

**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 COVID–19 going forward, building and expanding access to affordable, quality health care, addressing health disparities and promoting equity, 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—PROPOSED RULE STAGE**

Sequence No.	Title	Regulation Identifier No.
313 .....	Rulemaking on Discrimination on the Basis of Disability in Health and Human Services Programs or Activities ( <b>Reg Plan Seq No. 48</b> ).	0945–AA15

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

**SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION—FINAL RULE STAGE**

Sequence No.	Title	Regulation Identifier No.
314 .....	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.
315 .....	Control of Communicable Diseases; Foreign Quarantine ( <b>Reg Plan Seq No. 56</b> ) .....	0920–AA75

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

**FOOD AND DRUG ADMINISTRATION—PROPOSED RULE STAGE**

Sequence No.	Title	Regulation Identifier No.
316 .....	Medication Guide; Patient Medication Information .....	0910–AH68
317 .....	Administrative Detention of Tobacco Products .....	0910–AI05
318 .....	Conduct of Analytical and Clinical Pharmacology, Bioavailability, and Bioequivalence Studies .....	0910–AI57
319 .....	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 ( <b>Section 610 Review</b> ).	0910–AI70
320 .....	Distribution of Compounded Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act ( <b>Section 610 Review</b> ).	0910–AI71
321 .....	Tobacco Product Standard for Nicotine Level of Certain Tobacco Products ( <b>Reg Plan Seq No. 57</b> ) .....	0910–AI76
322 .....	Front-of-Package Nutrition Labeling ( <b>Reg Plan Seq No. 58</b> ) .....	0910–AI80
323 .....	Medical Devices; Laboratory Developed Tests ( <b>Reg Plan Seq No. 59</b> ) .....	0910–AI85
324 .....	Registration of Commercial Importers of Drugs; Good Importing Practice .....	0910–AI87

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 No.	Title	Regulation Identifier No.
325 .....	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
326 .....	Sunlamp Products; Amendment to the Performance Standard .....	0910-AG30
327 .....	General and Plastic Surgery Devices: Restricted Sale, Distribution, and Use of Sunlamp Products .....	0910-AH14
328 .....	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
329 .....	Requirements for Tobacco Product Manufacturing Practice .....	0910-AH91
330 .....	Nutrient Content Claims, Definition of Term: Healthy <b>(Reg Plan Seq No. 61)</b> .....	0910-AI13
331 .....	Tobacco Product Standard for Characterizing Flavors in Cigars <b>(Reg Plan Seq No. 62)</b> .....	0910-AI28
332 .....	Tobacco Product Standard for Menthol in Cigarettes <b>(Reg Plan Seq No. 64)</b> .....	0910-AI60

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

## FOOD AND DRUG ADMINISTRATION—LONG-TERM ACTIONS

Sequence No.	Title	Regulation Identifier No.
333 .....	National Standards for the Licensure of Wholesale Drug Distributors and Third-Party Logistics Providers ..	0910-AH11
334 .....	Nicotine Toxicity Warnings .....	0910-AH24
335 .....	Certain Requirements Regarding Prescription Drug Marketing (203 Amendment) .....	0910-AH56
336 .....	Postmarketing Safety Reporting Requirements, Pharmacovigilance Plans, and Pharmacovigilance Quality Systems for Human Drug and Biological Products.	0910-AI61

## FOOD AND DRUG ADMINISTRATION—COMPLETED ACTIONS

Sequence No.	Title	Regulation Identifier No.
337 .....	Revocation of Uses of Partially Hydrogenated Oils in Foods .....	0910-AI15

## CENTERS FOR MEDICARE &amp; MEDICAID SERVICES—PROPOSED RULE STAGE

Sequence No.	Title	Regulation Identifier No.
338 .....	CY 2025 Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Medicare Part B (CMS-1807) <b>(Section 610 Review)</b> .	0938-AV33
339 .....	Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals; the Long-Term Care Hospital Prospective Payment System; and FY 2025 Rates (CMS-1808) <b>(Section 610 Review)</b> .	0938-AV34
340 .....	CY 2025 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates (CMS-1809) <b>(Section 610 Review)</b> .	0938-AV35

