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: Madhura C. Valverde, 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 principal 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 reflects this complex mission through planned rulemakings structured to implement the Department's six arcs for implementation of its strategic plan: Leaving the Department Stronger; Keeping People Healthy and Safe; Reducing the Number of Uninsured and Providing Access to Affordable Quality Care; Leading in Science and Innovation; Delivering High Quality Care and Spending Our Health Care Dollars More Wisely; and Ensuring the Building Blocks for Success at Every Stage of Life.

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. HHS welcomes meaningful public participation in its retrospective review of regulations, through a comment form on the HHS retrospective review Web page (*http://www.HHS.gov/RetrospectiveReview*).

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*.

Madhura C. Valverde,

Executive Secretary to the Department.

OFFICE FOR CIVIL RIGHTS—PROPOSED RULE STAGE

Sequence No.	Title	Regulation Identifier No.
244	Nondiscrimination Under the Patient Protection and Affordable Care Act	0945–AA02

FOOD AND DRUG ADMINISTRATION—PROPOSED RULE STAGE

Sequence No.	Title	Regulation Identifier No.
245	Over-the-Counter (OTC) Drug Review—Cough/Cold (Antihistamine) Products	0910–AF31
246	Over-the-Counter (OTC) Drug Review—Topical Antimicrobial Drug Products	0910–AF69
247	Laser Products; Amendment to Performance Standard	0910–AF87
248	Updated Standards for Labeling of Pet Food	0910–AG09
249	Requirements for the Testing and Reporting of Tobacco Product Constituents, Ingredients, and Additives	0910–AG59
250	Format and Content of Reports Intended to Demonstrate Substantial Equivalence	0910–AG96
251	Food Labeling; Gluten-Free Labeling of Fermented, Hydrolyzed, or Distilled Foods	0910–AH00
252	Radiology Devices; Designation of Special Controls for the Computed Tomography X-Ray System	0910–AH03
253	Mammography Quality Standards Act; Regulatory Amendments	0910–AH04
254	Investigational New Drug Application Annual Reporting	0910–AH07
255	General and Plastic Surgery Devices: Sunlamp Products	0910–AH14
256	Requirements for Tobacco Product Manufacturing Practice	0910–AH22

FOOD AND DRUG ADMINISTRATION—FINAL RULE STAGE

Sequence No.	Title	Regulation Identifier No.
257	Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs, Including Drugs That Are Regulated Under a Biologics License Application, and Animal Drugs.	0910–AA49
258	Food Labeling: Revision of the Nutrition and Supplement Facts Labels **(Reg Plan Seq No. 32)**	0910–AF22
259	Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed At One Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain RACCs **(Reg Plan Seq No. 33)**.	0910–AF23
260	Abbreviated New Drug Applications and 505(b)(2)	0910–AF97
261	Electronic Distribution of Prescribing Information for Human Prescription Drugs Including Biological Products.	0910–AG18

FOOD AND DRUG ADMINISTRATION—FINAL RULE STAGE—Continued

Sequence No.	Title	Regulation Identifier No.
262	Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption **(Reg Plan Seq No. 34)**.	0910–AG35
263	''Tobacco Products'' Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act **(Reg Plan Seq No. 35)**.	0910–AG38
264	Human Subject Protection; Acceptance of Data From Clinical Investigations for Medical Devices	0910–AG48
265	Focused Mitigation Strategies To Protect Food Against Intentional Adulteration **(Reg Plan Seq No. 37)**	0910–AG63
266	Foreign Supplier Verification Program **(Reg Plan Seq No. 38)**	0910–AG64
267	Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products **(Reg Plan Seq No. 40)**.	0910–AG94
268	Sanitary Transportation of Human and Animal Food **(Reg Plan Seq No. 41)**	0910–AG98

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.
269	Regulations on Human Drug Compounding Under Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act.	0910–AH10

FOOD AND DRUG ADMINISTRATION—COMPLETED ACTIONS

Sequence No.	Title	Regulation Identifier No.
270	Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals.	0910–AG10
271	Current Good Manufacturing and Hazard Analysis, and Risk-Based Preventive Controls for Human Food	0910–AG36
272	Veterinary Feed Directive	0910–AG95

CENTERS FOR MEDICARE & MEDICAID SERVICES—PROPOSED RULE STAGE

Sequence No.	Title	Regulation Identifier No.
273	Hospital and Critical Access Hospital (CAH) Changes to Promote Innovation, Flexibility, and Improvement in Patient Care (CMS–3295–P) **(Rulemaking Resulting From a Section 610 Review)**.	0938–AS21
274	Medicare Clinical Diagnostic Laboratory Test Payment System (CMS–1621–F) **(Section 610 Review)**	0938–AS33
275	Merit-Based Incentive Payment System (MIPS) and Alternative Payment Models (APMs) in Medicare Fee-for-Service (CMS–5517–P) **(Section 610 Review) (Reg Plan Seq No. 44)**.	0938–AS69
276	Hospital Inpatient Prospective Payment System for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and FY 2017 Rates (CMS–1655–P) **(Section 610 Review) (Reg Plan Seq No. 45)**.	0938–AS77
277	CY 2017 Home Health Prospective Payment System Refinements and Rate Update (CMS–1648–P) **(Section 610 Review)**.	0938–AS80
278	CY 2017 Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Medicare Part B (CMS–1654–P) **(Section 610 Review) (Reg Plan Seq No. 46)**.	0938–AS81
279	CY 2017 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates (CMS–1656–P) **(Section 610 Review) (Reg Plan Seq No. 47)**.	0938–AS82

