DEPARTMEN

Office of the Secretary

21 CFR Ch. I

25 CFR Ch. V

42 CFR Chs. I-V

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

Regulatory Agenda

AGENCY: Office of the Secretary, HHS.

ACTION: Semiannual Regulatory Agenda.

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

FOR FURTHER INFORMATION CONTACT: Karuna Seshasai, 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 the Biden-Harris Administration and HHS Secretary Xavier Becerra. Accordingly, this Agenda contains rulemakings aimed at advancing equity and ensuring nondiscrimination in health; ending the COVID-19 public health emergency; enhancing access to quality, affordable health care; addressing child welfare and maternal health; safeguarding the quality of medical products; protecting the public health by reducing tobacco use; revising prior actions that are inconsistent with the policy of this Administration; and supporting other priority areas.

Please note that because the Department's most recent Statement of Regulatory Priorities was published in Fall 2020 and under a previous Administration, it no longer reflects the views of the Department or this Administration. The Department will have the opportunity to issue a new Statement of Regulatory

Priorities reflecting its policy direction alongside the Fall 2021 Agenda. At present, more information about the policy priorities of the Biden-Harris Administration is available through Executive Orders, Presidential Memoranda, other Presidential Actions, regulatory actions, and sub-regulatory guidance issued by the Biden-Harris Administration since January 20, 2021.

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.

Karuna Seshasai,

Executive Secretary to the Department.

Office of the Secretary—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
85	Limiting the Effect of Exclusions Implemented Under the Social Security Act **(Rulemaking Resulting From a Section 610 Review)**	0991–AC11

Office for Civil Rights—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number

86	Rulemaking on Discrimination on the Basis of Disability in Critical Health and Human Services Programs or Activities **(Rulemaking Resulting From a Section 610 Review)**	0945–AA15

Office of the National Coordinator for Health Information Technology—Completed Actions

Sequence Number	Title	Regulation Identifier Number
87	Information Blocking and the ONC Health IT Certification Program: Extension of Compliance Dates and Timeframes in Response to the COVID-19 Public Health Emergency	0955–AA02

Centers for Disease Control and Prevention—Final Rule Stage

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

Food and Drug Administration—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number

89	National Standards for the Licensure of Wholesale Drug Distributors and Third-Party Logistics Providers	0910–AH11
90	Certain Requirements Regarding Prescription Drug Marketing (203 Amendment)	0910–AH56
91	Medication Guide; Patient Medication Information	0910–AH68
92	Requirements for Tobacco Product Manufacturing Practice	0910–AH91
93	Administrative Detention of Tobacco Products	0910–AI05
94	Nutrient Content Claims, Definition of Term: Healthy	0910–AI13
95	Revocation of Uses of Partially Hydrogenated Oils in Foods	0910–AI15
96	Tobacco Product Standard for Characterizing Flavors in Cigars	0910–AI28
97	Conduct of Analytical and Clinical Pharmacology, Bioavailability and Bioequivalence Studies	0910–AI57

Food and Drug Administration—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
98	Mammography Quality Standards Act	0910–AH04
99	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

Food and Drug Administration—Long-Term Actions

Sequence Number	Title	Regulation Identifier Number
100	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
101	Sunlamp Products; Amendment to the Performance Standard	0910–AG30
102	General and Plastic Surgery Devices: Restricted Sale, Distribution, and Use of Sunlamp Products	0910–AH14
103	Nicotine Toxicity Warnings	0910–AH24
104	Requirements For Additional Traceability Records For Certain Foods	0910–AI44

Food and Drug Administration—Completed Actions

Sequence Number	Title	Regulation Identifier Number
105	Milk and Cream Product and Yogurt Products, Final Rule to Revoke the Standards for Lowfat Yogurt and Nonfat Yogurt and to Amend the Standard for Yogurt	0910–AI40

Centers for Medicare & Medicaid Services—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
106	Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs (CMS-4192)	0938–AU30
107	CY 2022 Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Medicare Part B (CMS-1751) **(Section 610 Review)**	0938–AU42
108	CY 2022 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates (CMS-1753) **(Section 610 Review)**	0938–AU43
109	Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals; the Long-Term Care Hospital Prospective Payment System; and FY 2022 Rates (CMS-1752) **(Section 610 Review)**	0938–AU44
110	Medicare Advantage and Medicare Prescription Drug Benefit Program Payment Policy (CMS-4198)	0938–AU59