## CENTERS FOR MEDICARE &amp; MEDICAID SERVICES—FINAL RULE STAGE

Sequence No.	Title	Regulation Identifier No.
341 .....	CY 2024 Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Medicare Part B (CMS-1784) <b>(Section 610 Review)</b> .	0938-AV07
342 .....	CY 2024 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates (CMS-1786) <b>(Section 610 Review)</b> .	0938-AV09

## CENTERS FOR MEDICARE &amp; MEDICAID SERVICES—COMPLETED ACTIONS

Sequence No.	Title	Regulation Identifier No.
343 .....	FY 2024 Skilled Nursing Facility (SNF) PPS and Consolidated Billing and Updates to the Value-Based Purchasing and Quality Reporting Programs (CMS-1779) <b>(Completion of a Section 610 Review)</b> .	0938-AV02
344 .....	CY 2024 Home Health Prospective Payment System Rate Update and Home Infusion Therapy Services Payment Update (CMS-1780) <b>(Completion of a Section 610 Review)</b> .	0938-AV03
345 .....	FY 2024 Inpatient Psychiatric Facilities Prospective Payment System Rate and Quality Reporting Updates (CMS-1783) <b>(Completion of a Section 610 Review)</b> .	0938-AV06
346 .....	Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals; the Long-Term Care Hospital Prospective Payment System; and FY 2024 Rates (CMS-1785) <b>(Completion of a Section 610 Review)</b> .	0938-AV08

CENTERS FOR MEDICARE & MEDICAID SERVICES—COMPLETED ACTIONS—Continued

Sequence No.	Title	Regulation Identifier No.
347 .....	FY 2024 Hospice Wage Index, Payment Rate Update, and Quality Reporting Requirements (CMS-1787) <b>(Completion of a Section 610 Review)</b> .	0938-AV10
348 .....	Hospital Outpatient Prospective Payment System: Remedy for 340B-Acquired Drugs Purchased in Cost Years 2018-2022 (CMS-1793) <b>(Section 610 Review) (Reg Plan Seq No. 77)</b> .	0938-AV18

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

ADMINISTRATION FOR CHILDREN AND FAMILIES—PROPOSED RULE STAGE

Sequence No.	Title	Regulation Identifier No.
349 .....	Supporting the Head Start Workforce and Other Quality Improvements <b>(Reg Plan Seq No. 80)</b> .....	0970-AD01
350 .....	Safe and Appropriate Foster Care Placement Requirements for Titles IV-E and IV-B <b>(Section 610 Review) (Reg Plan Seq No. 81)</b> .	0970-AD03

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

**DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)**

*Office for Civil Rights (OCR)*

Proposed Rule Stage

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

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

RIN: 0945-AA15

**DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)**

*Substance Abuse and Mental Health Services Administration (SAMHSA)*

Final Rule Stage

**314. 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.

*Timetable:*

Action	Date	FR Cite
NPRM .....	12/16/22	87 FR 77330
Supplemental NPRM.	02/13/23	88 FR 9221
NPRM Comment Period End.	02/14/23	
Supplemental NPRM Comment Period End.	03/14/23	
Final Action .....	01/00/24	

*Regulatory Flexibility Analysis Required:* Yes.

*Agency Contact:* Dr. Neeraj Gandotra, Chief Medical Officer, Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, 5600 Fishers Lane, 18E67, Rockville, MD 20857, 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

**315. Control of Communicable Diseases; Foreign Quarantine [0920-AA75]**

*Regulatory Plan:* This entry is Seq. No. 56 in part II of this issue of the **Federal Register**.

RIN: 0920-AA75

**DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)**

*Food and Drug Administration (FDA)*

Proposed Rule Stage

**316. 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 Action .....	03/00/26	

*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:* [chris.wheeler@fda.hhs.gov](mailto:chris.wheeler@fda.hhs.gov). *RIN:* 0910-AH68

**317. 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 .....	10/00/24	

*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](mailto: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](mailto:ctpregulations@fda.hhs.gov).

