DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

21 CFR Ch. I

25 CFR Ch. V

42 CFR Chs. I, II, III, IV and 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 12866 require the Department semiannually to issue an inventory of rulemaking actions under development to provide the public a summary of forthcoming regulatory actions. This information will help the public more effectively participate in the Department's regulatory activity, and the Department welcomes comments on any aspect of this agenda.

FOR FURTHER INFORMATION CONTACT: Jennifer M. Cannistra, Executive Secretary, Department of Health and Human Services, Washington, DC 20201.

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. The mission of HHS is to enhance the health and well-being of Americans by providing for 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 rulemaking activities that the Department expects to undertake in the foreseeable future to advance this mission. The agenda furthers several Departmental goals, including strengthening health care; advancing scientific knowledge and innovation; advancing the health, safety, and well-being of the American people; increasing efficiency, transparency, and accountability of HHS programs; and strengthening the Nation's health and human services infrastructure and workforce.

The purpose of the agenda is to encourage more effective public participation in the regulatory process. HHS is currently furthering this goal by engaging in a Department-wide effort to identify ways to make the rulemaking process more accessible to the general public. This effort is in response to President Obama's January 18, 2011, Executive Order 13563, ''Improving Regulation and Regulatory Review,'' which requires ongoing retrospective review of current agency regulations and encourages Federal agencies to develop balanced regulations through a process that ''allows for public participation and an open exchange of ideas.'' HHS's efforts include continuing to update its main regulatory Web site to highlight useful information for the public, such as HHS rules currently open for public comment, and actively encouraging meaningful public participation in retrospective review and rulemaking through education and outreach.

The rulemaking abstracts included in this paper issue of the **Federal Register** only 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 *www.reginfo.gov* in an interactive format that offers users enhanced capabilities to obtain information from the agenda's database.

Dated: August 30, 2012.

Jennifer M. Cannistra,

Executive Secretary to the Department.

SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION—COMPLETED ACTIONS

Sequence No.	Title	Regulation Identifier No.
265	Opioid Drugs in Maintenance or Detoxification Treatment of Opiate Addiction **(Completion of a Section 610 Review)**.	0930–AA14

CENTERS FOR DISEASE CONTROL AND PREVENTION—PROPOSED RULE STAGE

Sequence No.	Title	Regulation Identifier No.
266	Establishment of Minimum Standards for Birth Certificates	0920–AA46

FOOD AND DRUG ADMINISTRATION—PRERULE STAGE

Sequence No,	Title	Regulation Identifier No.
267	Over-the-Counter (OTC) Drug Review—Sunscreen Products	0910–AF43

FOOD AND DRUG ADMINISTRATION—PROPOSED RULE STAGE

Sequence No.	Title	Regulation Identifier No.
268	Food Labeling; Revision of the Nutrition and Supplement Facts Labels	0910–AF22
269	Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed in One Eating Occasion; Dual Column Labeling; and Modifying the Reference Amounts Customarily Consumed.	0910–AF23
270	Over-the-Counter (OTC) Drug Review—Cough/Cold (Antihistamine) Products	0910–AF31
271	Over-the-Counter (OTC) Drug Review—Internal Analgesic Products	0910–AF36
272	Over-the-Counter (OTC) Drug Review—Topical Antimicrobial Drug Products	0910–AF69

FOOD AND DRUG ADMINISTRATION—PROPOSED RULE STAGE—Continued

Sequence No.	Title	Regulation Identifier No.
273	Laser Products; Amendment to Performance Standard	0910–AF87
274	Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals **(Reg Plan Seq No. 33)**.	0910–AG10
275	Over-the-Counter (OTC) Drug Review—Pediatric Dosing for Cough/Cold Products	0910–AG12
276	Electronic Distribution of Prescribing Information for Human Drugs Including Biological Products	0910–AG18
277	Produce Safety Regulation **(Reg Plan Seq No. 34)**	0910–AG35
278	Hazard Analysis and Risk-Based Preventive Controls **(Reg Plan Seq No. 35)**	0910–AG36
279	''Tobacco Products'' Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act.	0910–AG38
280	General Hospital and Personal Use Devices: Issuance of Draft Special Controls Guidance for Infusion Pumps.	0910–AG54
281	Requirements for the Testing and Reporting of Tobacco Product Constituents, Ingredients, and Additives	0910–AG59
282	Amendments to the Current Good Manufacturing Practice Regulations for Finished Pharmaceuticals—Components.	0910–AG70
283	Use of Symbols in Labeling	0910–AG74
284	Requirements for the Submission of Data Needed to Calculate User Fees for Manufacturers and Importers of Tobacco Products.	0910–AG81
285	Food Labeling: Hard Candies and Breath Mints	0910–AG82
286	Food Labeling: Serving Sizes; Reference Amounts for Candies	0910–AG83

