

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: Ann C. Agnew, Executive Secretary,

Department of Health and Human Services, 200 Independence Avenue SW, Washington, DC 20201; (202) 690–5627.

SUPPLEMENTARY INFORMATION: The Department of Health and Human Services (HHS) is the Federal government's lead agency for protecting the health of all Americans and providing essential human services, especially for those who are least able to help themselves. HHS enhances the health and well-being of Americans by promoting effective health and human services and by fostering sound, sustained advances in the sciences underlying medicine, public health, and social services.

This Agenda presents the regulatory activities that the Department expects to undertake in the foreseeable future to advance this mission. HHS has an agency-wide effort to support the Agenda's purpose of encouraging more effective public participation in the regulatory process. For example, to encourage public participation, we regularly update our regulatory webpage

(<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 also actively encourages meaningful public participation in its retrospective review of regulations through a comment form on the HHS retrospective review webpage (<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>.

Ann C. Agnew,

Executive Secretary to the Department.

OFFICE FOR CIVIL RIGHTS—PROPOSED RULE STAGE

| Sequence No. | Title | Regulation Identifier No. |
|--------------|--|---------------------------|
| 254 | Nondiscrimination in Health Programs or Activities | 0945-AA11 |

OFFICE FOR CIVIL RIGHTS—COMPLETED ACTIONS

| Sequence No. | Title | Regulation Identifier No. |
|--------------|--|---------------------------|
| 255 | HIPAA Privacy Rule: Changing Requirement to Obtain Acknowledgment of Receipt of the Notice of Privacy Practices. | 0945-AA08 |

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

| Sequence No. | Title | Regulation Identifier No. |
|--------------|--|---------------------------|
| 256 | 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program. | 0955-AA01 |

FOOD AND DRUG ADMINISTRATION—PROPOSED RULE STAGE

| Sequence No. | Title | Regulation Identifier No. |
|--------------|--|---------------------------|
| 257 | Over-the-Counter (OTC) Drug Review-Cough/Cold (Antihistamine) Products | 0910-AF31 |
| 258 | Sunscreen Drug Products For Over-The-Counter-Human Use; Tentative Final Monograph | 0910-AF43 |
| 259 | Label Requirement for Food That Has Been Refused Admission Into the United States | 0910-AF61 |
| 260 | Laser Products; Amendment to Performance Standard | 0910-AF87 |
| 261 | Mammography Quality Standards Act; Amendments to Part 900 Regulations (Reg Plan Seq No. 49) | 0910-AH04 |
| 262 | Medication Guides; Patient Medication Information | 0910-AH68 |
| 263 | Testing Standards for Batteries and Battery Management Systems in Electronic Nicotine Delivery Systems. | 0910-AH90 |
| 264 | Rule to Revoke Uses of Partially Hydrogenated Oils in Foods | 0910-AI15 |

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. |
|--------------|--|---------------------------|
| 265 | Postmarketing Safety Reporting Requirements for Human Drug and Biological Products | 0910-AA97 |
| 266 | Food Labeling; Gluten-Free Labeling of Fermented, Hydrolyzed, or Distilled Foods | 0910-AH00 |

FOOD AND DRUG ADMINISTRATION—LONG-TERM ACTIONS

| Sequence No. | Title | Regulation Identifier No. |
|--------------|---|---------------------------|
| 267 | Over-the-Counter (OTC) Drug Review—External Analgesic Products | 0910-AF35 |
| 268 | Over-the-Counter (OTC) Drug Review—Internal Analgesic Products | 0910-AF36 |
| 269 | Over-the-Counter (OTC) Drug Review—Laxative Drug Products | 0910-AF38 |
| 270 | Over-the-Counter (OTC) Drug Review—Weight Control Products | 0910-AF45 |
| 271 | Over-the-Counter (OTC) Drug Review—Pediatric Dosing for Cough/Cold Products | 0910-AG12 |
| 272 | Electronic Distribution of Prescribing Information for Human Prescription Drugs Including Biological Products. | 0910-AG18 |
| 273 | Sunlamp Products; Amendment to the Performance Standard | 0910-AG30 |
| 274 | General and Plastic Surgery Devices: Sunlamp Products | 0910-AH14 |
| 275 | Combinations of Bronchodilators With Expectorants; Cold, Cough, Allergy, Bronchodilator, and Anti-asthmatic Drug Products for Over-the-Counter Human Use. | 0910-AH16 |
| 276 | Acute Nicotine Toxicity Warnings for E-Liquids | 0910-AH24 |
| 277 | Administration Detention of Tobacco Products | 0910-AI05 |

