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: The Executive Secretariat, 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, especially for those who are least able to help themselves. 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. HHS has an agency-wide effort to support the Agenda's purpose of encouraging more effective public participation in the regulatory process. For example, to encourage public participation, we regularly update our regulatory web page (*http://www.HHS.gov/regulations*) which includes links to HHS rules currently open for public comment, and also provides a ''regulations toolkit'' with background information on regulations, the commenting process, how public comments influence the development of a rule, and how the public can provide effective comments.

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.*

Samuel A. Shipley,

Senior Regulations Coordinator.

OFFICE OF THE SECRETARY—PROPOSED RULE STAGE

Sequence No.	Title	Regulation Identifier No.
205	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 No.	Title	Regulation Identifier No.
206	Implementation of the Religious Freedom Restoration Act **(Section 610 Review)**	0945–AA13
207	Special Responsibilities of Medicare Hospitals in Emergency Cases, and Discrimination on the Basis of Disability in Critical Health and Human Services Programs or Activities **(Section 610 Review) (Reg Plan Seq No. 33)**.	0945–AA14
208	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

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

OFFICE FOR CIVIL RIGHTS—COMPLETED ACTIONS

Sequence No.	Title	Regulation Identifier No.
209	Nondiscrimination in Health and Health Education Programs or Activities	0945–AA11

OFFICE OF THE NATIONAL COORDINATOR FOR HEALTH INFORMATION TECHNOLOGY—FINAL RULE STAGE

Sequence No.	Title	Regulation Identifier No.
210	Information Blocking and the ONC Health IT Certification Program: Extension of Compliance Dates and Timeframes in Response to the COVID–19 Public Health Emergency **(Reg Plan Seq No. 35)**.	0955–AA02

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

OFFICE OF THE NATIONAL COORDINATOR FOR HEALTH INFORMATION TECHNOLOGY—COMPLETED ACTIONS

Sequence No.	Title	Regulation Identifier No.
211	21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program.	0955–AA01

CENTERS FOR DISEASE CONTROL AND PREVENTION—FINAL RULE STAGE

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

CENTERS FOR DISEASE CONTROL AND PREVENTION—COMPLETED ACTIONS

Sequence No.	Title	Regulation Identifier No.
213	Control of Communicable Diseases; Foreign Quarantine: Suspension of the Right to Introduction and Prohibition of Introduction of Persons into United States from Designated Foreign Countries or Places.	0920–AA76

FOOD AND DRUG ADMINISTRATION—PROPOSED RULE STAGE

Sequence No.	Title	Regulation Identifier No.
214	Medication Guide; Patient Medication Information	0910–AH68
215	Requirements for Tobacco Product Manufacturing Practice	0910–AH91
216	Administrative Detention of Tobacco Products	0910–AI05
217	Nutrient Content Claims, Definition of Term: Healthy	0910–AI13
218	Revocation of Uses of Partially Hydrogenated Oils in Foods	0910–AI15
219	Conduct of Analytical and Clinical Pharmacology, Bioavailability and Bioequivalence Studies	0910–AI57

FOOD AND DRUG ADMINISTRATION—FINAL RULE STAGE

Sequence No.	Title	Regulation Identifier No.
220	Sunlamp Products; Amendment to the Performance Standard	0910–AG30
221	Mammography Quality Standards Act **(Reg Plan Seq No. 37)**	0910–AH04
222	General and Plastic Surgery Devices: Restricted Sale, Distribution, and Use of Sunlamp Products	0910–AH14
223	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
224	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

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.
225	Acute Nicotine Toxicity Warnings for E-Liquids	0910–AH24

FOOD AND DRUG ADMINISTRATION—COMPLETED ACTIONS

Sequence No.	Title	Regulation Identifier No.
226	Postmarketing Safety Reporting Requirements for Human Drug and Biological Products	0910–AA97
227	Over-the-Counter (OTC) Drug Review—Cough/Cold (Antihistamine) Products	0910–AF31
228	Food Labeling; Gluten-Free Labeling of Fermented or Hydrolyzed Foods	0910–AH00
229	Testing Standards for Batteries and Battery Management Systems in Battery-Operated Tobacco Products	0910–AH90