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

FOOD AND DRUG ADMINISTRATION—FINAL RULE STAGE

Sequence No.	Title	Regulation Identifier No.
287	Infant Formula: Current Good Manufacturing Practices; Quality Control Procedures; Notification Requirements; Records and Reports; and Quality Factors.	0910–AF27
288	Over-the-Counter (OTC) Drug Review—Cough/Cold (Combination) Products	0910–AF33
289	Unique Device Identification **(Reg Plan Seq No. 39)**	0910–AG31
290	Food Labeling: Nutrition Labeling for Food Sold in Vending Machines **(Reg Plan Seq No. 40)**	0910–AG56
291	Food Labeling: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments **(Reg Plan Seq No. 41)**.	0910–AG57

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.
292	Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements, and Administrative Procedures **(Section 610 Review)**.	0910–AG14

FOOD AND DRUG ADMINISTRATION—COMPLETED ACTIONS

Sequence No.	Title	Regulation Identifier No.
293	Electronic Submission of Data From Studies Evaluating Human Drugs and Biologics	0910–AC52

CENTERS FOR MEDICARE & MEDICAID SERVICES—PROPOSED RULE STAGE

Sequence No.	Title	Regulation Identifier No.
294	Emergency Preparedness Requirements for Medicare Participating Providers and Suppliers (CMS–3178–P) **(Section 610 Review)**.	0938–AO91
295	Changes to the Hospital Inpatient and Long-Term Care Prospective Payment System for FY 2014 (CMS–1599–P) **(Reg Plan Seq No. 45)**.	0938–AR53
296	Changes to the Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System for CY 2014 (CMS–1601–P) **(Reg Plan Seq No. 46)**.	0938–AR54
297	Revisions to Payment Policies Under the Physician Fee Schedule and Medicare Part B for CY 2014 (CMS–1600–P) **(Reg Plan Seq No. 47)**.	0938–AR56
298	Prospective Payment System for Federally Qualified Health Centers (FQHCs) (CMS–1443–P) **(Section 610 Review) (Reg Plan Seq No. 48)**.	0938–AR62

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.
299	Covered Outpatient Drugs (CMS–2345–F) **(Section 610 Review)**	0938–AQ41

CENTERS FOR MEDICARE & MEDICAID SERVICES—LONG-TERM ACTIONS

Sequence No.	Title	Regulation Identifier No.
300	Transparency Reports and Reporting of Physician Ownership of Investment Interests (CMS–5060–F)	0938–AR33

CENTERS FOR MEDICARE & MEDICAID SERVICES—COMPLETED ACTIONS

Sequence No.	Title	Regulation Identifier No.
301	Administrative Simplification: Standard Unique Identifier for Health Plans and ICD–10 Compliance Date Delay (CMS–0040–F) **(Completion of a Section 610 Review)**.	0938–AQ13
302	Medicare and Medicaid Electronic Health Record Incentive Program—Stage 2 (CMS–0044–F)	0938–AQ84
303	Proposed Changes to Hospital OPPS and CY 2013 Payment Rates; ASC Payment System and CY 2013 Payment Rates (CMS–1589–FC) **(Completion of a Section 610 Review)**.	0938–AR10
304	Revisions to Payment Policies Under the Physician Fee Schedule and Part B for CY 2013 (CMS–1590–FC) **(Completion of a Section 610 Review)**.	0938–AR11
305	Changes to the Hospital Inpatient and Long-Term Care Prospective Payment Systems for FY 2013 (CMS–1588–F) **(Completion of a Section 610 Review)**.	0938–AR12
306	Home Health Prospective Payment System Rate for CY 2013 (CMS–1358–F) **(Completion of a Section 610 Review)**.	0938–AR18

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Substance Abuse and Mental Health Services Administration (SAMHSA)

Completed Actions

265. Opioid Drugs in Maintenance or Detoxification Treatment of Opiate Addiction (Completion of a Section 610 Review)

Legal Authority: 21 U.S.C. 823 (9); 42 U.S.C. 257a; 42 U.S.C. 290aa(d); 42 U.S.C. 290dd–2; 42 U.S.C. 300x–23; 42 U.S.C. 300x–27(a); 42 U.S.C. 300y–11

Abstract: This rule would amend the Federal opioid treatment program regulations. It would modify the dispensing requirements for buprenorphine and buprenorphine combination products that are approved by the Food and Drug Administration (FDA) for opioid dependence and used in federally certified and registered opioid treatment programs. In particular, this rule would allow opioid treatment programs more flexibility in dispensing take-home supplies of buprenorphine after the assessment and documentation of patients' responsibility and stability to receive opioid addiction treatment medication.