CENTERS FOR MEDICARE & MEDICAID SERVICES—PROPOSED RULE STAGE

| Sequence No. | Title | Regulation Identifier No. |
|--------------|--|---------------------------|
| 278 | Requirements for Long-Term Care Facilities: Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction (CMS-3347-P) (Section 610 Review) (Reg Plan Seq No. 55) . | 0938-AT36 |
| 279 | CY 2020 Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Medicare Part B (CMS-1715-P) (Section 610 Review) . | 0938-AT72 |
| 280 | Hospital Inpatient Prospective Payment System for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and FY 2020 Rates (CMS-1716-P) (Section 610 Review) . | 0938-AT73 |
| 281 | CY 2020 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates (CMS-1717-P) (Section 610 Review) . | 0938-AT74 |

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. |
|--------------|--|---------------------------|
| 282 | Hospital and Critical Access Hospital (CAH) Changes to Promote Innovation, Flexibility, and Improvement in Patient Care (CMS-3295-F) (Rulemaking Resulting From a Section 610 Review) . | 0938-AS21 |
| 283 | CY 2019 Changes to the End-Stage Renal Disease (ESRD) Prospective Payment System, Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) (CMS-1691-F) (Section 610 Review) . | 0938-AT28 |
| 284 | CY 2019 Home Health Prospective Payment System Rate Update and CY 2020 Case-Mix Adjustment Methodology Refinements; Value-Based Purchasing Model; Quality Reporting Requirements (CMS-1689-F) (Section 610 Review) . | 0938-AT29 |
| 285 | CY 2019 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates (CMS-1695-F) (Section 610 Review) . | 0938-AT30 |
| 286 | CY 2019 Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Medicare Part B and the Quality Payment Program (CMS-1693-F) (Section 610 Review) . | 0938-AT31 |

CENTERS FOR MEDICARE & MEDICAID SERVICES—LONG-TERM ACTIONS

| Sequence No. | Title | Regulation Identifier No. |
|--------------|--|---------------------------|
| 287 | Durable Medical Equipment Fee Schedule, Adjustments to Resume the Transitional 50/50 Blended Rates to Provide Relief in Non-Competitive Bidding Areas (CMS-1687-F) (Section 610 Review) . | 0938-AT21 |

CENTERS FOR MEDICARE & MEDICAID SERVICES—COMPLETED ACTIONS

| Sequence No. | Title | Regulation Identifier No. |
|--------------|---|---------------------------|
| 288 | Hospital Inpatient Prospective Payment System for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and FY 2019 Rates (CMS-1694-F) (Completion of a Section 610 Review). | 0938-AT27 |
| 289 | FY 2019 Inpatient Psychiatric Facilities Prospective Payment System—Rate and Quality Reporting Updates (CMS-1690-F) (Completion of a Section 610 Review). | 0938-AT32 |

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)*Office for Civil Rights (OCR)*

Proposed Rule Stage

254. Nondiscrimination in Health Programs or Activities*E.O. 13771 Designation:* Deregulatory.*Legal Authority:* Sec. 1557 of the Patient Protection and Affordable Care Act (42 U.S.C. 18116)

Abstract: This proposed rule implements Section 1557 of the Patient Protection and Affordable Care Act (PPACA), which prohibits discrimination on the basis of race, color, national origin, sex, age, and disability under any health program or activity, any part of which is receiving Federal financial assistance, including credits, subsidies, or contracts of insurance, or under any program or activity that is administered by an Executive Agency or any entity established under Title I of the PPACA.

Timetable:

| Action | Date | FR Cite |
|------------|----------|---------|
| NPRM | 10/00/18 | |

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Luben Montoya, Section Chief, Civil Rights Division, Department of Health and Human Services, Office for Civil Rights, 200 Independence Avenue SW, Washington, DC 20201, *Phone:* 800 368-1019, *TDD Phone:* 800 537-7697, *Email:* ocrmail@hhs.gov.