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

CENTERS FOR MEDICARE & MEDICAID SERVICES—FINAL RULE STAGE

Sequence No.	Title	Regulation Identifier No.
280	Covered Outpatient Drugs (CMS–2345–F) **(Section 610 Review)**	0938–AQ41
281	Reform of Requirements for Long-Term Care Facilities (CMS–3260–F) **(Rulemaking Resulting From a Section 610 Review)**.	0938–AR61
282	CY 2016 Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Medicare Part B (CMS–1631–FC) **(Section 610 Review)**.	0938–AS40
283	CY 2016 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates (CMS–1633–FC) **(Section 610 Review)**.	0938–AS42
284	Comprehensive Care for Joint Replacement (CMS–5516–F) **(Section 610 Review)**	0938–AS64

CENTERS FOR MEDICARE & MEDICAID SERVICES—LONG-TERM ACTIONS

Sequence No.	Title	Regulation Identifier No.
285	Home Health Agency Conditions of Participation (CMS–3819–F) **(Rulemaking Resulting From a Section 610 Review)**.	0938–AG81
286	Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers (CMS–3178–F) **(Section 610 Review)**.	0938–AO91

CENTERS FOR MEDICARE & MEDICAID SERVICES—COMPLETED ACTIONS

Sequence No.	Title	Regulation Identifier No.
287	Medicare Shared Savings Program; Accountable Care Organizations (CMS–1461–F) **(Completion of a Section 610 Review)**.	0938–AS06
288	Electronic Health Record Incentive Program—Stage 3 and Modifications to Meaningful Use in 2015 through 2017 (CMS–3310–F) **(Section 610 Review)**.	0938–AS26
289	Hospital Inpatient Prospective Payment System for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and FY 2016 Rates (CMS–1632–FC) **(Completion of a Section 610 Review)**.	0938–AS41
290	FY 2016 Inpatient Rehabilitation Facility Prospective Payment System (CMS–1624–F) **(Completion of a Section 610 Review)**.	0938–AS45
291	CY 2016 Home Health Prospective Payment System Refinements and Rate Update (CMS–1625–F) **(Section 610 Review)**.	0938–AS46
292	Electronic Health Record Incentive Program—Modifications to Meaningful Use in 2015 through 2017 (CMS–3311–F) **(Completion of a Section 610 Review)**.	0938–AS58

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Office for Civil Rights (OCR)

Proposed Rule Stage

244. Nondiscrimination Under the Patient Protection and Affordable Care Act

Legal Authority: 42 U.S.C. 18116

Abstract: This final rule implements prohibitions against discrimination on the basis of race, color, national origin, sex, age, and disability as provided in section 1557 of the Affordable Care Act. Section 1557 provides protection from discrimination in health programs and activities of covered entities. This section also identifies additional forms of Federal financial assistance to which the section will apply.

Timetable:

Action	Date	FR Cite
NPRM	09/08/15	80 FR 54172
NPRM Comment Period End.	11/09/15	
Final Action	06/00/16	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Eileen Hanrahan, Senior Civil Rights Analyst, Department of Health and Human Services, Office for Civil Rights, 200 Independence Avenue SW., Washington, DC 20201, *Phone:* 202 205–4925, *Email: eileen.hanrahan@hhs.gov*.

RIN: 0945–AA02

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Food and Drug Administration (FDA)

Proposed Rule Stage

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

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 (RCC) 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 OTC drug monograph elements.

Timetable:

Action	Date	FR Cite
Reopening of Administrative Record.	08/25/00	65 FR 51780
Comment Period End.	11/24/00	
NPRM (Amendment) (Common Cold).	03/00/16	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Janice Adams–King, Regulatory Health Project Manager, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 22, Room 5416, 10903 New Hampshire Avenue, Silver Spring, MD 20993, *Phone:* 301 796–3713, *Fax:* 301 796–9899, *Email: janice.adams-king@fda.hhs.gov*.

RIN: 0910–AF31

246. Over-the-Counter (OTC) Drug Review—Topical Antimicrobial Drug Products

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: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective, and not misbranded. After a final monograph (*i.e.,* final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action addresses antimicrobial agents in consumer antiseptic hand wash.

Timetable:

Action	Date	FR Cite
NPRM (Healthcare).	06/17/94	59 FR 31402
Comment Period End.	12/15/95	
NPRM (Consumer Hand Wash Products).	12/17/13	78 FR 76443

Action	Date	FR Cite
NPRM (Consumer Hand Wash) Comment Period End.	06/16/14	
NPRM (Healthcare Antiseptic).	05/01/15	80 FR 25166
NPRM Comment Period End (Healthcare Antiseptic).	10/28/15	
NPRM (Consumer Hand Rub).	06/00/16	
Final Rule (Consumer Hand Wash).	09/00/16	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Janice Adams–King, Regulatory Health Project Manager, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 22, Room 5416, 10903 New Hampshire Avenue, Silver Spring, MD 20993, *Phone:* 301 796–3713, *Fax:* 301 796–9899, *Email: janice.adams-king@fda.hhs.gov*.

RIN: 0910–AF69

247. Laser Products; Amendment to Performance Standard

Legal Authority: 21 U.S.C. 360hh to 360ss; 21 U.S.C. 371; 21 U.S.C. 393

Abstract: FDA is proposing to amend the 2013 proposed rule for the performance standard for laser products, which will amend the performance standard for laser products to achieve closer harmonization between the current standard and the recently amended International Electrotechnical Commission (IEC) standard for laser products and medical laser products. The amendment is intended to update FDA's performance standard to reflect advancements in technology.

Timetable:

Action	Date	FR Cite
NPRM	06/24/13	78 FR 37723
NPRM Comment Period End.	09/23/13	
NPRM (Reproposal).	07/00/16	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Nancy Pirt, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, WO 66, Room 4438, 10903 New Hampshire Avenue, Silver Spring, MD 20993, *Phone:* 301 796–6248, *Fax:* 301 847–8145, *Email: nancy.pirt@fda.hhs.gov*.