Centers for Medicare & Medicaid Services—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
111	Requirements Related to Surprise Billing; Part II (CMS-9908)	0938–AU62
112	Requirements Related to Surprise Billing; Part I (CMS-9909)	0938–AU63

Centers for Medicare & Medicaid Services—Long-Term Actions

Sequence Number	Title	Regulation Identifier Number
113	Durable Medical Equipment Fee Schedule, Adjustments to Resume the Transitional 50/50 Blended Rates to Provide Relief in Non-Competitive Bidding Areas (CMS-1687) **(Section 610 Review)**	0938–AT21
114	Requirements for Long-Term Care Facilities: Regulatory Provisions to Promote Increased Safety (CMS-3347) **(Section 610 Review)**	0938–AT36

Centers for Medicare & Medicaid Services—Completed Actions

Sequence Number	Title	Regulation Identifier Number
115	Most Favored Nation (MFN) Model (CMS-5528) **(Completion of a Section 610 Review)**	0938–AT91
116	Medicaid; Reducing Provider and Patient Burden by Improving Prior Authorization Processes and Promoting Patients' Electronic Access to Health Information (CMS-9123)	0938–AT99
117	CY 2021 Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Medicare Part B (CMS-1734) **(Completion of a Section 610 Review)**	0938–AU10
118	CY 2021 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy	0938–AU12

	Changes and Payment Rates (CMS-1736) **(Completion of a Section 610 Review)**	
119	Promoting Electronic Access to Health Information for Patients and for Medicare- and Medicaid-Participating Providers and Suppliers (CMS-0057)	0938–AU53

Administration for Children and Families—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
120	Updating Native Employment Works Requirements **(Rulemaking Resulting From a Section 610 Review)**	0970–AC83

Department of Health and Human Services (HHS)	**Proposed Rule Stage**
Office of the Secretary (OS)	

85. LIMITING THE EFFECT OF EXCLUSIONS IMPLEMENTED UNDER THE SOCIAL SECURITY ACT (RULEMAKING RESULTING FROM A SECTION 610 REVIEW)

Legal Authority: 5 U.S.C. 301; 31 U.S.C. 6101

Abstract: Exclusions implemented under the Social Security Act prevent individuals convicted of certain crimes or individuals whose health care licenses have been revoked from participating in Federal health care programs. Instead of only being barred from participating in all Federal healthcare programs, certain regulatory provisions have resulted in these type of exclusion actions being given an overly broad government-wide effect, and excluded parties have been barred from participating in all Federal procurement and non-procurement actions. However, because Social Security Act exclusions are not

issued under an agency's suspension and debarment authority, they do not stop individuals from participating in all Federal procurement and non-procurement actions. For an agency to bar individuals from participating in all procurement and non-procurement activities, it must exercise its suspension and debarment authority under the Federal Acquisition Regulation or the Nonprocurement Common Rule. This rulemaking would remove the regulatory provisions at issue, in order to align the regulation with the intent of the Social Security Act and current practice.

Timetable:

Action	Date	FR Cite
NPRM	08/00/21	

Regulatory Flexibility Analysis Required: No

Agency Contact: Tiffani Redding, Program Analyst, Department of Health and Human Services, Office of the Secretary, 200 Independence Avenue SW, Washington, DC 20201

Phone: 202 205–4321

Email: tiffani.redding@hhs.gov

RIN: 0991–AC11

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

86. RULEMAKING ON DISCRIMINATION ON THE BASIS OF DISABILITY IN CRITICAL HEALTH AND HUMAN SERVICES PROGRAMS OR ACTIVITIES (RULEMAKING RESULTING FROM A SECTION 610 REVIEW)

Legal Authority: sec. 504 of the Rehabilitation Act of 19

Abstract: This proposed rule would revise regulations under, among other statutes, section 504 of the Rehabilitation Act of 1973 to address unlawful discrimination on the basis of disability in certain vital HHS-funded health and human services programs. Covered topics include non-discrimination in life-sustaining care, organ transplantation, suicide prevention services, child welfare programs and services, health care value assessment methodologies, accessible medical equipment, auxiliary aids and services, Crisis Standards of Care and other relevant health and human services activities.