CENTERS FOR MEDICARE & MEDICAID SERVICES—PROPOSED RULE STAGE

Sequence No.	Title	Regulation Identifier No.
230	Medicaid Programs Reducing Provider and Patient Burden, and Promoting Patients' Electronic Access to Health Information (CMS–9123).	0938–AT99
231	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
232	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
233	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

CENTERS FOR MEDICARE & MEDICAID SERVICES—FINAL RULE STAGE

Sequence No.	Title	Regulation Identifier No.
234	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
235	International Pricing Index Model For Medicare Part B Drugs (CMS–5528) **(Section 610 Review)**	0938–AT91
236	CY 2021 Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Medicare Part B (CMS–1734) **(Section 610 Review)**.	0938–AU10
237	CY 2021 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates (CMS–1736) **(Section 610 Review)**.	0938–AU12

CENTERS FOR MEDICARE & MEDICAID SERVICES—LONG-TERM ACTIONS

Sequence No.	Title	Regulation Identifier No.
238	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 No.	Title	Regulation Identifier No.
239	Organ Procurement Organizations (OPOs) (CMS–3380) **(Completion of a Section 610 Review)**	0938–AU02
240	Transparency in Coverage (CMS–9915)	0938–AU04
241	FY 2021 Inpatient Rehabilitation Facility (IRF) Prospective Payment System Rate Update (CMS–1729) **(Completion of a Section 610 Review)**.	0938–AU05
242	FY 2021 Inpatient Psychiatric Facilities Prospective Payment System Rate Updates (CMS–1731) **(Completion of a Section 610 Review)**.	0938–AU07
243	Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals; the Long-Term Care Hospital Prospective Payment System; and FY 2021 Rates (CMS–1735) **(Section 610 Review)**.	0938–AU11
244	Clinical Laboratory Improvement Amendments and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency (CMS–3401) **(Completion of a Section 610 Review)**.	0938–AU33

ADMINISTRATION FOR CHILDREN AND FAMILIES—PROPOSED RULE STAGE

Sequence No.	Title	Regulation Identifier No.
245	Updating Native Employment Works Requirements **(Rulemaking Resulting From a Section 610 Review)**.	0970–AC83

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Office of the Secretary (OS)

Proposed Rule Stage

205. Limiting the Effect of Exclusions Implemented Under the Social Security Act (Rulemaking Resulting From a Section 610 Review)

E.O. 13771 Designation: Deregulatory.

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	11/00/20	

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)

Office for Civil Rights (OCR)

Proposed Rule Stage

206. • Implementation of the Religious Freedom Restoration Act (Section 610 Review)

E.O. 13771 Designation: Regulatory.

Legal Authority: Not Yet Determined

Abstract: This proposed rule would set forth substantive standards the Department will use in its interpretation and application of RFRA. These would include elaboration on how HHS will interpret terms in RFRA such as religious exercise, substantial burden, and compelling interest, based on the guidance issued by the Attorney General concerning those terms, as well as applicable case law. The rule's standards would guide both OCR and the Department's components in understanding how RFRA's requirements govern the Department's various activities. The rulemaking would rely upon, other authorities, 42 U.S.C. 2000bb–1, and the statutes that provide legal authority to issue programmatic regulations with respect to HHS programs, as well as HHS's interpretive authority.

Timetable:

Action	Date	FR Cite
NPRM	01/00/21	

Regulatory Flexibility Analysis Required: Undetermined.

Agency Contact: Christine Pratt, Senior Advisor on Conscience and Religious Freedom, 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–AA13

207. • Special Responsibilities of Medicare Hospitals in Emergency Cases, and Discrimination on the Basis of Disability in Critical Health and Human Services Programs or Activities (Section 610 Review)

Regulatory Plan: This entry is Seq. No. 33 in part II of this issue of the **Federal Register**.