RIN: 0910–AF87

248. Updated Standards for Labeling of Pet Food

Legal Authority: 21 U.S.C. 343; 21 U.S.C. 371; Pub. L. 110–85, sec 1002(a)(3)

Abstract: FDA is proposing updated standards for the labeling of pet food that include nutritional and ingredient information, as well as style and formatting standards. FDA is taking this action to provide pet owners and animal health professionals more complete and consistent information about the nutrient content and ingredient composition of pet food products.

Timetable:

Action	Date	FR Cite
NPRM	06/00/16	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: William Burkholder, Veterinary Medical Officer, Department of Health and Human Services, Food and Drug Administration, Center for Veterinary Medicine, MPN–4, Room 2642, HFV–228, 7519 Standish Place, Rockville, MD 20855, *Phone:* 240 402–5900, *Email: william.burkholder@fda.hhs.gov*.

RIN: 0910–AG09

249. Requirements for the Testing and Reporting of Tobacco Product Constituents, Ingredients, and Additives

Legal Authority: 21 U.S.C. 301 *et seq.et seq.;* 21 U.S.C. 387; The Family Smoking Prevention and Tobacco Control Act

Abstract: The Federal Food, Drug, and Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Control Act, requires the Food and Drug Administration to promulgate regulations that require the testing and reporting of tobacco product constituents, ingredients, and additives, including smoke constituents, that the Agency determines should be tested to protect the public health.

Timetable:

Action	Date	FR Cite
NPRM	07/00/16	

Regulatory Flexibility Analysis Required: Yes.

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

RIN: 0910–AG59

250. Format and Content of Reports Intended to Demonstrate Substantial Equivalence

Legal Authority: 21 U.S.C. 387e(j); 21 U.S.C. 387j(a); secs 905(j) and 910(a) of the Federal Food, Drug, and Cosmetic Act

Abstract: This regulation would establish the format and content of reports intended to demonstrate substantial equivalence. This regulation also would provide information as to how the Agency will review and act on these submissions.

Timetable:

Action	Date	FR Cite
NPRM	07/00/16	

Regulatory Flexibility Analysis Required: Yes

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

RIN: 0910–AG96

251. Food Labeling; Gluten-Free Labeling of Fermented, Hydrolyzed, or Distilled Foods

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 proposed rule would establish requirements concerning compliance for using a ''gluten-free'' labeling claim for those foods for which there is no scientifically valid analytical method available that can reliably detect and accurately quantify the presence of 20 parts per million (ppm) gluten in the food.

Timetable:

Action	Date	FR Cite
NPRM	11/00/15	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Carol D'Lima, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition, Room 4D022, HFS 820, 5100 Paint Branch Parkway, College Park, MD 20740, *Phone:* 240

402–2371, *Fax:* 301 436–2636, *Email: carol.dlima@fda.hhs.gov*.

RIN: 0910–AH00

252. Radiology Devices; Designation of Special Controls for the Computed Tomography X-RAY SYSTEM

Legal Authority: 21 U.S.C. 360c

Abstract: The proposed rule would establish special controls for the computed tomography (CT) X-ray system. A CT X-ray system is a diagnostic X-ray imaging system intended to produce cross-sectional images of the body through use of a computer to reconstruct an image from the same axial plane taken at different angles. High doses of ionizing radiation can cause acute (deterministic) effects such as burns, reddening of the skin, cataracts, hair loss, sterility, and, in extremely high doses, radiation poisoning. The design of a CT X-ray system should balance the benefits of the device (*i.e.,* the ability of the device to produce a diagnostic quality image) with the known risks (*e.g.,* exposure to ionizing radiation). FDA is establishing proposed special controls, which are necessary to provide reasonable assurance of the safety and effectiveness of a class II CT X-ray system.

Timetable:

Action	Date	FR Cite
NPRM	07/00/16	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Erica Blake, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, WO 66, Room 4426, 10903 New Hampshire Avenue, Silver Spring, MD 20993, *Phone:* 301 796–6248, *Fax:* 301 847–8145, *Email: erica.blake@fda.hhs.gov*.

RIN: 0910–AH03

253. Mammography Quality Standards Act; Regulatory Amendments

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 proposing to amend its regulations governing mammography. The amendments would update the regulations issued under the Mammography Quality Standards Act of 1992 (MQSA). FDA is taking this action to address changes in mammography technology and mammography processes, such as breast density reporting, that have occurred since the regulations were published in 1997.

Timetable:

Action	Date	FR Cite
NPRM	05/00/16	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Nancy Pirt, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, WO 66, Room 4438, 10903 New Hampshire Avenue, Silver Spring, MD 20993, *Phone:* 301 796–6248, *Fax:* 301 847–8145, *Email: nancy.pirt@fda.hhs.gov*.

RIN: 0910–AH04

254. Investigational New Drug Application Annual Reporting

Legal Authority: 21 U.S.C. 321; 21 U.S.C. 331; 21 U.S.C. 351; 21 U.S.C. 352; 21 U.S.C. 353; 21 U.S.C. 355(i); 21 U.S.C. 371(a); 42 U.S.C. 262(a)

Abstract: This proposed rule would revise the requirements concerning annual reports submitted to investigational new drug applications (INDs) by replacing the current annual reporting requirement with a requirement that is generally consistent with the format, content, and timing of submission of the development safety update report devised by the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).

Timetable:

Action	Date	FR Cite
NPRM	10/00/16	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Ebla Ali Ibrahim, Project Manager, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Building 51, Room 6302, 10903 New Hampshire Avenue, Silver Spring, MD 20993, *Phone:* 301 796–3691, *Email: ebla.ali-ibrahim@fda.hhs.gov*.

RIN: 0910–AH07

255. General and Plastic Surgery Devices: Sunlamp Products

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

Abstract: This proposed rule would apply device restrictions to sunlamp products.