Timetable:

Action	Date	FR Cite
NPRM	06/19/09	74 FR 29153
NPRM Comment Period End.	08/18/09	
Final Action	12/06/12	77 FR 72752

Regulatory Flexibility Analysis Required: No.

Agency Contact: Nicholas Reuter, Supervising Public Health Advisor, Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, Suite 2–1063, One Choke Cherry Road, Rockville, MD 20857 *Phone:* 240 276–2716, *Email:* *nicholas.reuter@samhsa.hhs.gov*.

RIN: 0930–AA14

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Centers for Disease Control and Prevention (CDC)

Proposed Rule Stage

266. Establishment of Minimum Standards for Birth Certificates

Legal Authority: 42 U.S.C. 264

Abstract: This proposed rule establishes minimum standards to improve security related to the use of birth certificates by Federal agencies for official purposes.

Timetable:

Action	Date	FR Cite
NPRM	03/00/13	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Charles Rothwell, Director, Division of Vital Statistics, Department of Health and Human Services, Centers for Disease Control and Prevention, 3311 Toledo Road, Room 7311, M, Hyattsville, MD 20782, *Phone:* 301 458–4555.

RIN: 0920–AA46

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Food and Drug Administration (FDA)

Prerule Stage

267. Over-the-Counter (OTC) Drug Review—Sunscreen 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. The first of the future actions

will address the safety of sunscreen active ingredients. The second of the future actions will address active ingredients reviewed under time and extent applications.

Timetable:

Action	Date	FR Cite
ANPRM (Sunscreen and Insect Repellent).	02/22/07	72 FR 7941
ANPRM Comment Period End.	05/23/07	
NPRM (UVA/UVB).	08/27/07	72 FR 49070
NPRM Comment Period End.	12/26/07	
Final Action (UVA/UVB).	06/17/11	76 FR 35620
NPRM (Effectiveness).	06/17/11	76 FR 35672
NPRM (Effectiveness) Comment Period End.	09/15/11	
ANPRM (Dosage Forms).	06/17/11	76 FR 35669
ANPRM (Dosage Forms) Comment Period End.	09/15/11	
ANPRM (Safety)	07/00/13	
NPRM (Time and Extent Applications).	09/00/13	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: David Eng, Regulatory Project Manager, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 22, Room 5487, 10903 New Hampshire Avenue, Silver Spring, MD 20993, *Phone:* 301 796–2773, *Fax:* 301 796–9899, *Email: david.eng@fda.hhs.gov*.

RIN: 0910–AF43

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Food and Drug Administration (FDA)

Proposed Rule Stage

268. Food Labeling; Revision of the Nutrition and Supplement Facts Labels

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

Abstract: FDA is proposing to amend the labeling regulations for conventional foods and dietary supplements to provide updated nutrition information on the label to assist consumers in maintaining healthy dietary practices. If finalized, this rule will modernize the nutrition information found on the Nutrition Facts label, as well as the format and appearance of the label.

Timetable:

Action	Date	FR Cite
ANPRM	07/11/03	68 FR 41507
ANPRM Comment Period End.	10/09/03	
ANPRM	04/04/05	70 FR 17008
ANPRM Comment Period End.	06/20/05	
ANPRM	11/02/07	72 FR 62149
ANPRM Comment Period End.	01/31/08	
NPRM	02/00/13	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Blakeley Fitzpatrick, Interdisciplinary Scientist, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition (HFS–830), HFS–830, 5100 Paint Branch Parkway, College Park, MD 20740, *Phone:* 240 402–1450, *Email: blakeley.fitzpatrick@fda.hhs.gov.*

RIN: 0910–AF22

269. Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed in One Eating Occasion; Dual Column Labeling; and Modifying the Reference Amounts Customarily Consumed

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

Abstract: FDA is proposing to amend its labeling regulations for foods to provide updated Reference Amounts Customarily Consumed (RACCs) for certain food categories. If finalized, this rule would provide consumers with nutrition information based on the amount of food that is customarily consumed, which would assist consumers in maintaining healthy dietary practices. In addition to updating certain RACCs, FDA is also considering amending the definition of single-serving containers and providing for dual-column labeling, which would provide nutrition information per serving and per container, for certain containers.

Timetable:

Action	Date	FR Cite
ANPRM	04/04/05	70 FR 17010
ANPRM Comment Period End.	06/20/05	
NPRM	02/00/13	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Cherisa Henderson, Nutritionist, Department of Health and Human Services, Food and Drug Administration, HFS–830, 5100 Paint Branch Parkway, College Park, MD 20740, *Phone:* 202 402–1450, *Fax:* 301 436–1191, *Email: cherisa.henderson@fda.hhs.gov*.