Timetable:

Action	Date	FR Cite
NPRM	09/00/21	

Regulatory Flexibility Analysis Required: No

Agency Contact: Carla Carter, Supervisory Civil Rights Analyst, Department of Health and Human Services, Office for Civil Rights, 200 Independence Avenue SW, Washington, DC 20201

Phone: 800 368–1019

Email: ocrmail@hhs.gov

RIN: 0945–AA15

Department of Health and Human Services (HHS)	Completed Actions
Office of the National Coordinator for Health Information Technology (ONC)	

87. INFORMATION BLOCKING AND THE ONC HEALTH IT CERTIFICATION PROGRAM: EXTENSION OF COMPLIANCE DATES AND TIMEFRAMES IN RESPONSE TO THE COVID–19 PUBLIC HEALTH EMERGENCY

Legal Authority: 42 U.S.C. 300jj–11; 42 U.S.C. 300jj–14; ...

Abstract: In light of COVID-19, ONC issued an interim final rule with comment period (IFC) that gives health IT developers and health care providers flexibilities to effectively respond to the serious public health threats posed by the spread of COVID-19. The IFC extends certain applicability and compliance dates and timeframes in the 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Final Rule (ONC Cures Act Final Rule), including applicability and compliance dates for the information blocking provisions, certain 2015 Edition health IT certification criteria, and Conditions and Maintenance of Certification requirements under the ONC Health IT Certification Program. The IFC also updated certain standards and made technical corrections and clarifications to the ONC Cures Act Final Rule, which was published in the Federal Register on May 1, 2020.

Completed:

Reason	Date	FR Cite
Interim Final Rule	11/04/20	85 FR 70064
Interim Final Rule Comment Period End	01/04/21	
Final Action—Agency Expects No Further Action	05/25/21	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Michael Lipinski

Phone: 202 690–7151

RIN: 0955–AA02

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

Centers for Disease Control and Prevention (CDC)	

88. CONTROL OF COMMUNICABLE DISEASES; FOREIGN QUARANTINE

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

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

Timetable:

Action	Date	FR Cite
Interim Final Rule Effective	02/07/20	
Interim Final Rule	02/12/20	85 FR 7874
Interim Final Rule Comment Period End	03/13/20	
Final Action	04/00/22	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Ashley C. Altenburger JD, Public Health Analyst, Department of Health and Human Services, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS: H 16–4, Atlanta, GA 30307

Phone: 800 232–4636

Email: dgmqpolicyoffice@cdc.gov

RIN: 0920–AA75

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

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

Legal Authority: Pub. L. 113–54

Abstract: The rulemaking, once finalized, will establish standards for State licensing of prescription drug wholesale distributors and third-party logistics providers. The rulemaking will also establish 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	09/00/21	

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

---

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

Legal Authority: Pub. L. 113–54

Abstract: The Food and Drug Administration (FDA) is amending the 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). In this proposed rulemaking, the Agency is amending 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	09/00/21	

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

---

91. 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

Abstract: The proposed rule would amend FDA medication guide regulations to require a new form of patient labeling, Patient Medication Information, for submission to and review by the FDA for human prescription drug products and certain blood products used, dispensed, or administered on an outpatient basis. The proposed rule would include requirements for Patient Medication Information development and distribution. The proposed rule would 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	10/00/21	

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

RIN: 0910–AH68

---

92. REQUIREMENTS FOR TOBACCO PRODUCT MANUFACTURING PRACTICE

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

Abstract: The rule is proposing to establish tobacco product manufacturing practice (TPMP) requirements for manufacturers of finished and bulk tobacco products. This proposed rule, if finalized, would set forth requirements for the manufacture, pre-production design validation, packing, and storage of a tobacco product. This proposal would help prevent the manufacture and distribution of contaminated and otherwise nonconforming tobacco products. This proposed rule provides manufacturers with flexibility in the manner in which they comply with the proposed 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	10/00/21	

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, Building 71, Room G335, Silver Spring, MD 20993

Phone: 877 287–1373

Fax: 240 276–3904

Email: ctpregulations@fda.hhs.gov

RIN: 0910–AH91

---

93. ADMINISTRATIVE DETENTION OF TOBACCO PRODUCTS

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

Abstract: The FDA is proposing regulations to establish requirements for the administrative detention of tobacco products. This action, if finalized, would allow FDA to administratively detain tobacco products encountered during inspections that an officer or employee 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 a regulatory legal action.