*RIN:* 0910-AI05

**318. 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 .....	04/00/24	

*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 51, Room 5215, Silver Spring, MD 20993-0002, *Phone:* 240 402-4089, *Email:* [brian.folian@fda.hhs.gov](mailto:brian.folian@fda.hhs.gov). *RIN:* 0910-AI57

**319. 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](mailto:rosilend.lawson@fda.hhs.gov).

*RIN:* 0910-AI70

**320. 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 .....	12/00/23	

*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-A171

321. Tobacco Product Standard for Nicotine Level of Certain Tobacco Products [0910-A176]

Regulatory Plan: This entry is Seq. No. 57 in part II of this issue of the Federal Register. RIN: 0910-A176

322. Front-of-Package Nutrition Labeling [0910-A180]

Regulatory Plan: This entry is Seq. No. 58 in part II of this issue of the Federal Register. RIN: 0910-A180

323. Medical Devices; Laboratory Developed Tests [0910-A185]

Regulatory Plan: This entry is Seq. No. 59 in part II of this issue of the Federal Register. RIN: 0910-A185

324. Registration of Commercial Importers of Drugs; Good Importing Practice [0910-A187]

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:

Table with 3 columns: Action, Date, FR Cite. Row: NPRM ..... 01/00/24

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-A187

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Food and Drug Administration (FDA) Final Rule Stage

325. 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.

Timetable:

Table with 3 columns: Action, Date, FR Cite. Rows: NPRM ..... 03/29/10, NPRM Comment Period End. 06/28/10, NPRM Comment Period Re-opened. 01/27/12, NPRM Comment Period End. 02/27/12, NPRM Comment Period Re-opened. 03/29/12, NPRM Comment Period Re-opened End. 04/09/12, Final Rule ..... 11/00/23

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Suzanna Boyle, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, 10903 New Hampshire Avenue, WO 51, Room 3214, Silver Spring, MD 20993, Phone: 240 402-4723, Email: suzanna.boyle@fda.hhs.gov. RIN: 0910-AG27

326. 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:

Table with 3 columns: Action, Date, FR Cite. Row: NPRM ..... 12/22/15, NPRM Comment Period End. 03/21/16, Final Rule ..... 03/00/24

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](mailto:ian.ostermiller@fda.hhs.gov).

RIN: 0910-AG30

**327. 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. The incidence of skin cancer, including melanoma, has been increasing, and a large number of skin cancer cases are attributable to the use of sunlamp products. The devices may cause about 400,000 cases of skin cancer per year, and 6,000 of which are melanoma. Beginning use of sunlamp products at young ages, as well as frequently using sunlamp products, both increases the risk of developing skin cancers and other illnesses, and sustaining other injuries. Even infrequent use, particularly at younger ages, can significantly increase these risks.

*Timetable:*

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

*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 75, Room 7613, Silver Spring, MD 20993, Phone: 301 796-3350, Email: [daniel.schieffer@fda.hhs.gov](mailto:daniel.schieffer@fda.hhs.gov).

RIN: 0910-AH14

**328. 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:* 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](mailto:rosilend.lawson@fda.hhs.gov).

RIN: 0910-AH81

**329. 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.

*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

Action	Date	FR Cite
Final Action .....	10/00/24	

*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](mailto:ctpregulations@fda.hhs.gov).

RIN: 0910-AH91

**330. Nutrient Content Claims, Definition of Term: Healthy [0910-AI13]**

*Regulatory Plan:* This entry is Seq. No. 61 in part II of this issue of the **Federal Register**.

RIN: 0910-AI13

**331. Tobacco Product Standard for Characterizing Flavors in Cigars [0910-AI28]**

*Regulatory Plan:* This entry is Seq. No. 62 in part II of this issue of the **Federal Register**.