Timetable:

Action	Date	FR Cite
NPRM	11/00/15	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Paul Gadiock, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, 10903 New Hampshire Avenue, W0–66, Room 4432, Silver Spring, MD 20993–0002, *Phone:* 301 796–5736, *Fax:* 301 847–8145, *Email: paul.gadiock@fda.hhs.gov*.

RIN: 0910–AH14

256. Requirements for Tobacco Product Manufacturing Practice

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

Abstract: FDA is proposing requirements that govern the methods used in, and the facilities and controls used for, the pre-production design validation, manufacture, packing, and storage of tobacco products.

Timetable:

Action	Date	FR Cite
ANPRM	03/19/13	78 FR 16824
ANPRM Comment Period End.	05/20/13	
NPRM	04/00/16	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Darin Achilles, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, 10903 New Hampshire Avenue, Document Control Center, Building 71, Room G335, Silver Spring, MD 20993, *Phone:* 877 287–1373, *Fax:* 301 595–1426, *Email: ctpregulations@fda.hhs.gov*.

RIN: 0910–AH22

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Food and Drug Administration (FDA)

Final Rule Stage

257. Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs, Including Drugs That are Regulated Under a Biologics License Application, and Animal Drugs

Legal Authority: 21 U.S.C. 321 and 331; 21 U.S.C. 351 to 353; 21 U.S.C. 355 to 356c; 21 U.S.C. 360 and 360b; 21 U.S.C. 360c to 360f; 21 U.S.C. 360h to 360j; 21 U.S.C. 371 and 374; 21 U.S.C. 379e and 381; 21 U.S.C. 393; 15 U.S.C. 1451 to 1561; 42 U.S.C. 262 and 264; 42 U.S.C. 271

Abstract: The rule will reorganize, consolidate, clarify, and modify current regulations concerning who must register establishments and list human drugs, including certain biological

drugs, and animal drugs. These regulations contain information on when, how, and where to register drug establishments and list drugs, and what information must be submitted. They also address National Drug Codes.

Timetable:

Action	Date	FR Cite
NPRM	08/29/06	71 FR 51276
NPRM Comment Period End.	02/26/07	
Final Action	04/00/16	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: David Joy, Senior Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, 10903 New Hampshire Avenue, Building 51, Room 6254, Silver Spring, MD 20993, *Phone:* 301 796–2242, *Email: david.joy@fda.hhs.gov*.

RIN: 0910–AA49

258. Food Labeling: Revision of the Nutrition and Supplement Facts Labels

Regulatory Plan: This entry is Seq. No. 32 in part II of this issue of the **Federal Register**.

RIN: 0910–AF22

259. Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed At One Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain RACCS

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

RIN: 0910–AF23

260. Abbreviated New Drug Applications and 505(B)(2)

Legal Authority: Pub. L. 108–173, title XI; 21 U.S.C. 355; 21 U.S.C. 371

Abstract: This proposed rule would make changes to certain procedures for Abbreviated New Drug Applications and related applications to patent certifications, notice to patent owners and application holders, the availability of a 30-month stay of approval, amendments and supplements, and the types of bioavailability and bioequivalence data that can be used to support these applications.

Timetable:

Action	Date	FR Cite
NPRM	02/06/15	80 FR 6802
NPRM Comment Period End.	05/07/15	
NPRM Comment Period Extended.	04/24/15	80 FR 22953
NPRM Comment Period Extended End.	06/08/15	
Final Action	08/00/16	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Janice L. Weiner, Senior Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, 10903 New Hampshire Avenue, Building 51, Room 6268, Silver Spring, MD 20993–0002, *Phone:* 301 796–3601, *Fax:* 301 847–8440, *Email: janice.weiner@fda.hhs.gov*.

RIN: 0910–AF97

261. Electronic Distribution of Prescribing Information for Human Prescription Drugs Including Biological Products

Legal Authority: 21 U.S.C. 321; 21 U.S.C. 331; 21 U.S.C. 351; 21 U.S.C. 352; 21 U.S.C. 353; 21 U.S.C. 355; 21 U.S.C. 358; 21 U.S.C. 360; 21 U.S.C. 360b; 21 U.S.C. 360gg to 360ss; 21 U.S.C. 371; 21 U.S.C. 374; 21 U.S.C. 379e; 42 U.S.C. 216; 42 U.S.C. 241; 42 U.S.C. 262; 42 U.S.C. 264

Abstract: This rule would require electronic package inserts for human drug and biological prescription products with limited exceptions, in lieu of paper, which is currently used. These inserts contain prescribing information intended for healthcare practitioners. This would ensure that the information accompanying the product is the most up-to-date information regarding important safety and efficacy issues about these products.

Timetable:

Action	Date	FR Cite
NPRM	12/18/14	79 FR 75506
NPRM Comment Period Extended.	03/09/15	80 FR 12364
NPRM Comment Period End.	03/18/15	
NPRM Comment Period Extended End.	05/18/15	
Final Action	10/00/16	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Emily Gebbia, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, 10903 New Hampshire Avenue, Building 51, Room 6226, Silver Spring, MD 20993, *Phone:* 240 402–0980, *Email: emily.gebbia@fda.hhs.gov*.

RIN: 0910–AG18

262. Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption

Regulatory Plan: This entry is Seq. No. 34 in part II of this issue of the **Federal Register**.

RIN: 0910–AG35

263. ''Tobacco Products'' Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act

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

RIN: 0910–AG38

264. Human Subject Protection; Acceptance of Data From Clinical Investigations for Medical Devices

Legal Authority: 21 U.S.C. 321; 21 U.S.C. 331; 21 U.S.C. 351; 21 U.S.C. 352; 21 U.S.C. 360; 21 U.S.C. 360c; 21 U.S.C. 360e; 21 U.S.C. 360i; 21 U.S.C. 360j; 21 U.S.C. 371; 21 U.S.C. 374; 21 U.S.C. 381; 21 U.S.C. 393; 42 U.S.C. 264; 42 U.S.C. 271; . . .