RIN: 0945–AA14

208. • Rulemaking on Discrimination on the Basis of Disability in Critical Health and Human Services Programs or Activities (Rulemaking Resulting From a Section 610 Review)

E.O. 13771 Designation: Fully or Partially Exempt.

Legal Authority: Section 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 robustly address unlawful discrimination on the basis of disability in certain vital HHS-funded health and human services programs.

Timetable:

Action	Date	FR Cite
NPRM	01/00/21	

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)

Office for Civil Rights (OCR)

Completed Actions

209. Nondiscrimination in Health and Health Education Programs or Activities

E.O. 13771 Designation: Deregulatory.

Legal Authority: Sec. 1557 of the Patient Protection and Affordable Care Act (42 U.S.C. 18116)

Abstract: This rulemaking would finalize, with appropriate changes in response to public comments, the proposed rule implementing section 1557 of the Patient Protection and Affordable Care Act (PPACA), and conforming amendments to related HHS rules. Section 1557 of PPACA prohibits discrimination on the basis of race, color, national origin, sex, age, or disability under any health program or activity, any part of which is receiving Federal financial assistance, including credits, subsidies, or contracts of insurance, or under any program or activity that is administered by an Executive Agency or any entity established under title I of the PPACA.

Completed:

Reason	Date	FR Cite
Final Action	06/19/20	85 FR 37160
Final Action Effective.	08/18/20	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Luben Montoya, *Phone:* 800 368–1019, *TDD Phone:* 800 537–7697, *Email: ocrmail@hhs.gov*.

RIN: 0945–AA11

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Office of the National Coordinator for Health Information Technology (ONC)

Final Rule Stage

210. • Information Blocking and the ONC Health IT Certification Program: Extension of Compliance Dates and Timeframes in Response to the Covid–19 Public Health Emergency

Regulatory Plan: This entry is Seq. No. 35 in part II of this issue of the **Federal Register**.

RIN: 0955–AA02

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Office of the National Coordinator for Health Information Technology (ONC)

Completed Actions

211. 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program

E.O. 13771 Designation: Regulatory.

Legal Authority: Pub. L. 114–255

Abstract: The final rule implements certain provisions of the 21st Century Cures Act, including Conditions and Maintenance of Certification requirements for health information technology (health IT) developers under the ONC Health IT Certification Program (Program), the voluntary certification of health IT for use by pediatric healthcare providers and reasonable and necessary activities that do not constitute information blocking. The implementation of these provisions will advance interoperability and support the access, exchange, and use of electronic health information. The rule also finalizes certain modifications to the 2015 Edition health IT certification criteria and Program in additional ways to advance interoperability, enhance health IT certification, and reduce burden and costs.

Completed:

Reason	Date	FR Cite
Final Action	05/01/20	85 FR 25642
Final Action Effective.	06/30/20	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Michael Lipinski, *Phone:* 202 690–7151.

RIN: 0955–AA01

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Centers for Disease Control and Prevention (CDC)

Final Rule Stage

212. Control of Communicable Diseases; Foreign Quarantine

E.O. 13771 Designation: Regulatory.

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	04/00/21	

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)

Centers for Disease Control and Prevention (CDC)

Completed Actions

213. Control of Communicable Diseases; Foreign Quarantine: Suspension of the Right to Introduction and Prohibition of Introduction of Persons Into United States From Designated Foreign Countries or Places

E.O. 13771 Designation: Fully or Partially Exempt.

Legal Authority: 42 U.S.C. 265

Abstract: HHS/CDC is amending its Foreign Quarantine regulations to provide a procedure for CDC to suspend the introduction of persons from designated countries or places, if required, in the interest of public health.

Completed:

Reason	Date	FR Cite
Interim Final Rule Comment Period End.	04/23/20	
Final Action	09/11/20	85 FR 56724
Final Action Effective.	10/13/20	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Nina Witkofsky, *Phone:* 404 498–7000, *Email: cdcregulations@cdc.gov.*

RIN: 0920–AA76

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Food and Drug Administration (FDA)

Proposed Rule Stage

214. Medication Guide; Patient Medication Information

E.O. 13771 Designation: Regulatory.