RIN: 0910–AF23

270. 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). The objectives of the RCC monograph alignment working group are to conduct a pilot program to develop aligned monograph elements for a selected over-the-counter (OTC) drug category (e.g., aligned directions, warnings, indications, and conditions of use) and subsequently, develop recommendations to determine the feasibility of an ongoing mechanism for alignment in review and adoption of these 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).	06/00/13	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Mary Chung, Regulatory Health Project Manager, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 22, Room 5488, 10903 New Hampshire Avenue, Silver Spring, MD 20993, *Phone:* 301 796–0260, *Fax:* 301 796–9899, *Email: mary.chung@fda.hhs.gov.*

RIN: 0910–AF31

271. Over-the-Counter (OTC) Drug Review—Internal Analgesic 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; 21 U.S.C. 374; 21 U.S.C. 379e

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. The first action addresses

acetaminophen safety. The second action addresses products marketed for children under 2 years old and weight- and age-based dosing for children's products.

Timetable:

Action	Date	FR Cite
NPRM (Amendment) (Required Warnings and Other Labeling).	12/26/06	71 FR 77314
NPRM Comment Period End.	05/25/07	
Final Action (Required Warnings and Other Labeling).	04/29/09	74 FR 19385
Final Action (Correction).	06/30/09	74 FR 31177
Final Action (Technical Amendment).	11/25/09	74 FR 61512
NPRM (Amendment) (Acetaminophen).	08/00/13	
NPRM (Amendment) (Pediatric).	12/00/13	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Mary Chung, Regulatory Health Project Manager, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 22, Room 5488, 10903 New Hampshire Avenue, Silver Spring, MD 20993, *Phone:* 301 796–0260, *Fax:* 301 796–9899, *Email: mary.chung@fda.hhs.gov.*

RIN: 0910–AF36

272. 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. The first action addresses consumer hand wash products. The second action addresses consumer leave-on antiseptic products.

Timetable:

Action	Date	FR Cite
NPRM (Healthcare).	06/17/94	59 FR 31402
Comment Period End.	12/15/95	
NPRM (Consumer Hand Wash Products).	02/00/13	
NPRM (Consumer Leave-on Products).	07/00/13	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: David Eng, Regulatory Project Manager, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 22, Room 5487, 10903 New Hampshire Avenue, Silver Spring, MD 20993, *Phone:* 301 796–2773, *Fax:* 301 796–9899, *Email: david.eng@fda.hhs.gov.*

RIN: 0910–AF69

273. 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 performance standard for laser products to achieve closer harmonization between the current standard and the International Electrotechnical Commission (IEC) standard for laser products and medical laser products. The proposed amendment is intended to update FDA's performance standard to reflect advancements in technology.

Timetable:

Action	Date	FR Cite
NPRM	12/00/12	

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

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

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

RIN: 0910–AG10

275. Over-the-Counter (OTC) Drug Review—Pediatric Dosing for Cough/Cold Products

Legal Authority: 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 will propose changes to the final monograph to address safety and efficacy issues associated with pediatric cough and cold products.

Timetable:

Action	Date	FR Cite
NPRM	06/00/13	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Mary Chung, Regulatory Health Project Manager, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 22, Room 5488, 10903 New Hampshire Avenue, Silver Spring, MD 20993, *Phone:* 301 796–0260, *Fax:* 301 796–9899, *Email: mary.chung@fda.hhs.gov.*

RIN: 0910–AG12

276. Electronic Distribution of Prescribing Information for Human 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	06/00/13	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Megan Clark-Velez, Policy Analyst, Department of Health and Human Services, Food and Drug Administration, Office of Policy, WO 32, Room 4249, 10903 New Hampshire Avenue, Silver Spring, MD 20993, *Phone:* 301 796–9301, *Email: megan.clark@fda.hhs.gov.*

RIN: 0910–AG18

277. Produce Safety Regulation

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

RIN: 0910–AG35

278. Hazard Analysis and Risk-Based Preventive Controls

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

RIN: 0910–AG36

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

Legal Authority: 21 U.S.C. 301 *et seq.,* The Federal Food, Drug, and Cosmetic Act; Pub. L. 111–31, The Family Smoking Prevention and Tobacco Control Act

Abstract: The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) provides the Food and Drug Administration (FDA) authority to regulate cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Tobacco Control Act, permits FDA to issue regulations deeming other tobacco products to be subject to the FD&C Act. This proposed rule would deem products meeting the statutory definition of ''tobacco product'' to be subject to the FD&C Act and would specify additional restrictions.