Abstract: This rule will amend FDA's regulations on acceptance of data for medical devices to require that clinical investigations submitted in support of a premarket approval application, humanitarian device exemption application, an investigational device exemption application, or a premarket notification submission be conducted in accordance with good clinical practice if conducted outside the United States.

Timetable:

Action	Date	FR Cite
NPRM	02/25/13	78 FR 12664
NPRM Comment Period End.	05/28/13	
Final Action	05/00/16	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Aaliyah K. Eaves, Policy Advisor, Office of the Director, Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, WO 66, Room 5422, 10903 New Hampshire Avenue, Silver Spring, MD 20993, *Phone:* 301 796–2948, *Fax:* 301 847–8120, *Email: aaliyah.eaves-leanos@fda.hhs.gov*.

RIN: 0910–AG48

265. Focused Mitigation Strategies To Protect Food Against Intentional Adulteration

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

RIN: 0910–AG63

266. Foreign Supplier Verification Program

Regulatory Plan: This entry is Seq. No. 38 in part II of this issue of the **Federal Register**.

RIN: 0910–AG64

267. Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products

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

RIN: 0910–AG94

268. Sanitary Transportation of Human and Animal Food

Regulatory Plan: This entry is Seq. No. 41 in part II of this issue of the **Federal Register**.

RIN: 0910–AG98

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Food and Drug Administration (FDA)

Long-Term Actions

269. Regulations on Human Drug Compounding Under Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act

Legal Authority: 21 U.S.C. 353a; 21 U.S.C. 353b; 21 U.S.C. 371

Abstract: FDA will propose regulations to define and implement certain statutory conditions under which compounded products may qualify for exemptions from certain requirements.

Timetable:

Action	Date	FR Cite
NPRM	12/00/16	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Sarah Rothman, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, 10903 New Hampshire Avenue, Building 51, Room 5197, Silver Spring, MD 20993, *Phone:* 301 796–3536, *Email: sarah.rothman@fda.hhs.gov*.

RIN: 0910–AH10

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Food and Drug Administration (FDA)

Completed Actions

270. Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals

Legal Authority: 21 U.S.C. 321; 21 U.S.C. 331; 21 U.S.C. 342; 21 U.S.C. 350c; 21 U.S.C. 350d note; 21 U.S.C. 350g; 21 U.S.C. 350g note; 21 U.S.C. 371; 21 U.S.C. 374; 42 U.S.C. 264; 42 U.S.C. 243; 42 U.S.C. 271; . . .

Abstract: This rule establishes requirements for good manufacturing practice, and requires that certain facilities establish and implement hazard analysis and risk-based preventive controls for animal food, including ingredients and mixed animal feed. This action is intended to provide greater assurance that food for all animals, including pets, is safe.

Timetable:

Action	Date	FR Cite
NPRM	10/29/13	78 FR 64736
NPRM Comment Period Extension.	02/03/14	79 FR 6111
NPRM Comment Period End.	02/26/14	
NPRM Comment Period Extension End.	03/31/14	
Supplemental NPRM.	09/29/14	79 FR 58475
Supplemental NPRM Comment Period End.	12/15/14	
Final Rule	09/17/15	80 FR 56169
Final Rule Effective.	11/16/15	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Jeanette (Jenny) B. Murphy, Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, Center for Veterinary Medicine, Room 2671 (MPN–4, HFV–200), 7519 Standish Place, Rockville, MD 20855, *Phone:* 240 453–6845, *Email: jenny.murphy@fda.hhs.gov*.

RIN: 0910–AG10

271. Current Good Manufacturing and Hazard Analysis, and Risk-Based Preventive Controls for Human Food

Legal Authority: 21 U.S.C. 342; 21 U.S.C. 371; 42 U.S.C. 264; Pub. L. 111–353 (signed on Jan. 4, 2011)

Abstract: This rule would require a food facility to have and implement preventive controls to significantly minimize or prevent the occurrence of hazards that could affect food manufactured, processed, packed, or held by the facility. This action is intended to prevent or, at a minimum, quickly identify foodborne pathogens before they get into the food supply.

Timetable:

Action	Date	FR Cite
NPRM	01/16/13	78 FR 3646
NPRM Comment Period End.	05/16/13	
NPRM Comment Period Extended.	04/26/13	78 FR 24691
NPRM Comment Period Extended End.	09/16/13	
NPRM Comment Period Extended.	08/09/13	78 FR 48636
NPRM Comment Period Extended End.	11/15/13	
NPRM Comment Period Extended.	11/20/13	78 FR 69604
NPRM Comment Period Extended End.	11/22/13	
Supplemental NPRM.	09/29/14	79 FR 58523
Supplemental NPRM Comment Period End.	12/15/14	
Final Rule	09/17/15	80 FR 55907
Final Action Effective.	11/16/15	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Jenny Scott, Senior Advisor, Department of Health and Human Services, Food and Drug Administration, Office of Food Safety, 5100 Paint Branch Parkway, College Park, MD 20740, *Phone:* 240 402–1488, *Email: jenny.scott@fda.hhs.gov*.

RIN: 0910–AG36

272. Veterinary Feed Directive

Legal Authority: 21 U.S.C. 354; 21 U.S.C. 360b; 21 U.S.C. 360ccc; 21 U.S.C. 360ccc–1; 21 U.S.C. 371

Abstract: The Animal Drug Availability Act created a new category of products called veterinary feed directive (VFD) drugs. This rulemaking is intended to provide for the increased efficiency of the VFD program.

Timetable:

Action	Date	FR Cite
ANPRM	03/29/10	75 FR 15387
ANPRM Comment Period End.	06/28/10	
NPRM	12/12/13	78 FR 75515
NPRM Comment Period End.	03/12/14	

Action	Date	FR Cite
Final Action	06/03/15	80 FR 31708
Final Action (Correction).	06/23/15	80 FR 35841

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Sharon Benz, Supervisory Animal Scientist, Department of Health and Human Services, Food and Drug Administration, Center for Veterinary Medicine, MPN–4, Room 2648, HFV–220, 7519 Standish Place, Rockville, MD 20855, *Phone:* 240 402–5939, *Email: sharon.benz@fda.hhs.gov*.