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	02/00/21	

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

215. Requirements for Tobacco Product Manufacturing Practice

E.O. 13771 Designation: Regulatory.

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	02/00/21	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Matthew Brenner, 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

216. Administrative Detention of Tobacco Products

E.O. 13771 Designation: Other.

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 violative tobacco products until FDA has had time to consider the appropriate action to take and, where appropriate, to initiate a regulatory action.

Timetable:

Action	Date	FR Cite
NPRM	08/00/21	

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.*

RIN: 0910–AI05

217. Nutrient Content Claims, Definition of Term: Healthy

E.O. 13771 Designation: Regulatory.

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	11/00/20	

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

218. Revocation of Uses of Partially Hydrogenated Oils in Foods

E.O. 13771 Designation: Regulatory.

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	07/00/21	

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

219. • Conduct of Analytical and Clinical Pharmacology, Bioavailability and Bioequivalence Studies

E.O. 13771 Designation: Deregulatory.

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	08/00/21	

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)

Food and Drug Administration (FDA)

Final Rule Stage

220. Sunlamp Products; Amendment to the Performance Standard

E.O. 13771 Designation: Fully or Partially Exempt.

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	05/00/21	

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

221. Mammography Quality Standards Act

Regulatory Plan: This entry is Seq. No. 37 in part II of this issue of the **Federal Register**.

RIN: 0910–AH04

222. General and Plastic Surgery Devices: Restricted Sale, Distribution, and Use of Sunlamp Products

E.O. 13771 Designation: Regulatory.

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	10/00/21	

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

223. 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

E.O. 13771 Designation: Fully or Partially Exempt.

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). The final rule will amend the 503A Bulks List by placing five additional bulk drug substances on the list. This rule will also identify 26 bulk drug substances that FDA has considered and decided 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	12/00/20	

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

224. 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

E.O. 13771 Designation: Fully or Partially Exempt.

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. Such is consistent with the formal rulemaking provisions of the Administrative Procedures Act (5 U.S.C. 556 and 557). 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.

Timetable:

Action	Date	FR Cite
ANPRM	07/03/03	68 FR 39873
ANPRM Comment Period End.	10/01/03	
NPRM	01/15/09	74 FR 2443
NPRM Comment Period End.	04/29/09	
Final Rule	11/00/20	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Terri Wenger, Food Technologist, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5001 Campus Drive, College Park, MD 20740, *Phone:* 240 402–2371, *Email: terri.wenger@fda.hhs.gov.*

RIN: 0910–AI40

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Food and Drug Administration (FDA)

Long-Term Actions

225. Acute Nicotine Toxicity Warnings for E-Liquids

E.O. 13771 Designation: Regulatory.

Legal Authority: 21 U.S.C. 301 *et seq.;* 21 U.S.C. 331; 21 U.S.C. 371; 21 U.S.C. 374; 21 U.S.C. 387

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, Senior Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, 10903 New Hampshire Ave., Building 71, Room G335, Silver Spring, MD 20993, *Phone:* 877 287–1373, *Fax:* 877 287–1426, *Email: ctpregulations@fda.hhs.gov.*

RIN: 0910–AH24

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Food and Drug Administration (FDA)

Completed Actions

226. Postmarketing Safety Reporting Requirements for Human Drug and Biological Products

E.O. 13771 Designation: Regulatory.