Timetable:

Action	Date	FR Cite
NPRM	04/00/13	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: May Nelson, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Tobacco Products, 9200 Corporate Boulevard, Rockville, MD 20850, *Phone:* 877 287–1373, *Fax:* 240 276–3904, *Email: may.nelson@fda.hhs.gov.*

RIN: 0910–AG38

280. General Hospital and Personal Use Devices: Issuance of Draft Special Controls Guidance for Infusion Pumps

Legal Authority: 21 U.S.C. 351; 21 U.S.C. 360; 21 U.S.C. 360c; 21 U.S.C. 360e; 21 U.S.C. 360j; 21 U.S.C. 371

Abstract: FDA is proposing to amend the classification of infusion pumps from class II (performance standards) to class II (special controls). FDA is taking this action to provide reasonable assurance of the safety and effectiveness of these devices.

Timetable:

Action	Date	FR Cite
NPRM	03/00/13	

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–AG54

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

Legal Authority: 21 U.S.C. 301 *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	04/00/13	
NPRM Comment Period End.	06/00/13	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Carol Drew, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Tobacco Products, 9200 Corporate Boulevard, Room 240 H, Rockville, MD 20850, *Phone:* 877 287–1373, *Fax:* 240 276–3904, *Email: carol.drew@fda.hhs.gov.*

RIN: 0910–AG59

282. Amendments to the Current Good Manufacturing Practice Regulations for Finished Pharmaceuticals—Components

Legal Authority: 21 U.S.C. 321; 21 U.S.C. 351; 21 U.S.C. 352; 21 U.S.C. 355; 21 U.S.C. 360b; 21 U.S.C. 371; 21 U.S.C. 374; 42 U.S.C. 262; 42 U.S.C. 264

Abstract: This rule proposes to amend regulations regarding the control over components used in manufacturing finished pharmaceuticals.

Timetable:

Action	Date	FR Cite
NPRM	05/00/13	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Brian Hasselbalch, Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 51, Room 4364, 10903 New Hampshire Avenue, Silver Spring, MD 20993, *Phone:* 301 796–3279, *Email: brian.hasselbalch@fda.hhs.gov.*

Paula Katz, Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 51, Room 1320, 10903 New Hampshire Avenue, Silver Spring, MD 20993, *Phone:* 301 796–6972, *Email: paula.katz@fda.hhs.gov.*

RIN: 0910–AG70

283. Use of Symbols in Labeling

Legal Authority: Sec 502(c) of the Food Drug and Cosmetic Act (FD&C Act), 21 U.S.C. 352(c); sec 514(c) of FD&C Act, 21 U.S.C. 360d(c), enacted by the Food and Drug Modernization Act of 1997 (FDAMA)

Abstract: The purpose of this proposed rule is to implement section 502(c) of the FD&C Act and to revise 21 CFR 801.15 (prominence of required label statements) using the authority under section 514(c) of the FD&C Act to allow for the inclusion of certain standardized symbols recognized by FDA for use on the labeling of medical devices. If this proposed rule is finalized, certain symbols in compliance with International Standards Organization (ISO) Standard 15223 may be used in medical device labeling with explanatory text or symbols glossary with accompanying labeling, as may other standardized symbols in the future when adopted by a national or international standards development organization and if recognized by FDA guidance or other regulatory action.

Timetable:

Action	Date	FR Cite
NPRM	04/00/13	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Mary Follette Story, Human Factors and Accessible Medical Technology Specialist, Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, Room 2553, 10903 New Hampshire Avenue, Silver Spring, MD 20993, *Phone:* 301 796–1456, *Email: molly.story@fda.hhs.gov.*

RIN: 0910–AG74

284. Requirements for the Submission of Data Needed To Calculate User Fees for Manufacturers and Importers of Tobacco Products

Legal Authority: 21 U.S.C. 371; 21 U.S.C. 387s; PL111–31

Abstract: FDA is proposing to require manufacturers and importers of tobacco products to submit certain market share data to FDA. USDA currently collects such data, but its program sunsets at the end of September 2014 and USDA will cease collection of this information. FDA is taking this action so that it may continue to calculate market share percentages needed to compute user fees.

Timetable:

Action	Date	FR Cite
NPRM	02/00/13	

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, 9200 Corporate Boulevard, Room 340K, Rockville, MD 20850, *Phone:* 877 287–1373, *Fax:* 240 276–3904, *Email: annette.marthaler@fda.hhs.gov.*

RIN: 0910–AG81

285. Food Labeling: Hard Candies and Breath Mints

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

Abstract: FDA is proposing to change the nutrition label serving size for breath mints to one mint. FDA is taking this action in response to comments received on an advance notice of proposed rulemaking published in 2005.