RIN: 0910-AI28

**332. Tobacco Product Standard for Menthol in Cigarettes [0910-AI60]**

*Regulatory Plan:* This entry is Seq. No. 64 in part II of this issue of the **Federal Register**.

RIN: 0910-AI60

**DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)**

*Food and Drug Administration (FDA)*

Long-Term Actions

**333. 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 .....	04/00/25	

*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

**334. 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 .....	04/00/25	

*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

**335. 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 .....	04/00/25	

*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

**336. 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

**DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)**

*Food and Drug Administration (FDA)*

Completed Actions

**337. Revocation of Uses of Partially Hydrogenated Oils in Foods [0910–AI15]**

*Legal Authority:* 21 U.S.C. 321; 21 U.S.C. 341; 21 U.S.C. 342; 21 U.S.C. 343; 21 U.S.C. 348; 21 U.S.C. 371; 21 U.S.C. 379e

*Abstract:* In the **Federal Register** of June 17, 2015 (80 FR 34650), FDA published a declaratory order announcing our final determination that there is no longer a consensus among qualified experts that partially hydrogenated oils (PHOs) are generally recognized as safe (GRAS) for any use in human food. In the **Federal Register** of May 21, 2018 (83 FR 23382), we denied a food additive petition requesting that the food additive regulations be amended to provide for the safe use of PHOs in certain food applications. Next, on August 9, 2023, we issued a direct final rule and companion proposed rule that would update our regulations to remove all mention of PHOs from FDA’s GRAS regulations and as an optional ingredient in standards of identity. This action would also revoke all prior sanctions for uses of PHOs in food.

*Completed:*

Reason	Date	FR Cite
NPRM .....	08/09/23	88 FR 53827
Direct Final Rule	08/09/23	88 FR 53764

Reason	Date	FR Cite
Direct Final Rule Effective.	12/22/23	

*Regulatory Flexibility Analysis Required: Yes.*  
*Agency Contact:* Ellen Anderson, Phone: 240 402-1309, Email: ellen.anderson@fda.hhs.gov. RIN: 0910-A115

**DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)**

*Centers for Medicare & Medicaid Services (CMS)*

Proposed Rule Stage

**338. • 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 policies 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 .....	06/00/24	

*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

**339. • 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 proposed rule would revise the Medicare hospital inpatient and long-term care hospital

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

*Timetable:*

Action	Date	FR Cite
NPRM .....	04/00/24	

*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

**340. • 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 .....	06/00/24	

*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

**341. CY 2024 Revisions To Payment Policies Under the Physician Fee Schedule and Other Revisions to Medicare Part B (CMS-1784) (Section 610 Review) [0938-AV07]**

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

*Abstract:* This annual final rule revises payment policies 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 .....	01/00/24	

*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-AV07

**342. CY 2024 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates (CMS-1786) (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 .....	01/00/24	

*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-AV09

**DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)**

*Centers for Medicare & Medicaid Services (CMS)*

Completed Actions

**343. FY 2024 Skilled Nursing Facility (SNF) PPS and Consolidated Billing and Updates to the Value-Based Purchasing and Quality Reporting Programs (CMS-1779) (Completion of a Section 610 Review) [0938-AV02]**

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

*Abstract:* This annual final rule updates the payment rates used under the prospective payment system for SNFs for fiscal year 2024. The rule also includes changes for the SNF Quality Reporting Program (QRP) and for the Skilled Nursing Facility Value-Based Purchasing (VBP) Program that will affect Medicare payment to SNFs.

*Timetable:*

Action	Date	FR Cite
NPRM .....	04/10/23	88 FR 21316
NPRM Comment Period End.	06/05/23	
Final Action .....	08/07/23	88 FR 53200
Final Action Effective.	10/01/23	

*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-AV02

**344. CY 2024 Home Health Prospective Payment System Rate Update and Home Infusion Therapy Services Payment Update (CMS-1780) (Completion of a Section 610 Review) [0938-AV03]**