RIN: 0910–AG95

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Centers for Medicare & Medicaid Services (CMS)

Proposed Rule Stage

273. Hospital and Critical Access Hospital (CAH) Changes To Promote Innovation, Flexibility, and Improvement in Patient Care (CMS–3295–P) (Rulemaking Resulting From a Section 610 Review)

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

Abstract: This proposed rule would update the requirements that hospitals and Critical Access Hospitals (CAHs) must meet to participate in the Medicare and Medicaid programs. These proposals are intended to conform the requirements to current standards of practice and to support improvements in quality of care, reduce barriers to care, and reduce some issues that may exacerbate workforce shortage concerns.

Timetable:

Action	Date	FR Cite
NPRM	02/00/16	

Regulatory Flexibility Analysis Required: Yes.

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

RIN: 0938–AS21

274. Medicare Clinical Diagnostic Laboratory Test Payment System (CMS–1621–F) (Section 610 Review)

Legal Authority: Pub. L. 113–93, sec 216

Abstract: This final rule requires Medicare payment for clinical laboratory tests to be based on private payor rates beginning January 1, 2017, as required by section 216(a) of the Protecting Access to Medicare Act of 2014.

Timetable:

Action	Date	FR Cite
NPRM	10/01/15	80 FR 59385
NPRM Comment Period End.	11/25/15	
Final Action	10/00/18	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Valerie Miller, Deputy Director, Division of Ambulatory Services, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, Mail Stop C4–01–26, 7500 Security Boulevard, Baltimore, MD 21244, *Phone:* 410 786–4535, *Email: valerie.miller@cms.hhs.gov*.

Sarah Harding, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, MS: C4–01–26, 7500 Security Boulevard, Baltimore, MD 21244, *Phone:* 410 786–4535, *Email: sarah.harding@cms.hhs.gov*.

RIN: 0938–AS33

275. • Merit-Based Incentive Payment System (MIPS) and Alternative Payment Models (APMS) in Medicare Fee-for-Service (CMS–5517–P) (Section 610 Review)

Regulatory Plan: This entry is Seq. No. 44 in part II of this issue of the **Federal Register**.

RIN: 0938–AS69

276. • Hospital Inpatient Prospective Payment System for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and FY 2017 Rates (CMS–1655–P) (Section 610 Review)

Regulatory Plan: This entry is Seq. No. 45 in part II of this issue of the **Federal Register**.

RIN: 0938–AS77

277. • CY 2017 Home Health Prospective Payment System Refinements and Rate Update (CMS–1648–P) (Section 610 Review)

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

Abstract: This annual proposed rule would update the 60-day national episode rate based on the applicable home health market basket update and case-mix adjustment. It would also update the national per-visit rates used to calculate low utilization payment adjustments (LUPAs) and outlier payments under the Medicare prospective payment system for home health agencies. These changes would apply to services furnished during home health episodes beginning on or after January 1, 2017.

Timetable:

Action	Date	FR Cite
NPRM	06/00/16	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Hillary Loeffler, Technical Advisor, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, MS: C5–07–28, 7500 Security Boulevard, Baltimore, MD 21244, *Phone:* 410 786–0456, *Email: hillary.loeffler@cms.hhs.gov*.

RIN: 0938–AS80

278. • CY 2017 Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Medicare Part B (CMS–1654–P) (Section 610 Review)

Regulatory Plan: This entry is Seq. No. 46 in part II of this issue of the **Federal Register**.

RIN: 0938–AS81

279. • CY 2017 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates (CMS–1656–P) (Section 610 Review)

Regulatory Plan: This entry is Seq. No. 47 in part II of this issue of the **Federal Register**.

RIN: 0938–AS82

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Centers for Medicare & Medicaid Services (CMS)

Final Rule Stage

280. Covered Outpatient Drugs (CMS–2345–F) (Section 610 Review)

Legal Authority: Pub. L. 111– 48, sec 2501; Pub. L. 111– 48, 2503; Pub. L. 111– 48, 3301(d)(2); Pub. L. 111–152, sec 1206; Pub. L. 111–8, sec 221

Abstract: This final rule revises requirements pertaining to Medicaid

reimbursement for covered outpatient drugs to implement provisions of the Affordable Care Act. This rule also revises other requirements related to covered outpatient drugs, including key aspects of Medicaid coverage, payment, and the drug rebate program.

Timetable:

Action	Date	FR Cite
NPRM	02/02/12	77 FR 5318
NPRM Comment Period End.	04/02/12	
Final Action	11/00/15	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Wendy Tuttle, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicaid and State Operations, Mail Stop S2–14–26, 7500 Security Boulevard, Baltimore, MD 21244, *Phone:* 410 786–8690, *Email: wendy.tuttle@cms.hhs.gov*.

RIN: 0938–AQ41

281. Reform of Requirements for Long-Term Care Facilities (CMS–3260–F) (Rulemaking Resulting From a Section 610 Review)

Legal Authority: Pub. L. 111–148, sec 6102; 42 U.S.C. 263a; 42 U.S.C. 1302; 42 U.S.C. 1395hh; 42 U.S.C. 1395rr

Abstract: This final rule revises the requirements that long-term care facilities must meet to participate in the Medicare and Medicaid programs. These changes are necessary to reflect the substantial advances that have been made over the past several years in the theory and practice of service delivery and safety. The rule is also an integral part of CMS efforts to achieve broad-based improvements both in the quality of health care furnished through federal programs, and in patient safety, while at the same time reducing procedural burdens on providers.