RIN: 0945-AA11

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)*Office for Civil Rights (OCR)*

Completed Actions

255. HIPAA Privacy Rule: Changing Requirement To Obtain Acknowledgment of Receipt of the Notice of Privacy Practices*E.O. 13771 Designation:* Deregulatory.*Legal Authority:* Health Insurance Portability and Accountability (HIPAA) Act of 1996, Pub. L. 104-191

Abstract: This proposed rule would change the requirement that health care providers make a good faith effort to obtain from individuals a written acknowledgment of receipt of the provider's notice of privacy practices, and if not obtained, to document its good faith efforts and the reason the acknowledgment was not obtained.

Completed:

| Reason | Date | FR Cite |
|------------------------|----------|---------|
| Merged With 0945-AA00. | 07/27/18 | |

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Andra Wicks, *Phone:* 202 774-3081, *TDD Phone:* 800 537-7697, *Email:* andra.wicks@hhs.gov.

RIN: 0945-AA08

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)*Office of the National Coordinator for Health Information Technology (ONC)*

Proposed Rule Stage

256. 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program*E.O. 13771 Designation:* Regulatory.*Legal Authority:* Pub. L. 114-255

Abstract: The rulemaking would implement certain provisions of the 21st Century Cures Act, including conditions and maintenance of certification requirements for health information technology (IT) developers under the ONC Health IT Certification Program (Program), the voluntary certification of health IT for use by pediatric healthcare providers and reasonable and necessary activities that do not constitute information blocking. The rulemaking would also modify the 2015 Edition health IT certification criteria and Program in additional ways to advance interoperability, enhance health IT

certification, and reduce burden and costs.

Timetable:

| Action | Date | FR Cite |
|------------|----------|---------|
| NPRM | 11/00/18 | |

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Michael Lipinski, Director, Regulatory Affairs Division, Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, Mary E. Switzer Building, 330 C Street SW, Washington, DC 20201, *Phone:* 202 690-7151.

RIN: 0955-AA01

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Proposed Rule Stage

*Food and Drug Administration (FDA)***257. Over-the-Counter (OTC) Drug Review-Cough/Cold (Antihistamine) Products***E.O. 13771 Designation:* Deregulatory.*Legal Authority:* 21 U.S.C. 321p; 21 U.S.C. 331; 21 U.S.C. 351 to 353; 21 U.S.C. 355; 21 U.S.C. 360; 21 U.S.C. 371

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

| Action | Date | FR Cite |
|---------------------------------|----------|---------|
| NPRM (Amendment) (Common Cold). | 11/00/18 | |

*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**258. Sunscreen Drug Products for Over-the-Counter-Human Use; Tentative Final Monograph**

E.O. 13771 Designation: Regulatory.
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 proposed rule will address the general recognition of safety and effectiveness (GRASE) status of the 16 sunscreen monograph ingredients and describe data gaps that FDA believes need to be filled in order for FDA to permit the continued marketing of these ingredients without submitting new drug applications for premarket review. Consistent with the Sunscreen Innovation Act, we also expect to address sunscreen dosage forms and maximum SPF values.

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 | |
| NPRM | 11/00/18 | |

*Regulatory Flexibility Analysis**Required: Yes.*

Agency Contact: Kristen Hardin, Department of Health and Human

Services, Food and Drug Administration, Center for Drug Evaluation and Research, 10903 New Hampshire Avenue, WO 22, Room 5491, Silver Spring, MD 20993, *Phone:* 240 402-4246, *Fax:* 301 796-9841, *Email:* kristen.hardin@fda.hhs.gov.

RIN: 0910-AF43**259. Label Requirement for Food That Has Been Refused Admission Into the United States**

E.O. 13771 Designation: Deregulatory.
Legal Authority: 15 U.S.C. 1453 to 1455; 21 U.S.C. 321; 21 U.S.C. 342 and 343; 21 U.S.C. 371; 21 U.S.C. 374; 21 U.S.C. 381; 42 U.S.C. 216; 42 U.S.C. 264
Abstract: On September 18, 2008, FDA issued a proposed rule that would have required owners or consignees to label imported food that was refused entry into the United States. FDA does not plan to finalize the rule.