Timetable:

Action	Date	FR Cite
NPRM	12/30/97	62 FR 67775
NPRM Comment Period End.	03/16/98	
ANPRM	04/05/05	70 FR 17010
ANPRM Comment Period End.	06/20/05	
NPRM	02/00/13	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Mark Kantor, Nutritionist, Department of Health and Human Services, Food and Drug Administration, 5100 Paint Branch Parkway, HFS–830, College Park, MD 20740, *Phone:* 240 402–1450, *Fax:* 301 436–1191, *Email: mark.kantor@fda.hhs.gov.*

RIN: 0910–AG82

286. Food Labeling: Serving Sizes; Reference Amounts for Candies

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

Abstract: FDA is proposing to change its serving size regulations to provide updated Reference Amounts Customarily Consumed for candies. FDA is taking this action in response to comments received on an advance notice of proposed rulemaking published in 2005.

Timetable:

Action	Date	FR Cite
NPRM	01/08/98	63 FR 1078
NPRM Comment Period End.	02/09/98	
ANPRM	04/05/05	70 FR 17010
ANPRM Comment Period End.	06/20/05	
NPRM	02/00/13	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Mark Kantor, Nutritionist, Department of Health and Human Services, Food and Drug Administration, 5100 Paint Branch Parkway, HFS–830, College Park, MD 20740, *Phone:* 240 402–1450, *Fax:* 301 436–1191, *Email: mark.kantor@fda.hhs.gov.*

RIN: 0910–AG83

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Food and Drug Administration (FDA)

Final Rule Stage

287. Infant Formula: Current Good Manufacturing Practices; Quality Control Procedures; Notification Requirements; Records and Reports; and Quality Factors

Legal Authority: 21 U.S.C. 321; 21 U.S.C. 342; 21 U.S.C. 350a; 21 U.S.C. 371

Abstract: The Food and Drug Administration (FDA) is revising its infant formula regulations in 21 CFR parts 106 and 107 to establish requirements for current good manufacturing practices (CGMP), including audits; to establish requirements for quality factors; and to amend FDA's quality control procedures, notification, and record and reporting requirements for infant formula. FDA is taking this action to improve the protection of infants who consume infant formula products.

Timetable:

Action	Date	FR Cite
NPRM	07/09/96	61 FR 36154
NPRM Comment Period End.	12/06/96	
NPRM Comment Period Re-opened.	04/28/03	68 FR 22341
NPRM Comment Period Extended.	06/27/03	68 FR 38247
NPRM Comment Period End.	08/26/03	
NPRM Comment Period Re-opened.	08/01/06	71 FR 43392
NPRM Comment Period End.	09/15/06	
Final Rule	04/00/13	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Benson Silverman, Staff Director, Infant Formula and Medical Foods, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition (HFS–850), 5100 Paint Branch Parkway, College Park, MD 20740, *Phone:* 240 402–1459, *Email: benson.silverman@fda.hhs.gov.*

RIN: 0910–AF27

288. Over-the-Counter (OTC) Drug Review—Cough/Cold (Combination) 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 cough/cold drug products containing an oral bronchodilator (ephedrine and its salts) in combination with any expectorant or any oral nasal decongestant.

Timetable:

Action	Date	FR Cite
NPRM (Amendment).	07/13/05	70 FR 40232
NPRM Comment Period End.	11/10/05	
Final Action (Technical Amendment).	03/19/07	72 FR 12730
Final Action	03/00/13	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Mary Chung, Regulatory Health Project Manager, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 22, Room 5488, 10903 New Hampshire Avenue, Silver Spring, MD 20993, *Phone:* 301 796–0260, *Fax:* 301 796–9899, *Email: mary.chung@fda.hhs.gov.*

RIN: 0910–AF33

289. Unique Device Identification

Regulatory Plan: This entry is Seq. No. 39 in part II of this issue of the **Federal Register.**

RIN: 0910–AG31

290. Food Labeling: Nutrition Labeling for Food Sold in Vending Machines

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

RIN: 0910–AG56

291. Food Labeling: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments

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

RIN: 0910–AG57

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Food and Drug Administration (FDA)

Long-Term Actions

292. Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements, and Administrative Procedures (Section 610 Review)

Legal Authority: 21 U.S.C. 331; 21 U.S.C. 333; 21 U.S.C. 351 to 353; 21 U.S.C. 360; 21 U.S.C. 371; 21 U.S.C. 374; 21 U.S.C. 381

Abstract: FDA is currently reviewing regulations promulgated under the Prescription Drug Marketing Act (PDMA). FDA is undertaking this review to determine whether the regulations should be changed or rescinded to minimize adverse impacts on a substantial number of small entities. FDA has extended again the completion date by 1 year and will complete the review by December 2013.