Timetable:

Action	Date	FR Cite
NPRM	07/16/15	80 FR 42167
NPRM Comment Period Extension.	09/15/15	80 FR 55284
NPRM Comment Period End.	10/14/15	
Final Action	09/00/16	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Ronisha Blackstone, 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:* 410 786–6882, *Email: ronisha.blackstone@cms.hhs.gov*.

RIN: 0938–AR61

282. CY 2016 Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Medicare Part B (CMS–1631–FC) (Section 610 Review)

Legal Authority: 42 U.S.C. 405(a), 1302, 1395x, 1395y(a), 1395ff, 1395kk, 1395rr and 1395ww(k); 42 U.S.C. 263a; 42 U.S.C. 1395m, 1395hh, and 1395ddd; 42 U.S.C. 1395w–101 through 1395w–152, and 1395nn; . . .

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, 2016.

Timetable:

Action	Date	FR Cite
NPRM	07/15/15	80 FR 41686
NPRM Comment Period End.	09/08/15	
Final Action	11/00/15	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Ryan Howe, 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:* 410 786–3355, *Email: ryan.howe@cms.hhs.gov*.

RIN: 0938–AS40

283. CY 2016 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates (CMS–1633–FC) (Section 610 Review)

Legal Authority: 42 U.S.C. 1302, 1395m, 1395hh, and 1395ddd

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 changes the ambulatory surgical center payment system list of services and rates.

Timetable:

Action	Date	FR Cite
NPRM	07/08/15	80 FR 39200
NPRM Comment Period End.	08/31/15	
Final Action	11/00/15	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Marjorie Baldo, 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:* 410 786–4617, *Email: marjorie.baldo@cms.hhs.gov*.

RIN: 0938–AS42

284. • Comprehensive Care for Joint Replacement (CMS–5516–F) (Section 610 Review)

Legal Authority: Social Security Act, sec 1115A

Abstract: This final rule implements a new Medicare Part A and B payment model under section 1115A of the Social Security Act, called the Comprehensive Care Joint Replacement Model, in which acute care hospitals in certain selected geographic areas receive retrospective bundled payments for episodes of care for lower extremity joint replacement or reattachment of a lower extremity. All related care within 90 days of hospital discharge from the joint replacement procedures would be included in the episode of care. We believe this model furthers our goals in improving the efficiency and quality of care for Medicare beneficiaries for these common medical procedures.

Timetable:

Action	Date	FR Cite
NPRM	07/14/15	80 FR 41198
NPRM Comment Period End.	09/08/15	
Final Action	11/00/15	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Gabriel Scott, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare & Medicaid Innovation, MS: WB–06–05, 7500 Security Blvd., Baltimore, MD 21244, *Phone:* 410 786–3928, *Email: gabriel.scott@cms.hhs.gov*.

RIN: 0938–AS64

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Centers for Medicare & Medicaid Services (CMS)

Long-Term Actions

285. Home Health Agency Conditions of Participation (CMS–3819–F) (Rulemaking Resulting From a Section 610 Review)

Legal Authority: 42 U.S.C. 1302; 42 U.S.C. 1395x; 42 U.S.C. 1395cc(a); 42 U.S.C. 1395hh; 42 U.S.C. 1395bb

Abstract: This final rule revises the existing Conditions of Participation that Home Health Agencies (HHA) must meet to participate in the Medicare program. The new requirements focus on the actual care delivered to patients by HHAs, reflect an interdisciplinary view of patient care, allow HHAs greater flexibility in meeting quality standards, and eliminate unnecessary procedural requirements. These changes are an integral part of our efforts to improve patient safety and achieve broad-based improvements in the quality of care furnished through Federal programs, while at the same time reducing procedural burdens on providers.

Timetable:

Action	Date	FR Cite
NPRM	03/10/97	62 FR 11005
NPRM Comment Period End.	06/09/97	
Second NPRM	10/09/14	79 FR 61163
NPRM Comment Period Extended.	12/01/14	79 FR 71081
Second NPRM Comment Period End.	01/07/15	
Final Action	10/00/17	

Regulatory Flexibility Analysis Required: No.

Agency Contact: Danielle Shearer, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Clinical Standards & Quality, MS: S3–02–01, 7500 Security Boulevard, Baltimore, MD 21244, *Phone:* 410 786–6617, *Email: danielle.shearer@cms.hhs.gov*.

RIN: 0938–AG81

286. Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers (CMS–3178–F) (Section 610 Review)

Legal Authority: 42 U.S.C. 1821; 42 U.S.C. 1861ff (3)(B)(i)(ii); 42 U.S.C. 1913(c)(1) et al

Abstract: This rule finalizes emergency preparedness requirements for Medicare and Medicaid participating providers and suppliers to ensure that they adequately plan for both natural and man-made disasters and coordinate with Federal, State, tribal, regional, and local emergency preparedness systems. This rule ensures providers and suppliers are adequately prepared to meet the needs of patients, residents, clients, and participants during disasters and emergency situations.

Timetable:

Action	Date	FR Cite
NPRM	12/27/13	78 FR 79082
NPRM Comment Period Extended.	02/21/14	79 FR 9872
NPRM Comment Period End.	03/31/14	
Final Action	12/00/16	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Janice Graham, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Clincial Standards and Quality, Mail Stop S3–02–01, 7500 Security Boulevard, Baltimore, MD 21244–1850, *Phone:* 410 786–8020, *Email: janice.graham@cms.hhs.gov*.

RIN: 0938–AO91

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Centers for Medicare & Medicaid Services (CMS)

Completed Actions

287. Medicare Shared Savings Program; Accountable Care Organizations (CMS–1461–F) (Completion of a Section 610 Review)

Legal Authority: Pub. L. 111–148, sec 3022

Abstract: This rule finalizes changes to the Medicare Shared Savings Program (Shared Savings Program), including provisions relating to the payment of Accountable Care Organizations (ACOs) participating in the Shared Savings Program. Under the Shared Savings Program, providers of services and suppliers that participate in an ACO continue to receive traditional Medicare fee for service (FFS) payments under Parts A and B and are eligible for additional payments from the ACO if they meet specified quality and savings requirements.