Timetable:

Action	Date	FR Cite
NPRM	12/00/21	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Nathan Mease, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, 10903 New Hampshire Avenue, WO 71, Room G335, Silver Spring, MD 20993

Phone: 877 287–1373

Email: ctpregulations@fda.hhs.gov

Lauren Belcher, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, 10903 New Hampshire Avenue, WO 71, Room G335, Silver Spring, MD 20993

Phone: 877 287–1373

Email: ctpregulations@fda.hhs.gov

RIN: 0910–AI05

---

94. NUTRIENT CONTENT CLAIMS, DEFINITION OF TERM: HEALTHY

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

Abstract: The proposed rule would update the definition for the implied nutrient content claim "healthy" to be consistent with current nutrition science and federal dietary guidelines. The proposed rule would revise the requirements for when the claim "healthy" can be voluntarily used in the labeling of human food products so that the claim reflects current science and dietary guidelines and helps consumers maintain healthy dietary practices.

Timetable:

Action	Date	FR Cite
NPRM	09/00/21	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Vincent De Jesus, Nutritionist, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition, (HFS–830), Room 3D–031, 5100 Paint Branch Parkway, College Park, MD 20740

Phone: 240 402–1774

Fax: 301 436–1191

Email: vincent.dejesus@fda.hhs.gov

RIN: 0910–AI13

95. REVOCATION OF USES OF PARTIALLY HYDROGENATED OILS IN FOODS

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), we 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. We are now proposing to update our regulations to remove all mention of partially hydrogenated oils from FDA's GRAS regulations and as an optional ingredient in standards of identity. We are also proposing to revoke all prior sanctions for uses of PHOs in food.

Timetable:

Action	Date	FR Cite
NPRM	10/00/21	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Ellen Anderson, Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, HFS–265, 4300 River Road, College Park, MD 20740

Phone: 240 402–1309

Email: ellen.anderson@fda.hhs.gov

RIN: 0910–AI15

96. TOBACCO PRODUCT STANDARD FOR CHARACTERIZING FLAVORS IN CIGARS

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

Abstract: Evidence shows that flavored tobacco products, especially those that are sweet, appeal to youth and also shows that youth may be more likely to initiate tobacco use with such products. Characterizing flavors in cigars, such as strawberry, grape, orange, and cocoa, enhance taste and make them easier to use. Nearly one million youth in the United States use flavored cigars, placing these youth at risk for cigar-related disease and death. This proposed rule is a tobacco product standard that would ban characterizing flavors in all cigars. We are taking this action to reduce the tobacco-related death associated with cigars.

Timetable:

Action	Date	FR Cite
ANPRM	03/21/18	83 FR 12294
ANPRM Comment Period End	07/19/18	
NPRM	08/00/21	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Samantha LohCollado, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, 10903 New Hampshire Avenue, Building 71, Room G335, Silver Spring, MD 20993

Phone: 877 287–1373

Fax: 877 287–1426

Email: ctpregulations@fda.hhs.gov

RIN: 0910–AI28

---

97. 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

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 analytical and clinical pharmacology, bioavailability (BA) and bioequivalence (BE) studies that support human research and 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	03/00/22	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Brian Joseph Folian, Regulatory Counsel, 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

RIN: 0910–AI57

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

98. MAMMOGRAPHY QUALITY STANDARDS ACT

Legal Authority: 21 U.S.C. 360i; 21 U.S.C. 360nn; 21 U.S.C. 374(e); 42 U.S.C. 263b

Abstract: FDA is amending its regulations governing mammography. The amendments will update the regulations issued under the Mammography Quality Standards Act of 1992 (MQSA) and the Federal Food, Drug, and Cosmetic Act (FD&C Act). FDA is taking this action to address changes in mammography technology and mammography processes that have occurred since the regulations were published in 1997 and to address breast density reporting to patient and healthcare providers.

Timetable:

Action	Date	FR Cite
NPRM	03/28/19	84 FR 11669
NPRM Comment Period End	06/26/19	
Final Rule	09/00/21	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Jean M. Olson, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, 10903 New Hampshire Avenue, Building 66, Room 5506, Silver Spring, MD 20993

Phone: 301 796–6579

Email: jean.olson@fda.hhs.gov

RIN: 0910–AH04

---

99. 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

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 five additional bulk drug substances on the list. FDA has also identified 26 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 a future rulemaking.