Legal Authority: 42 U.S.C. 216; 42 U.S.C. 241; 42 U.S.C. 242a; 42 U.S.C. 262 and 263; 42 U.S.C. 263a; 42 U.S.C. 264; 42 U.S.C. 300aa–25; 21 U.S.C. 321; 21 U.S.C. 331; 21 U.S.C. 351 to 353; 21 U.S.C. 355; 21 U.S.C. 360; 21 U.S.C. 360b to 360f; 21 U.S.C. 360i to 360j; 21 U.S.C. 371; 21 U.S.C. 374; 21 U.S.C. 379

Abstract: The proposed rule would amend the postmarketing safety reporting regulations for human drugs and biological products including blood and blood products in order to better align FDA requirements with guidelines of the International Council on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), and to update reporting requirements in light of current pharmacovigilance practice and safety information sources and enhance the quality of safety reports received by FDA. Revisions to the postmarketing safety reporting requirements were proposed as part of a single rulemaking (68 FR 12406) to clarify and revise both premarketing and postmarketing safety reporting requirements for human drug and biological products. FDA is reproposing the proposed postmarketing requirements with revisions. Premarketing safety reporting requirements were finalized in a separate final rule published on September 29, 2010, (75 FR 59961).

Completed:

Reason	Date	FR Cite
Withdrawn	09/04/20	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Jane E. Baluss, *Phone:* 301 796–3469, *Fax:* 301 847–8440, *Email: jane.baluss@fda.hhs.gov.*

RIN: 0910–AA97

227. Over-the-Counter (OTC) Drug Review—Cough/Cold (Antihistamine) Products

E.O. 13771 Designation: Deregulatory.

Legal Authority: 21 U.S.C. 321p; 21 U.S.C. 331; 21 U.S.C. 351 to 353; 21 U.S.C. 355; 21 U.S.C. 360; 21 U.S.C. 371

Abstract: FDA will be proposing a rule to add the common cold indication to certain over-the-counter (OTC) antihistamine active ingredients. This proposed rule is the result of collaboration under the U.S. Canada Regulatory Cooperation Council as part of efforts to reduce unnecessary duplication and differences. This pilot exercise will help determine the feasibility of developing an ongoing mechanism for alignment in review and adoption of certain aspects of the OTC Drug Review.

Completed:

Reason	Date	FR Cite
Withdrawn	11/23/20	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Janice Adams-King, *Phone:* 301 796–3713, *Fax:* 301 796–9899, *Email: janice.adams-king@fda.hhs.gov.*

RIN: 0910–AF31

228. Food Labeling; Gluten-Free Labeling of Fermented or Hydrolyzed Foods

E.O. 13771 Designation: Regulatory.

Legal Authority: Sec. 206 of the Food Allergen Labeling and Consumer Protection Act; 21 U.S.C. 343(a)(1); 21 U.S.C. 321(n); 21 U.S.C. 371(a)

Abstract: This final rule would establish requirements concerning ''gluten-free'' labeling for foods that are fermented or hydrolyzed or that contain fermented or hydrolyzed ingredients. These additional requirements for the ''gluten-free'' labeling rule are needed to help ensure that individuals with celiac disease are not misled and receive truthful and accurate information with respect to fermented or hydrolyzed foods labeled as ''gluten-free.''

Completed:

Reason	Date	FR Cite
Final Rule	08/13/20	85 FR 49240
Final Rule Effective.	10/13/20	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Carol D'Lima, *Phone:* 240 402–2371, *Fax:* 301 436–2636, *Email: carol.dlima@fda.hhs.gov.*

RIN: 0910–AH00

229. Testing Standards for Batteries and Battery Management Systems in Battery-Operated Tobacco Products

E.O. 13771 Designation: Regulatory.

Legal Authority: 21 U.S.C. 301 *et seq.;* 21 U.S.C. 371; 21 U.S.C. 387b; 21 U.S.C. 387g; 21 U.S.C. 387i

Abstract: This rule would propose to establish a product standard to require testing standards for batteries used in

electronic nicotine delivery systems (ENDS) and require design protections including a battery management system for ENDS using batteries and protective housing for replaceable batteries. This product standard would protect the safety of users of battery-powered tobacco products and will help to streamline the FDA premarket review process, ultimately reducing the burden on both manufacturers and the Agency. The proposed rule would be applicable to tobacco products that include a non-user replaceable battery as well as products that include a user replaceable battery.