Timetable:

Action	Date	FR Cite
Begin Review of Current Regulation.	11/24/08	
End Review of Current Regulation.	12/00/13	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Howard Muller, Office of Regulatory Policy, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 51, Room 6234, 10903 New Hampshire Avenue, Silver Spring, MD 20993–0002, *Phone:* 301 796–3601, *Fax:* 301 847–8440, *Email: pdma610(c)review@fda.hhs.gov.*

RIN: 0910–AG14

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Food and Drug Administration (FDA)

Completed Actions

293. Electronic Submission of Data From Studies Evaluating Human Drugs and Biologics

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

Abstract: The Food and Drug Administration is proposing to amend the regulations governing the format in which clinical study data and bioequivalence data are required to be submitted for new drug applications (NDAs), biological license applications (BLAs), and abbreviated new drug applications (ANDAs). The proposal would revise our regulations to require that data submitted for NDAs, BLAs, and ANDAs, and their supplements and amendments, be provided in an electronic format that FDA can process, review, and archive.

Timetable:

Action	Date	FR Cite
Withdrawn	08/01/12	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Martha Nguyen, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 51, Room 6352, 10903 New Hampshire Avenue, Silver Spring, MD 20993–0002, *Phone:* 301 796–3471, *Fax:* 301 847–8440, *Email: martha.nguyen@fda.hhs.gov.*

RIN: 0910–AC52

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Centers for Medicare & Medicaid Services (CMS)

Proposed Rule Stage

294. Emergency Preparedness Requirements for Medicare Participating Providers and Suppliers (CMS–3178–P) (Section 610 Review)

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

Abstract: This rule proposes 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 will ensure 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	07/00/13	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Janice Graham, Health Insurance Specialist, Clincal Standards Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of

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

295. • Changes to the Hospital Inpatient and Long-Term Care Prospective Payment System for FY 2014 (CMS–1599–P)

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

RIN: 0938–AR53

296. • Changes to the Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System for CY 2014 (CMS–1601–P)

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

RIN: 0938–AR54

297. • Revisions to Payment Policies Under the Physician Fee Schedule and Medicare Part B for CY 2014 (CMS–1600–P)

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

RIN: 0938–AR56

298. • Prospective Payment System for Federally Qualified Health Centers (FQHCS) (CMS–1443–P) (Section 610 Review)

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

RIN: 0938–AR62

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Centers for Medicare & Medicaid Services (CMS)

Final Rule Stage

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

Legal Authority: Pub. L. 111– 48, secs 2501, 2503, 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	08/00/13	

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Centers for Medicare & Medicaid Services (CMS)

Long-Term Actions

300. Transparency Reports and Reporting of Physician Ownership of Investment Interests (CMS–5060–F)

Legal Authority: Pub. L. 111–148, sec 6002

Abstract: This final rule requires applicable manufacturers of drugs, devices, biologicals, or medical supplies covered by Medicare, Medicaid, or CHIP to annually report to the Secretary certain payments or transfers of value provided to physicians or teaching hospitals (covered recipients). In addition, applicable manufacturers and applicable group purchasing organizations (GPOs) are required to annually report certain physician ownership or investment interests.

Timetable:

Action	Date	FR Cite
NPRM	12/19/11	76 FR 78742
NPRM Comment Period End.	02/17/12	
Final Action	12/00/14	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Niall Brennan, Director, Policy and Data Analysis Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244, *Phone:* 202 690–6627, *Email: niall.brennan@cms.hhs.gov.*

RIN: 0938–AR33

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Centers for Medicare & Medicaid Services (CMS)

Completed Actions

301. Administrative Simplification: Standard Unique Identifier for Health Plans and ICD–10 Compliance Date Delay (CMS–0040–F) (Completion of a Section 610 Review)

Legal Authority: Pub. L. 111–148, sec 1104

Abstract: This rule implements provisions of the Affordable Care Act of 2010 under Administrative Simplification that establish a unique health plan identifier. This health plan identifier will be used to identify health plans in HIPAA standard transactions. The rule also finalizes a delay to comply with ICD–10.