Timetable:

Action	Date	FR Cite
NPRM	09/05/19	84 FR 46688
NPRM Comment Period End	12/04/19	
Final Rule	12/00/21	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Rosilend Lawson, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, 10903 New Hampshire Avenue, Building 51, Room 5197, Silver Spring, MD 20993

Phone: 240 402–6223

Email: rosilend.lawson@fda.hhs.gov

RIN: 0910–AH81

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

100. DIRECT–TO–CONSUMER PRESCRIPTION DRUG ADVERTISEMENTS: PRESENTATION OF THE MAJOR STATEMENT IN A CLEAR, CONSPICUOUS, NEUTRAL MANNER IN ADVERTISEMENTS IN TELEVISION AND RADIO FORMAT

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 risks in what is sometimes called the major statement. The rule would revise the regulation to reflect the statutory requirement require that in DTC advertisements for human drugs in television or radio format, the major statement relating to the side effects and contraindications of an advertised prescription drug 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:

Action	Date	FR Cite
NPRM	03/29/10	75 FR 15376
NPRM Comment Period End	06/28/10	
NPRM Comment Period Reopened	01/27/12	77 FR 4273
NPRM Comment Period End	02/27/12	
NPRM Comment Period Reopened	03/29/12	77 FR 16973
NPRM Comment Period Reopened End	04/09/12	
Final Rule	05/00/22	

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

---

101. SUNLAMP PRODUCTS; AMENDMENT TO THE PERFORMANCE STANDARD

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

Timetable:

Action	Date	FR Cite
NPRM	12/22/15	80 FR 79505
NPRM Comment Period End	03/21/16	
Final Rule	05/00/22	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Ian Ostermiller, Regulatory Counsel, Center for Devices and Radiological Health, Department of Health and Human Services, Food and Drug Administration, 10903 New Hampshire Avenue, WO 66, Room 5454, Silver Spring, MD 20993

Phone: 301 796–5678

Email: ian.ostermiller@fda.hhs.gov

RIN: 0910–AG30

---

102. GENERAL AND PLASTIC SURGERY DEVICES: RESTRICTED SALE, DISTRIBUTION, AND USE OF SUNLAMP PRODUCTS

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	05/00/22	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Ian Ostermiller, Regulatory Counsel, Center for Devices and Radiological Health, Department of Health and Human Services, Food and Drug Administration, 10903 New Hampshire Avenue, WO 66, Room 5454, Silver Spring, MD 20993

Phone: 301 796–5678

Email: ian.ostermiller@fda.hhs.gov

RIN: 0910–AH14

103. NICOTINE TOXICITY WARNINGS

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) that are made or derived from tobacco and 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	08/00/22	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Samantha LohCollado, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, 10903 New Hampshire Avenue, Building 71, Room G335, Silver Spring, MD 20993

Phone: 877 287–1373

Fax: 877 287–1426

Email: ctpregulations@fda.hhs.gov

RIN: 0910–AH24

104. REQUIREMENTS FOR ADDITIONAL TRACEABILITY RECORDS FOR CERTAIN FOODS

Legal Authority: sec. 204 of the FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–353) (21 U.S.C. 2223(d)); sec. 701(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(a)); sec. 361 of the Public Health Service Act (42 U.S.C. 264)

Abstract: This rule will establish additional recordkeeping requirements for facilities that manufacture, process, pack, or hold foods that are designated as high-risk foods.

Timetable:

Action	Date	FR Cite
NPRM	09/23/20	85 FR 59984
NPRM Comment Period End	01/21/21	
NPRM Comment Period Extended	12/18/20	85 FR 82393
NPRM Comment Period End	02/22/21	
Final Rule	11/00/22	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Katherine Vierk, Director, Division of Public Health Informatics and Analytics, Department of Health and Human Services, Food and Drug Administration, 5001 Campus Drive, CPK1, Room 2B014, HFS–005, College Park, MD 20740

Phone: 240 402–2122

Email: katherine.vierk@fda.hhs.gov

RIN: 0910–AI44

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

105. MILK AND CREAM PRODUCT AND YOGURT PRODUCTS, FINAL RULE TO REVOKE THE STANDARDS FOR LOWFAT YOGURT AND NONFAT YOGURT AND TO AMEND THE STANDARD FOR YOGURT

Legal Authority: 21 U.S.C. 321; 21 U.S.C. 336; 21 U.S.C. 341; 21 U.S.C. 343; 21 U.S.C. 348; 21 U.S.C. 371(e); 21 U.S.C. 379e

Abstract: This final rule amends the standard of identity for yogurt and revokes the standards of identity for lowfat yogurt and nonfat yogurt. It modernizes the standard for yogurt to allow for technological advances, to preserve the basic nature and essential characteristics of yogurt, and to promote honesty and fair dealing in the interest of consumers. Section 701(e)(1), of the Federal Food, Drug, and Cosmetic Act requires that the amendment or repeal of the definition and standard of identity for a dairy product proceed under a formal rulemaking process. Although, standard practice is not to include formal rulemaking in the Unified Agenda, this rule is included to highlight the de-regulatory work in this space.