Completed:

Reason	Date	FR Cite
Withdrawn	09/04/20	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Nathan Mease, *Phone:* 877 287–1373, *Email: ctpregulations@fda.hhs.gov.*

RIN: 0910–AH90

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Centers for Medicare & Medicaid Services (CMS)

Proposed Rule Stage

230. Medicaid Programs Reducing Provider and Patient Burden, and Promoting Patients' Electronic Access to Health Information (CMS–9123)

E.O. 13771 Designation: Regulatory.

Legal Authority: 42 U.S.C. 1302

Abstract: This proposed rule would place 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 proposing the adoption of certain specified implementation guides (IGs) needed to support the proposed 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.

Timetable:

Action	Date	FR Cite
NPRM	12/00/20	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Alexandra Mugge, Deputy Chief Health Informatics Officer, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of the Administrator, MS: C5–02–00, 7500 Security Boulevard, Baltimore, MD 21244, *Phone:* 410 786–4457, *Email: alexandra.mugge@cms.hhs.gov.*

RIN: 0938–AT99

231. • CY 2022 Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Medicare Part B (CMS–1751) (Section 610 Review)

E.O. 13771 Designation: Other.

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: 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–AU42

232. • 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)

E.O. 13771 Designation: Other.

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

233. • 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)

E.O. 13771 Designation: Other.

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	04/00/21	

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: C4–08–06, 7500 Security Boulevard, Baltimore, MD 21244, *Phone:* 410 786–6504, *Email: donald.thompson@cms.hhs.gov.*

RIN: 0938–AU44

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Centers for Medicare & Medicaid Services (CMS)

Final Rule Stage

234. 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)

E.O. 13771 Designation: Other.

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	
Final Action to be Merged With 0938–AU17.	05/00/21	

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

235. International Pricing Index Model for Medicare Part B Drugs (CMS–5528) (Section 610 Review)

E.O. 13771 Designation: Regulatory.

Legal Authority: Social Security Act, sec. 1115A

Abstract: This rule finalizes testing changes to payment for certain separately payable Part B drugs and biologicals.

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	
Final Action	11/00/23	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Andrew York, Social Science Research Analyst, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare and Medicaid Innovation, MS: WB–06–05, 7500 Security Boulevard, Baltimore, MD 21244, *Phone:* 410 786–8945, *Email: andrew.york1@cms.hhs.gov*.

RIN: 0938–AT91

236. CY 2021 Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Medicare Part B (CMS–1734) (Section 610 Review)

E.O. 13771 Designation: Regulatory.

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	01/00/21	

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

237. CY 2021 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates (CMS–1736) (Section 610 Review)

E.O. 13771 Designation: Regulatory.

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	01/00/21	

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–AU12

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Centers for Medicare & Medicaid Services (CMS)

Long-Term Actions

238. Requirements for Long-Term Care Facilities: Regulatory Provisions To Promote Increased Safety (CMS–3347) (Section 610 Review)

E.O. 13771 Designation: Deregulatory.

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)

Centers for Medicare & Medicaid Services (CMS)

Completed Actions

239. Organ Procurement Organizations (OPOS) (CMS–3380) (Completion of a Section 610 Review)

E.O. 13771 Designation: Regulatory.

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

Abstract: This final rule revises the Organ Procurement Organization (OPO) Conditions for Coverage (CfCs) to increase donation rates and organ transplantation rates by replacing the current measures with new transparent, reliable, and objective measures.

Timetable:

Action	Date	FR Cite
NPRM	12/23/19	84 FR 70628
NPRM Comment Period End.	02/21/20	
Final Action	12/02/20	85 FR 77898
Final Action Effective.	02/01/21	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Alpha-Banu Wilson, 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:* 410 786–8687, *Email: alphabanu.wilson@cms.hhs.gov*.

RIN: 0938–AU02

240. Transparency in Coverage (CMS–9915)

E.O. 13771 Designation: Regulatory.

Legal Authority: 42 U.S.C. 18031; 42 U.S.C. 300gg–15a

Abstract: This final rule would implement portions of Executive Order 13877 (''Improving Price and Quality Transparency in American Healthcare to Put Patients First'', June 24, 2019), which provides that the Secretaries of Health and Human Services, the Treasury, and Labor will facilitate access to information about expected health care costs for patients before they receive care.