Timetable:

| Action | Date | FR Cite |
|--------------------------|----------|-------------|
| NPRM | 09/18/08 | 73 FR 54106 |
| NPRM Comment Period End. | 12/02/08 | |
| NPRM; Withdrawal. | 10/00/18 | |

*Regulatory Flexibility Analysis**Required: Yes.*

Agency Contact: Anthony C. Taube, Branch Chief, Department of Health and Human Services, Food and Drug Administration, Office of Regulatory Affairs, Office of Regional Operations, 12420 Parklawn Drive, ELEM-4051, Rockville, MD 20857, *Phone:* 240 420-4565, *Fax:* 703 261-8625, *Email:* anthony.taube@fda.hhs.gov.

RIN: 0910-AF61**260. Laser Products; Amendment to Performance Standard**

E.O. 13771 Designation: Deregulatory.
Legal Authority: 21 U.S.C. 360hh to 360ss; 21 U.S.C. 371; 21 U.S.C. 393
Abstract: On June 24, 2013, FDA issued a proposed rule that would have amended the performance standard for laser products to achieve closer harmonization between the current standard and the amended International Electrotechnical Commission (IEC) standard for laser products and medical laser products. FDA does not plan to finalize the 2013 proposal.

Timetable:

| Action | Date | FR Cite |
|--------------------------|----------|-------------|
| NPRM | 06/24/13 | 78 FR 37723 |
| NPRM Comment Period End. | 09/23/13 | |
| NPRM; Withdrawal. | 10/00/18 | |

*Regulatory Flexibility Analysis**Required: Yes.*

Agency Contact: Erica Payne, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, 10903 New Hampshire Avenue, WO 66, Room 5522, Silver Spring, MD 20993, *Phone:* 301 796-3999, *Fax:* 301 847-8145, *Email:* erica.payne@fda.hhs.gov.

RIN: 0910-AF87**261. Mammography Quality Standards Act; Amendments to Part 900 Regulations**

Regulatory Plan: This entry is Seq. No. 49 in part II of this issue of the **Federal Register**.

RIN: 0910-AH04**262. Medication Guides; Patient Medication Information**

E.O. 13771 Designation: Regulatory.
Legal Authority: 21 U.S.C. 321 *et seq.*; 42 U.S.C. 262; 42 U.S.C. 264; 21 U.S.C. 371

Abstract: The proposed rule would amend FDA medication guide regulations to require a new form of patient labeling, Patient Medication Information, for submission to and review by the FDA for human prescription drug products and certain blood products used, dispensed, or administered on an outpatient basis. The proposed rule would include requirements for Patient Medication Information development and distribution. The proposed rule would require clear and concisely written prescription drug product information presented in a consistent and easily understood format to help patients use their prescription drug products safely and effectively.

Timetable:

| Action | Date | FR Cite |
|------------|----------|---------|
| NPRM | 07/00/19 | |

*Regulatory Flexibility Analysis**Required: Yes.*

Agency Contact: Chris Wheeler, Supervisory Project Manager, Department of Health and Human Services, Food and Drug Administration, 10903 New Hampshire Avenue, Building 51, Room 3330, Silver Spring, MD 20993, *Phone:* 301 796-0151, *Email:* chris.wheeler@fda.hhs.gov.

RIN: 0910-AH68**263. Testing Standards for Batteries and Battery Management Systems in Electronic Nicotine Delivery Systems**

E.O. 13771 Designation: Regulatory.

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

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

Timetable:

| Action | Date | FR Cite |
|------------|----------|---------|
| NPRM | 09/00/19 | |

Regulatory Flexibility Analysis Required: Yes.

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

RIN: 0910-AH90

264. • Rule To Revoke Uses of Partially Hydrogenated Oils in Foods

E.O. 13771 Designation: Regulatory.
Legal Authority: 21 U.S.C. 321, 341, 343, 348, 371, 379(e)

Abstract: In the **Federal Register** of June 17, 2015 (80 FR 34650), we published a declaratory order announcing our final determination that there is no longer a consensus among qualified experts that partially hydrogenated oils (PHOs) are generally recognized as safe (GRAS) for any use in human food. In the **Federal Register** of May 21, 2018 (83 FR 23382), we denied a food additive petition requesting that the food additive regulations be amended to provide for the safe use of PHOs in certain food applications. We are now proposing to update our regulations to remove all mention of partially hydrogenated oils and to revoke all prior sanctioned uses. This rulemaking implements FDA's findings that the available data demonstrate that PHOs used in food may cause the food to be unsafe.