Completed:

Reason	Date	FR Cite
Withdrawn From the Unified Agenda—This RIN is Being Pursued via Formal Rulemaking Process	06/01/21	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Terri Wenger

Phone: 240 402–2371

Email: terri.wenger@fda.hhs.gov

RIN: 0910–AI40

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

106. CONTRACT YEAR 2023 POLICY AND TECHNICAL CHANGES TO THE MEDICARE ADVANTAGE AND MEDICARE PRESCRIPTION DRUG BENEFIT PROGRAMS (CMS–4192)

Legal Authority: 42 U.S.C. 1395w

Abstract: This proposed rule would strengthen and improve the Medicare Advantage (MA or Part C) and Medicare Prescription Drug Benefit (Part D) programs, codify existing sub regulatory guidance, and implement any statutory changes (if necessary) for contract year 2023.

Timetable:

Action	Date	FR Cite
NPRM	09/00/21	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Christian Bauer, Director, Division of Part D Policy, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, MS: C1–26–16, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786–6043

Email: christian.bauer@cms.hhs.gov

RIN: 0938–AU30

---

107. CY 2022 REVISIONS TO PAYMENT POLICIES UNDER THE PHYSICIAN FEE SCHEDULE AND OTHER REVISIONS TO MEDICARE PART B (CMS–1751) (SECTION 610 REVIEW)

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

Abstract: This annual proposed rule would revise payment polices under the Medicare physician fee schedule, and make other policy changes to payment under Medicare Part B. These changes would apply to services furnished beginning January 1, 2022. Additionally, this rule proposes updates to the Quality Payment Program.

Timetable:

Action	Date	FR Cite
NPRM	06/00/21	

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–AU42

---

108. CY 2022 HOSPITAL OUTPATIENT PPS POLICY CHANGES AND PAYMENT RATES AND AMBULATORY SURGICAL CENTER PAYMENT SYSTEM POLICY CHANGES AND PAYMENT RATES (CMS–1753) (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. 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	06/00/21	

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–AU43

---

109. HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEMS FOR ACUTE CARE HOSPITALS; THE LONG–TERM CARE HOSPITAL PROSPECTIVE PAYMENT SYSTEM; AND FY 2022 RATES (CMS–1752) (SECTION 610 REVIEW)

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

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

Timetable:

Action	Date	FR Cite
NPRM	05/10/21	86 FR 25070
NPRM Comment Period End	06/28/21	

Final Action	10/00/21	

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: C4–03–18, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786–6504

Email: donald.thompson@cms.hhs.gov

RIN: 0938–AU44

---

110. • MEDICARE ADVANTAGE AND MEDICARE PRESCRIPTION DRUG BENEFIT PROGRAM PAYMENT POLICY (CMS–4198)

Legal Authority: 42 U.S.C. 1395w

Abstract: This proposed rule would codify long-established Medicare Advantage and Part D payment policies that are outside the scope of the annual Advance Notice/Rate Announcement.

Timetable:

Action	Date	FR Cite
NPRM	01/00/22	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Jennifer Shapiro, Director, Medicare Plan Payment Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, MS: C1–13–18, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786–7407

Email: jennifer.shapiro@cms.hhs.gov

RIN: 0938–AU59

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

111. • REQUIREMENTS RELATED TO SURPRISE BILLING; PART II (CMS–9908)

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

Abstract: This interim final rule with comment would implement additional protections against surprise medical bills under the No Surprises Act, including provisions related to the independent dispute resolution processes.

Timetable:

Action	Date	FR Cite
Interim Final Rule	08/00/21	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Deborah Bryant, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Consumer Information and Insurance Oversight, MS: W08–134, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 301 493–4293

Email: deborah.bryant@cms.hhs.gov

RIN: 0938–AU62

---

112. • REQUIREMENTS RELATED TO SURPRISE BILLING; PART I (CMS–9909)

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

Abstract: This interim final rule with comment would implement certain protections against surprise medical bills under the No Surprises Act.

