 48 in part II of this issue of the **Federal Register.**

RIN: 0910–AJ14

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

235. MEDICATION GUIDE; PATIENT MEDICATION INFORMATION

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

Relevant Executive Orders: 14212; 14303; 14273; 14221

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	12/00/26	

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

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RIN: 0910–AH68

236. FRONT–OF–PACKAGE NUTRITION LABELING

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

Relevant Executive Orders: 14212; 14303; 3544

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	
NPRM Comment Period Extended	05/09/25	90 FR 19664
NPRM Comment Period End	07/15/25	
Final Rule	12/00/26	

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, Human Foods Program, 5001 Campus Drive, College Park, MD 20740

Phone: 240 402–2371

Email: claudine.kavanaugh@fda.hhs.gov

RIN: 0910–AI80

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

237. NATIONAL STANDARDS FOR THE LICENSURE OF WHOLESALE DRUG DISTRIBUTORS AND THIRD–PARTY LOGISTICS PROVIDERS

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.

Relevant Executive Orders: 14212; 14293; 14219

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	06/00/28	

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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238. CERTAIN REQUIREMENTS REGARDING PRESCRIPTION DRUG MARKETING (203 AMENDMENT)

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

Relevant Executive Orders: 14212; 14293; 14219

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	06/00/28	

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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239. REQUIREMENTS FOR TOBACCO PRODUCT MANUFACTURING PRACTICE

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; ...

Relevant Executive Orders: 14212; 14303; 14219

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	07/00/27	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Matt 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: askctp@fda.hhs.gov

RIN: 0910–AH91

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

240. • HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEMS FOR ACUTE CARE HOSPITALS; THE LONG–TERM CARE HOSPITAL PROSPECTIVE PAYMENT SYSTEM; AND FY 2027 RATES (CMS–1849) (SECTION 610 REVIEW)

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

Abstract: This annual proposed rule would revise the Medicare hospital inpatient and long-term care hospital prospective payment systems for operating and capital-related costs. The rule would update the geographic payment adjustment for rural hospitals and contain deregulatory proposals for Graduate Medical Education that impede competition. This proposed rule would implement changes arising from our continuing experience with these systems. In addition, the rule proposes to establish new requirements or revise existing requirements for quality reporting by specific Medicare providers.

Timetable:

Action	**Date**	**FR Cite**
NPRM	07/00/26	

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–AV79

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241. • CY 2027 REVISIONS TO PAYMENT POLICIES UNDER THE PHYSICIAN FEE SCHEDULE AND OTHER REVISIONS TO MEDICARE PART B (CMS–1848) (SECTION 610 REVIEW)

Regulatory Plan: This entry is Seq. No. 58 in part II of this issue of the **Federal Register.**

RIN: 0938–AV82

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242. • CY 2027 HOSPITAL OUTPATIENT PPS POLICY CHANGES AND PAYMENT RATES AND AMBULATORY SURGICAL CENTER PAYMENT SYSTEM POLICY CHANGES AND PAYMENT RATES (CMS–1850) (SECTION 610 REVIEW)

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, including implementing the second year of the three-year phase-out of the inpatient only list requirement. 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	07/00/26	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AV83

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243. • MEDICARE DRUG PRICE NEGOTIATION PROGRAM (CMS–4215) (SECTION 610 REVIEW)

Legal Authority: Pub. L. 117–169, Sec. 11001 and 11002; Pub. L. 119–21, Sec. 71203

Relevant Executive Orders: 14273

Abstract: This proposed rule would codify the Medicare Drug Price Negotiation Program established in the Inflation Reduction Act. These changes would apply to the Negotiation Program effective initial price applicability year 2029.

Timetable:

Action	Date	FR Cite
NPRM	07/00/26	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AV90

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244. • EXCHANGE PRE–ENROLLMENT ELIGIBILITY VERIFICATION (CMS–9873) (SECTION 610 REVIEW)

Legal Authority: 26 U.S.C. 36B(c)(3)(A) (Pub. L 119–21 sec. 71303); 26 U.S.C. 36B(c)(5) to (c)(6) (Pub. L 119–21 sec. 71303)