*Legal Authority:* 42 U.S.C. 1302; 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 for home health agencies based on the applicable home health payment update percentage. Additionally, this rule updates payment rates for home infusion therapy services and makes changes to the Medicare enrollment requirements for hospices. These changes apply to services furnished on or after January 1, 2024. This rule also makes changes to how the separate payment for negative pressure wound therapy using a disposable device is made as required by section 4136 of the Consolidated Appropriations Act of 2023 (CAA, 2023), and implements the permanent home intravenous immune globulin services (IVIG) benefit as required by section 4134 of the CAA, 2023. This rule addresses the scope of the Medicare Part B benefit for leg, arm, back, and neck braces under section 1861(s)(9) of the Social Security Act, and newer technology devices, as well as the implementation of the Medicare Part B benefit for lymphedema compression treatment items under section 1861(s)(2) of the Social Security Act.

*Timetable:*

Action	Date	FR Cite
NPRM .....	07/10/23	88 FR 43654
NPRM Comment Period End.	08/29/23	
Final Action .....	11/13/23	88 FR 77676
Final Action Effective.	01/01/24	

*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-AV03

**345. FY 2024 Inpatient Psychiatric Facilities Prospective Payment System Rate and Quality Reporting Updates (CMS-1783) (Completion of a Section 610 Review) [0938-AV06]**

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

*Abstract:* This annual final rule updates the prospective payment system for inpatient psychiatric facilities (IPF) with discharges beginning on October 1, 2023. The rule also includes updates to the IPF Quality Reporting Program.

*Timetable:*

Action	Date	FR Cite
NPRM .....	04/10/23	88 FR 21238
NPRM Comment Period End.	06/05/23	
Final Action .....	08/02/23	88 FR 51054
Final Action Effective.	10/01/23	

*Regulatory Flexibility Analysis Required: Yes.*

*Agency Contact:* Nicolas Brock, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, MS: C5-05-27, 7500 Security Boulevard, Baltimore, MD 21244, *Phone:* 410 786-5148, *Email:* nicolas.brock@cms.hhs.gov.  
*RIN:* 0938-AV06

**346. Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals; the Long-Term Care Hospital Prospective Payment System; and FY 2024 Rates (CMS-1785) (Completion of a Section 610 Review) [0938-AV08]**

*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 .....	05/01/23	88 FR 26658
NPRM Comment Period End.	06/09/23	
Final Action .....	08/28/23	88 FR 58640
Final Action Effective.	10/01/23	

*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-AV08

**347. FY 2024 Hospice Wage Index, Payment Rate Update, and Quality Reporting Requirements (CMS-1787) (Completion of a Section 610 Review) [0938-AV10]**

*Legal Authority:* 42 U.S.C. 1302; 42 U.S.C. 1395hh  
*Abstract:* This annual final rule updates the hospice payment rates and the wage index for fiscal year 2024. The rule also finalizes changes to the Hospice Quality Reporting program.  
*Timetable:*

Action	Date	FR Cite
NPRM .....	04/04/23	88 FR 20022
NPRM Comment Period End.	05/30/23	

Action	Date	FR Cite
Final Action .....	08/02/23	88 FR 51164
Final Action Effective.	10/01/23	

*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-AV10

**348. Hospital Outpatient Prospective Payment System: Remedy for 340B-Acquired Drugs Purchased in Cost Years 2018-2022 (CMS-1793) (Section 610 Review) [0938-AV18]**

*Regulatory Plan:* This entry is Seq. No. 77 in part II of this issue of the **Federal Register**. RIN: 0938-AV18

**DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)**

*Administration for Children and Families (ACF)*

Proposed Rule Stage

**349. Supporting the Head Start Workforce and Other Quality Improvements [0970-AD01]**

*Regulatory Plan:* This entry is Seq. No. 80 in part II of this issue of the **Federal Register**.

RIN: 0970-AD01

**350. • Safe and Appropriate Foster Care Placement Requirements for Titles IV-E and IV-B (Section 610 Review) [0970-AD03]**

*Regulatory Plan:* This entry is Seq. No. 81 in part II of this issue of the **Federal Register**.

RIN: 0970-AD03

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