Timetable:

Action	Date	FR Cite
Interim Final Rule With Comment	07/00/21	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Lindsey Murtagh, Director, Market–Wide Regulation Division, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Consumer Information and Insurance Oversight, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 301 492–4106

Email: lindsey.murtagh@cms.hhs.gov

RIN: 0938–AU63

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

113. DURABLE MEDICAL EQUIPMENT FEE SCHEDULE, ADJUSTMENTS TO RESUME THE TRANSITIONAL 50/50 BLENDED RATES TO PROVIDE RELIEF IN NON–COMPETITIVE BIDDING AREAS (CMS–1687) (SECTION 610 REVIEW)

Legal Authority: 42 U.S.C. 1302, 1395hh, and 1395rr(b)(l)); Pub. L. 114–255, sec. 5004(b), 16007(a) and 16008

Abstract: This final rule follows the interim final rule that published May 11, 2018, and extended the end of the transition period from June 30, 2016, to December 31, 2016 for phasing in adjustments to the fee schedule amounts for certain durable medical equipment (DME) and enteral nutrition paid in areas not subject to the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP). In addition, the interim rule amended the regulation to resume the transition period for items furnished from August 1, 2017, through December 31, 2018. The interim rule also made technical amendments to existing regulations for DMEPOS items and services to exclude infusion drugs used with DME from the DMEPOS CBP.

Timetable:

Action	Date	FR Cite
Interim Final Rule	05/11/18	83 FR 21912
Interim Final Rule Comment Period End	07/09/18	
Continuation Notice	04/26/21	86 FR 21949
Final Action to be Merged With 0938-AU17	05/00/22	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Alexander Ullman, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, MS: C5–07–26, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786–9671

Email: alexander.ullman@cms.hhs.gov

RIN: 0938–AT21

---

114. REQUIREMENTS FOR LONG–TERM CARE FACILITIES: REGULATORY PROVISIONS TO PROMOTE INCREASED SAFETY (CMS–3347) (SECTION 610 REVIEW)

Legal Authority: secs. 1819 and 1919 of the Social Security Act; sec. 1819(d)(4)(B) and 1919(d)(4)(B) of the Social Security Act; sec. 1819(b)(1)(A) and 1919 (b)(1)(A) of the Social Security Act

Abstract: This final rule reforms the requirements that long-term care facilities must meet to participate in the Medicare and Medicaid programs in order to support the provision of safe care and preserve access to care.

Timetable:

Action	Date	FR Cite
NPRM	07/18/19	84 FR 34737
NPRM Comment Period End	09/16/19	
Final Action	07/00/22	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Diane Corning, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Clinical Standards and Quality, MS: S3–02–01, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786–8486

Email: diane.corning@cms.hhs.gov

RIN: 0938–AT36

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

115. MOST FAVORED NATION (MFN) MODEL (CMS–5528) (COMPLETION OF A SECTION 610 REVIEW)

Legal Authority: Social Security Act, sec. 1115A

Abstract: This interim final rule with comment period (IFC) implements the Most Favored Nation (MFN) Model, a new Medicare payment model under section 1115A of the Social Security Act (the Act). The MFN Model tests whether more closely aligning payment for Medicare Part B drugs and biologicals (hereafter, referred to as drugs) with international prices and removing incentives to use higher-cost drugs can control unsustainable growth in Medicare Part B spending without adversely affecting quality of care for beneficiaries.

Timetable:

Action	Date	FR Cite
ANPRM	10/30/18	83 FR 54546
ANPRM Comment Period End	12/31/18	
Interim Final Rule	11/27/20	85 FR 76180
Interim Final Rule Effective	11/27/20	
Interim Final Rule Comment Period End	01/26/21	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Laura Strawbridge, Director, Division of Ambulatory Payment Models, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare and Medicaid Innovation, 7500 Security Boulevard, MS: WB–06–05, Baltimore, MD 21244

Phone: 410 786–7400

Email: mfn@cms.hhs.gov

RIN: 0938–AT91

116. MEDICAID; REDUCING PROVIDER AND PATIENT BURDEN BY IMPROVING PRIOR AUTHORIZATION PROCESSES AND PROMOTING PATIENTS' ELECTRONIC ACCESS TO HEALTH INFORMATION (CMS–9123)

Legal Authority: 42 U.S.C. 1302

Abstract: This final rule places new requirements on state Medicaid and CHIP fee-for-service (FFS) programs, Medicaid managed care plans, CHIP managed care entities, and Qualified Health Plan (QHP) issuers on the Federally-facilitated Exchanges (FFEs) to improve the electronic exchange of health care data, and streamline processes related to prior authorization, while continuing CMS' drive toward interoperability, and reducing burden in the health care market. In addition, on behalf of the Department of Health and Human Service (HHS), the Office of the National Coordinator for Health Information Technology (ONC) is adopting certain specified implementation guides (IGs) needed to support the Application Programming Interface (API) policies included in this rule. Each of these elements plays a key role in reducing overall payer and provider burden and improving patient access to health information.