Completed:

Reason	Date	FR Cite
Final Action	11/12/20	85 FR 72158
Final Action Effective.	01/11/21	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Deborah Bryant, *Phone:* 301 493–4293, *Email: deborah.bryant@cms.hhs.gov*.

RIN: 0938–AU04

241. FY 2021 Inpatient Rehabilitation Facility (IRF) Prospective Payment System Rate Update (CMS–1729) (Completion of a Section 610 Review)

E.O. 13771 Designation: Other.

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

Abstract: This annual final rule updates the prospective payment rates for inpatient rehabilitation facilities (IRFs) for fiscal year 2021.

Timetable:

Action	Date	FR Cite
NPRM	04/21/20	85 FR 22065
NPRM Comment Period End.	06/15/20	
Final Action	08/10/20	85 FR 48424
Final Action Effective.	10/01/20	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Gwendolyn Johnson, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, MS: C5–06–27, 7500 Security Boulevard, Baltimore, MD 21244, *Phone:* 410 786–6954, *Email: gwendolyn.johnson@cms.hhs.gov*.

RIN: 0938–AU05

242. FY 2021 Inpatient Psychiatric Facilities Prospective Payment System Rate Updates (CMS–1731) (Completion of a Section 610 Review)

E.O. 13771 Designation: Other.

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 rates for inpatient psychiatric facilities (IPF) with discharges beginning on October 1, 2020.

Timetable:

Action	Date	FR Cite
NPRM	04/14/20	85 FR 20625
NPRM Comment Period End.	06/09/20	
Final Action	08/04/20	85 FR 47042
Final Action Effective.	10/01/20	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Sherlene Jacques, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, MS: C5–04–27, 7500 Security Boulevard, Baltimore, MD 21244, *Phone:* 410 786–0510, *Email: sherlene.jacques@cms.hhs.gov*.

RIN: 0938–AU07

243. Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals; the Long-Term Care Hospital Prospective Payment System; and FY 2021 Rates (CMS–1735) (Section 610 Review)

E.O. 13771 Designation: Regulatory.

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.

Completed:

Reason	Date	FR Cite
NPRM	05/29/20	85 FR 32460
Final Action	09/18/20	85 FR 58342
Final Action Effective.	10/01/20	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Donald Thompson, *Phone:* 410 786–6504, *Email: donald.thompson@cms.hhs.gov*.

RIN: 0938–AU11

244. • Clinical Laboratory Improvement Amendments and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response To The Covid–19 Public Health Emergency (CMS–3401) (Completion of a Section 610 Review)

E.O. 13771 Designation: Other.

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

Abstract: This interim final rule with comment period (IFC) strengthens CMS' ability to enforce compliance with Medicare and Medicaid Requirements for Participation, improves Long-Term Care (LTC) Facilities for Infection Control including reporting on information related to COVID–19 by specifying penalty amounts, revises regulations for tracking the incidence and impact of COVID–19 in hospitals and CAHs to assist public health officials in detecting outbreaks and saving lives, and requires all CLIA laboratories to report SARS–CoV–2 test results in such form and manner, and at such timing and frequency, as the Secretary during the Secretary's Public Health Emergency (PHE) declaration with respect to COVID19.

Timetable:

Action	Date	FR Cite
Interim Final Rule	09/02/20	85 FR 54820
Interim Final Rule Effective.	09/02/20	
Interim Final Rule Comment Period End.	11/02/20	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: CDR Scott J. Cooper, Health Insurance Specialist, Clinical Standards Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mail Stop S3–02–01, Baltimore, MD 21244, *Phone:* 410 786–9465, *Email: scott.cooper@cms.hhs.gov*.

RIN: 0938–AU33

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Administration for Children and Families (ACF)

Proposed Rule Stage

245. • Updating Native Employment Works Requirements (Rulemaking Resulting From a Section 610 Review)

E.O. 13771 Designation: Regulatory.

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	07/00/21	

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

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