Abstract: Public Law 119-21, known as the Working Families Tax Cut (WFTC) Legislation, amended the Internal Revenue Code (26 U.S. Code 36B) to establish new requirements for Federal and State-based Exchanges regarding eligibility verification for the premium tax credit (PTC). As a result, all Exchanges

must verify certain eligibility criteria for individuals seeking coverage through a qualified health plan (QHP) with the advance premium tax credit (APTC) before an individual is eligible for APTC. This new policy changes existing policy established by Affordable Care Act Section 1411(e)(4)(B)(i) that allowed the Exchange to provide APTC for a set period of time to individuals who needed to submit documentation to verify their eligibility. Beginning with plan year 2028, individuals will not receive APTC until they have successfully verified their eligibility through a documentation submission process. Given that the Open Enrollment Period for plan year 2028 begins November 1, 2027, these requirements must be implemented before this date. Public Law 119-21 also establishes an additional requirement beginning August 1, 2027, for all Exchanges to provide a pre-enrollment verification process no later than August 1st of the year preceding the plan year. At a minimum, this process must allow individuals to verify their income and eligibility for a QHP for the upcoming plan year. If an Exchange fails to provide this process, no individual enrolled through that exchange will be eligible for PTC. This proposed rule would outline how Exchanges will implement these new statutory requirements.

Timetable:

Action	Date	FR Cite
NPRM	07/00/26	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Jeff Wu, Deputy Director for Policy, 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: 301 492–4305

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RIN: 0938–AW03

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245. • CUTTING ADMINISTRATIVE REQUIREMENTS FOR EXCELLENCE IN PATIENT CARE (CMS–3484) (SECTION 610 REVIEW)

Legal Authority: 42 U.S.C. 1302,; 42 U.S.C. 1320a–7; 42 U.S.C. 1320b–8; 42 U.S.C. 1395hh; ...

Abstract: This proposed rule would enhance direct patient care by modernizing the Conditions of Participation, Conditions for Coverage, and Requirements for Medicare- and Medicaid-participating providers and suppliers, reducing burden and increasing flexibility to deliver high quality care. CMS identified obsolete, outdated, and excessively burdensome regulations that can be eliminated or reformed

to enhance the effectiveness of facility operations and services and free up resources that health care providers could otherwise use to improve patient health and safety.

Timetable:

Action	Date	FR Cite
NPRM	08/00/26	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AW04

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

246. INDEPENDENT DISPUTE RESOLUTION OPERATIONS (CMS–9897)

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

Relevant Executive Orders: 13610; 13951

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	07/00/26	

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

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RIN: 0938–AV15

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

247. HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEMS FOR ACUTE CARE HOSPITALS; THE LONG–TERM CARE HOSPITAL PROSPECTIVE PAYMENT SYSTEM; AND FY 2026 RATES (CMS–1833) (COMPLETION OF A SECTION 610 REVIEW)

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	08/04/25	90 FR 36536
Final Action Effective	10/01/25	

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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248. FY 2026 HOSPICE WAGE INDEX, PAYMENT RATE UPDATE, AND QUALITY REPORTING REQUIREMENTS (CMS–1835) (COMPLETION OF A SECTION 610 REVIEW)

Legal Authority: 42 U.S.C. 1302

Abstract: This annual final rule updates the hospice payment rates, the wage index, and the hospice aggregate 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	08/05/25	90 FR 37404

Final Action Effective	10/01/25	

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

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249. CY 2026 REVISIONS TO PAYMENT POLICIES UNDER THE PHYSICIAN FEE SCHEDULE AND OTHER REVISIONS TO MEDICARE PART B (CMS–1832) (COMPLETION OF A SECTION 610 REVIEW)

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

Relevant Executive Orders: 14212; 14168

Abstract: This annual final rule revises payment polices under the Medicare physician fee schedule, and makes other policy changes to payment under Medicare Part B. These changes apply to services furnished beginning January 1, 2026. Additionally, this rule updates the Quality Payment Program.