Completed:

Reason	Date	FR Cite
NPRM	12/18/20	85 FR 82586
Withdrawn	03/17/21	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Alexandra Mugge

Phone: 410 786–4457

Email: alexandra.mugge@cms.hhs.gov

RIN: 0938–AT99

117. CY 2021 REVISIONS TO PAYMENT POLICIES UNDER THE PHYSICIAN FEE SCHEDULE AND OTHER REVISIONS TO MEDICARE PART B (CMS–1734) (COMPLETION OF A SECTION 610 REVIEW)

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

Abstract: This annual final rule revises payment polices under the Medicare physician fee schedule, and makes other policy changes to payment under Medicare Part B. These changes apply to services furnished beginning January 1, 2021. Additionally, this rule updates the Quality Payment Program.

Timetable:

Action	Date	FR Cite
NPRM	08/17/20	85 FR 50074
NPRM Comment Period End	10/05/20	
Final Action	12/28/20	85 FR 84472
Final Action Effective	01/01/21	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Marge Watchorn, Deputy Director, Division of Practitioner Services, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, MS: C4–01–15, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786–4361

Email: marge.watchorn@cms.hhs.gov

RIN: 0938–AU10

---

118. CY 2021 HOSPITAL OUTPATIENT PPS POLICY CHANGES AND PAYMENT RATES AND AMBULATORY SURGICAL CENTER PAYMENT SYSTEM POLICY CHANGES AND PAYMENT RATES (CMS–1736) (COMPLETION OF A SECTION 610 REVIEW)

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

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 implements 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	08/12/20	85 FR 48772
NPRM Comment Period End	10/05/20	
Final Action	12/29/20	85 FR 85866
Final Action Effective	01/01/21	

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–AU12

---

119. PROMOTING ELECTRONIC ACCESS TO HEALTH INFORMATION FOR PATIENTS AND FOR MEDICARE– AND MEDICAID–PARTICIPATING PROVIDERS AND SUPPLIERS (CMS–0057)

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

Abstract: The proposed rule would also revise requirements that select Medicare- and Medicaid-participating providers and suppliers must meet for continued participation in the Medicare and Medicaid programs by requiring increased patient electronic access to their health care information. This proposed rule would also improve the electronic exchange of health information among the identified providers and suppliers, and finally, this proposed rule would improve patient safety by establishing patient identity management requirements for the identified providers and suppliers.

Completed:

Reason	Date	FR Cite
Withdrawn	03/17/21	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Alexandra Mugge

Phone: 410 786–4457

Email: alexandra.mugge@cms.hhs.gov

RIN: 0938–AU53

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

120. UPDATING NATIVE EMPLOYMENT WORKS REQUIREMENTS (RULEMAKING RESULTING FROM A SECTION 610 REVIEW)

Legal Authority: 42 U.S.C. 612

Abstract: The rule would update NEW regulations at 45 CFR part 287 to avoid inconsistencies and reflect the changes that have been made to the NEW statute and Administration for Children and Families (ACF) grant policy and procedures since the current regulation's publication on February 18, 2000. In particular, the regulations need to address changes made in section 404(e) of the Social Security Act as amended in 1999, Uniform Administrative Requirements, Cost Principles, and Audit Requirement for HHS Awards (45 CFR part 75) - Part 75 Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards, Public Law 106-107, the "Federal Financial Assistance Management, Improvement Act of 1999" (Nov. 20, 1999), and various minor technical changes. While some of these changes have been addressed and communicated to the public and grantees via program instructions and information memoranda, the regulations themselves are now inconsistent with current law and policy.

Timetable:

Action	Date	FR Cite
NPRM	12/00/21	

Regulatory Flexibility Analysis Required: No

Agency Contact: Tonya Ann Davis, Program Specialist, Department of Health and Human Services, Administration for Children and Families, 330 C Street SW, Room 3020, Washington, DC 20201

Phone: 202 401–4851

Email: tonya.davis@acf.hhs.gov

RIN: 0970–AC83

BILLING CODE 4150–03–P

[FR Doc. 2021-14870 Filed: 7/29/2021 8:45 am; Publication Date: 7/30/2021]