Timetable:

Action	Date	FR Cite
NPRM	12/08/14	79 FR 72760
NPRM Comment Period End.	02/06/15	
Final Action	06/09/15	80 FR 32691
Final Action Effective.	08/03/15	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Terri Postma, Medical Officer, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, MS:C5–15–24, 7500 Security Boulevard, Baltimore, MD 21244, *Phone:* 410 786–4169, *Email: terri.postma@cms.hhs.gov*.

RIN: 0938–AS06

288. Electronic Health Record Incentive Program—Stage 3 and Modifications to Meaningful Use in 2015 Through 2017 (CMS–3310–F) (Section 610 Review)

Legal Authority: Pub. L. 111–5, title IV of Division B

Abstract: This final rule specifies the requirements that eligible professionals, eligible hospitals, and critical access hospitals must meet in order to qualify for Medicare and Medicaid electronic health record (EHR) incentive payments and avoid downward payment adjustments under the Medicare EHR Incentive Program. In addition, it changes the Medicare and Medicaid EHR Incentive Programs reporting period in 2015 to a 90-day period aligned with the calendar year. This rule also removes reporting requirements on measures that have become redundant, duplicative, or topped out from the Medicare and Medicaid EHR incentive programs. In addition, this rule establishes the requirements for Stage 3 of the program as optional in 2017 and required for all participants beginning in 2018. The rule continues to encourage the electronic submission of clinical quality measure data, establishes requirements to transition the program to a single stage, and aligns reporting for providers in the Medicare and Medicaid EHR Incentive Programs.

Timetable:

Action	Date	FR Cite
NPRM	03/30/15	80 FR 16732
NPRM Comment Period End.	05/29/15	
Final Action	10/16/15	80 FR 62762
Final Action Effective.	12/12/15	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Elizabeth S. Holland, Technical Advisor, Department of Health and Human Services, Centers for

Medicare & Medicaid Services, Center for Clinical Standards and Quality, MS: S2–26–17, 7500 Security Boulevard, Baltimore, MD 21244, *Phone:* 410 786–1309, *Email: elizabeth.holland@cms.hhs.gov*.

RIN: 0938–AS26

289. Hospital Inpatient Prospective Payment System for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and FY 2016 Rates (CMS–1632–FC) (Completion of a Section 610 Review)

Legal Authority: sec 1886(d) of the Social Security Act

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.

Timetable:

Action	Date	FR Cite
NPRM	04/30/15	80 FR 24323
NPRM Comment Period End.	06/16/15	
Final Action and Interim Final Rule.	08/17/15	80 FR 49325
Interim Final Rule Comment Period End.	09/29/15	
Final Action Effective.	10/01/15	

Regulatory Flexibility Analysis Required: Yes.

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

RIN: 0938–AS41

290. FY 2016 Inpatient Rehabilitation Facility Prospective Payment System (CMS–1624–F) (Completion of a Section 610 Review)

Legal Authority: Social Security Act, sec 1886(j); Pub. L. 106–554; Pub. L. 106–113

Abstract: This annual final rule updates the prospective payment rates for inpatient rehabilitation facilities (IRFs) for fiscal year 2016.

Timetable:

Action	Date	FR Cite
NPRM	04/27/15	80 FR 23332
NPRM Comment Period End.	06/22/15	
Final Action	08/06/15	80 FR 47035
Final Action Effective.	10/01/15	

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–AS45

291. CY 2016 Home Health Prospective Payment System Refinements and Rate Update (CMS–1625–F) (Section 610 Review)

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

Abstract: This annual final rule updates the 60-day national episode rate based on the applicable home health market basket update and case-mix adjustment. It also updates the national per-visit rates used to calculate low utilization payment adjustments (LUPAs) and outlier payments under the Medicare prospective payment system for home health agencies. These changes apply to services furnished during home health episodes beginning on or after January 1, 2016. Additionally, this rule will implement a Home Health value-based purchasing model, beginning January 1, 2016, in which all Medicare-Certified Home Health Agencies in selected states will be required to participate.

Timetable:

Action	Date	FR Cite
NPRM	07/10/15	80 FR 39840
NPRM Comment Period End.	09/04/15	
Final Action	11/05/15	80 FR 68624
Final Rule Effective.	01/01/16	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Hillary Loeffler, Technical Advisor, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, MS: C5–07–28, 7500 Security Boulevard, Baltimore, MD 21244, *Phone:* 410 786–0456, *Email: hillary.loeffler@cms.hhs.gov*.

RIN: 0938–AS46

292. Electronic Health Record Incentive Program—Modifications to Meaningful Use in 2015 Through 2017 (CMS–3311–F) (Completion of a Section 610 Review)

Legal Authority: 42 U.S.C. 1302 and 1395hh; Pub. L. 111–5

Abstract: This rule would implement changes to the Medicare and Medicaid Electronic Health Record (EHR) Incentive Program EHR reporting requirements. These changes will be finalized in the ''Electronic Health Record Incentive Program—Stage 3 and Modifications to Meaningful Use in 2015 through 2017'' final rule.

Timetable:

Action	Date	FR Cite
NPRM	04/15/15	80 FR 20346
NPRM Comment Period End.	06/15/15	
Merged With 0938–AS26.	07/24/15	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Elizabeth S. Holland, Technical Advisor, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Clinical Standards and Quality, MS: S2–26–17, 7500 Security Boulevard, Baltimore, MD 21244, *Phone:* 410 786–1309, *Email: elizabeth.holland@cms.hhs.gov*.

RIN: 0938–AS58

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