Timetable:

Action	Date	FR Cite
NPRM	07/16/25	90 FR 32352
NPRM Comment Period End	09/12/25	
Final Action	11/05/25	90 FR 49266
Final Action Effective	01/01/26	

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

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RIN: 0938–AV50

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250. CY 2026 HOSPITAL OUTPATIENT PPS POLICY CHANGES AND PAYMENT RATES AND AMBULATORY SURGICAL CENTER PAYMENT SYSTEM POLICY CHANGES AND PAYMENT RATES (CMS–1834) (COMPLETION OF A SECTION 610 REVIEW)

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

Relevant Executive Orders: 14273; 14221; 14279

Abstract: This annual final rule revises the Medicare hospital outpatient prospective payment system to implement statutory requirements and changes arising from our continuing experience with this system. The rule describes changes to the amounts and factors used to determine payment rates for services. In addition, the rule finalizes changes to the ambulatory surgical center payment system list of services and rates. This rule 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	07/17/25	90 FR 33476
NPRM Comment Period End	09/15/25	
Final Action	11/25/25	90 FR 53448
Final Action Effective	01/01/26	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AV51

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251. CY 2026 CHANGES TO THE END–STAGE RENAL DISEASE (ESRD) PROSPECTIVE PAYMENT SYSTEM AND QUALITY INCENTIVE PROGRAM (CMS–1830) (COMPLETION OF A SECTION 610 REVIEW)

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

Abstract: This annual final rule updates the bundled payment system for ESRD facilities by January 1, 2026. The rule also updates the quality incentives in the ESRD program.

Timetable:

Action	Date	FR Cite
NPRM	07/02/25	90 FR 29342
NPRM Comment Period End	08/29/25	
Final Action	11/24/25	90 FR 53068
Final Action Effective	01/01/26	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AV52

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252. CY 2026 HOME HEALTH PROSPECTIVE PAYMENT SYSTEM RATE AND DURABLE MEDICAL EQUIPMENT, PROSTHETICS, ORTHOTICS, AND SUPPLIES COMPETITIVE BIDDING PROGRAM UPDATES (CMS–1828) (COMPLETION OF A SECTION 610 REVIEW)

Legal Authority: 42 U.S.C. 1395(x); 42 U.S.C. 1395(fff); 42 U.S.C. 1395(m)

Abstract: This annual final rule updates the national, standardized 30-day period payment rate, national per-visit rates used to calculate low utilization payment adjustments (LUPAs) and outlier payments under the Medicare prospective payment system (PPS) for home health agencies based on the applicable home health payment update percentage. This rule also includes changes to the Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) to help CMS continue to implement an effective, efficient, and sustainable program by generating savings and reducing fraud, waste, and abuse in the Medicare program. Additionally, CMS is finalizing several changes to the DMEPOS CBP to streamline a few operational processes to decrease the burden on bidders, as well as incorporating previous sub-regulatory guidance into regulation.

Timetable:

Action	Date	FR Cite
NPRM	07/02/25	90 FR 29108

NPRM Comment Period End	08/29/25	
Final Action	12/02/25	90 FR 55342
Final Action Effective	01/01/26	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AV53

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

253. NATIVE AMERICAN PROGRAMS FINANCIAL AND ADMINISTRATIVE REQUIREMENTS (SECTION 610 REVIEW)

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

Relevant Executive Orders: 14219; 13610; 13563

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 the 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	12/00/26	

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

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RIN: 0970–AD05

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254. TEMPORARY ASSISTANCE FOR NEEDY FAMILIES WORK PARTICIPATION RATE CALCULATION CHANGES (SECTION 610 REVIEW)

Legal Authority: secs. 301 and 303 of the Fiscal Responsibility Act of 2023 (FRA, Pub. L. 118–5)

Relevant Executive Orders: 14303; 13563; 13132

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	04/06/26	91 FR 17230
NPRM Comment Period End	05/06/26	

Regulatory Flexibility Analysis Required: No

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RIN: 0970–AD07

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255. UNACCOMPANIED CHILDREN PROGRAM PREVENTION OF SEXUAL ABUSE NPRM (SECTION 610 REVIEW)

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

Relevant Executive Orders: 13563; 13610; 14212

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. Ultimately, this new rule is required in order to update ORR's existing rule on the prevention, detection, and response to sexual abuse and sexual harassment at all of its facilities. The underlying IFR has been pending for more than one decade and requires finalization.

Timetable:

Action	Date	FR Cite
NPRM	11/00/26	

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)	

256. OFFICE OF REFUGEE RESETTLEMENT CHILD ABUSE AND NEGLECT INVESTIGATIONS RULE (SECTION 610 REVIEW)

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

Relevant Executive Orders: 14219; 13563; 13132

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. The Final Rule is required in order to accurately finalize the existing IFR in light of received public comments and full conclusion of the regulatory action.

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	07/00/26	

Regulatory Flexibility Analysis Required: No

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RIN: 0970–AD10

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