Timetable:

Action	Date	FR Cite
NPRM	04/17/12	77 FR 22950
NPRM Comment Period End.	05/17/12	
Final Action	09/05/12	77 FR 54664

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Christine Stahlecker, Acting Director, Administrative Simplification Group, Office of E-Health Standards and Services, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mail Stop S2–26–17, 7500 Security Boulevard, Baltimore, MD 21244, *Phone:* 410 786–6405, *Email: christine.stahlecker@cms.hhs.gov.*

RIN: 0938–AQ13

302. Medicare and Medicaid Electronic Health Record Incentive Program—Stage 2 (CMS–0044–F)

Legal Authority: Pub. L. 111–5 secs 4101, 4102, and 4202

Abstract: The final rule expands the criteria for meaningful use established for Stage 1 to advance the use of certified EHR technology by eligible professionals, eligible hospitals and critical access hospitals (CAHs). This rule is economically significant. The rule establishes the requirements for Stage 2, which encourages the use of continuous quality improvement at the point of care, and the exchange of information in the most structured format possible. For example, the electronic transmission of orders entered using computerized provider order entry, and the electronic transmission of diagnostic test results.

Timetable:

Action	Date	FR Cite
NPRM	03/07/12	77 FR 13698
NPRM Comment Period End.	05/07/12	
Final Action	09/04/12	77 FR 53967

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Elizabeth Holland, Director, Health Initiatives Group/Office of E-Health Standards and Services, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mail Stop S2–26–17, 7500 Security Boulevard, Baltimore, MD 21244, *Phone:* 410 786–1309, *Email: elizabeth.holland@cms.hhs.gov*.

RIN: 0938–AQ84

303. Proposed Changes to Hospital OPPS and CY 2013 Payment Rates; ASC Payment System and CY 2013 Payment Rates (CMS–1589–FC) (Completion of a Section 610 Review)

Legal Authority: Sec 1833 of the Social Security Act

Abstract: This final rule revises the Medicare hospital outpatient prospective payment system to implement applicable statutory requirements and changes arising from our continuing experience with this system. The rule also 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.

Timetable:

Action	Date	FR Cite
NPRM	07/30/12	77 FR 45061
NPRM Comment Period End.	09/04/12	
Final Action	11/15/12	77 FR 68210

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 Management, 7500 Security Boulevard, C4–03–06, Baltimore, MD 21244, *Phone:* 410 786–4617, *Email: marjorie.baldo@cms.hhs.gov*.

RIN: 0938–AR10

304. Revisions to Payment Policies Under the Physician Fee Schedule and Part B for CY 2013 (CMS–1590–FC) (Completion of a Section 610 Review)

Legal Authority: Social Security Act, secs 1102, 1871, 1848

Abstract: This annual final rule revises payment polices under the physician fee schedule, as well as other policy changes to payment under Part B. These changes are applicable to services furnished on or after January 1.

Timetable:

Action	Date	FR Cite
NPRM	07/30/12	77 FR 44721
NPRM Comment Period End.	09/04/12	
Final Action	11/16/12	77 FR 68892

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Christina Ritter, Director, Division of Practitioner Services, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mail Stop C4–03–06, 7500 Security Boulevard, Baltimore, MD 21244, *Phone:* 410 786–4636, *Email: christina.ritter@cms.hhs.gov*.

RIN: 0938–AR11

305. Changes to the Hospital Inpatient and Long-Term Care Prospective Payment Systems for FY 2013 (CMS–1588–F) (Completion of a Section 610 Review)

Legal Authority: Sec 1886(d) of the Social Security Act, Pub. L. 111–148, secs 3025, 5506, 3005

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	05/11/12	77 FR 27870
NPRM Comment Period End.	06/25/12	
Final Action	08/31/12	77 FR 53257

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Brian Slater, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mail Stop C4–07–07, 7500 Security Boulevard, Baltimore, MD 21244, *Phone:* 410 786–5229, *Email: brian.slater@cms.hhs.gov*.

RIN: 0938–AR12

306. Home Health Prospective Payment System Rate for CY 2013 (CMS–1358–F) (Completion of a Section 610 Review)

Legal Authority: Social Security Act, secs 1102 and 1871; 42 U.S.C. 1302 and 42 U.S.C. 1395(hh); Social Security Act, sec 1895; 42 U.S.C. 1395(fff)

Abstract: This 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 are applicable to services furnished on or after January 1.

Timetable:

Action	Date	FR Cite
NPRM	07/13/12	77 FR 41547
NPRM Comment Period End.	09/04/12	
Final Action	11/08/12	77 FR 67068

Regulatory Flexibility Analysis Required: No.

Agency Contact: Hillary Loeffler, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop C5–08–28, 7500 Security Boulevard, Baltimore, MD 21244, *Phone:* 410 786–0456, *Email: hillary.loeffler@cms.hhs.gov*.

RIN: 0938–AR18

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Part IX

Department of Homeland Security

Semiannual Regulatory Agenda