Timetable:

| Action | Date | FR Cite |
|------------|----------|---------|
| NPRM | 06/00/19 | |

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Ellen Anderson, Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, HFS-265, 4300 River Road, College Park, MD 20740, *Phone:* 240 402-1309, *Email:* ellen.anderson@fda.hhs.gov.

RIN: 0910-AI15

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Food and Drug Administration (FDA)

Final Rule Stage

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

E.O. 13771 Designation: Regulatory.
Legal Authority: 42 U.S.C. 216; 42 U.S.C. 241; 42 U.S.C. 242a; 42 U.S.C. 262 and 263; 42 U.S.C. 263a to 263n; 42 U.S.C. 264; 42 U.S.C. 300aa; 21 U.S.C. 321; 21 U.S.C. 331; 21 U.S.C. 351 to 353; 21 U.S.C. 355; 21 U.S.C. 360; 21 U.S.C. 360b to 360j; 21 U.S.C. 361a; 21 U.S.C. 371; 21 U.S.C. 374; 21 U.S.C. 375; 21 U.S.C. 379e; 21 U.S.C. 381

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

Timetable:

| Action | Date | FR Cite |
|-------------------------------|----------|-------------|
| NPRM | 03/14/03 | 68 FR 12406 |
| NPRM Comment Period Extended. | 06/18/03 | |

| Action | Date | FR Cite |
|------------------------------------|----------|---------|
| NPRM Comment Period End. | 07/14/03 | |
| NPRM Comment Period Extension End. | 10/14/03 | |
| Final Rule | 05/00/19 | |

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Jane E. Baluss, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 51, Room 6278, 10903 New Hampshire Avenue, Silver Spring, MD 20993-0002, *Phone:* 301 796-3469, *Fax:* 301 847-8440, *Email:* jane.baluss@fda.hhs.gov.
RIN: 0910-AA97

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

E.O. 13771 Designation: Regulatory.
Legal Authority: Sec. 206 of the Food Allergen Labeling and Consumer Protection Act; 21 U.S.C. 343(a)(1); 21 U.S.C. 321(n); 21 U.S.C. 371(a)

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

Timetable:

| Action | Date | FR Cite |
|------------------------------------|----------|-------------|
| NPRM | 11/18/15 | 80 FR 71990 |
| NPRM Comment Period Re-opened. | 01/22/16 | 81 FR 3751 |
| NPRM Comment Period End. | 02/16/16 | |
| NPRM Comment Period Re-opened End. | 02/22/16 | |
| NPRM Comment Period Re-opened. | 02/23/16 | 81 FR 8869 |
| NPRM Comment Period Re-opened End. | 04/25/16 | |
| Final Rule | 12/00/18 | |

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Carol D'Lima, Staff Fellow, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition, Room 4D022, HFS 820, 5001 Campus Drive, College

Park, MD 20740, Phone: 240 402-2371, Fax: 301 436-2636, Email: carol.dlima@fda.hhs.gov.
RIN: 0910-AH00

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Food and Drug Administration (FDA)

Long-Term Actions

267. Over-the-Counter (OTC) Drug Review—External Analgesic Products

E.O. 13771 Designation: Regulatory.
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 final action addresses the 2003 proposed rule on patches, plasters, and poultices. The proposed rule will address issues not addressed in previous rulemakings.

Timetable:

| Action | Date | FR Cite |
|------------|------------------|---------|
| NPRM | To Be Determined | |

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Janice Adams-King, Regulatory 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, Email: janice.adams-king@fda.hhs.gov.
RIN: 0910-AF35

268. Over-the-Counter (OTC) Drug Review—Internal Analgesic Products

E.O. 13771 Designation: Regulatory.
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). | To Be Determined | |

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-AF36

269. Over-the-Counter (OTC) Drug Review—Laxative Drug Products

E.O. 13771 Designation: Regulatory.
Legal Authority: 21 U.S.C. 321; 21 U.S.C. 331; 21 U.S.C. 351 to 353; 21 U.S.C. 355; 21 U.S.C. 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 final rule listed will address the professional labeling for sodium phosphate drug products.

Timetable:

| Action | Date | FR Cite |
|--|----------|-------------|
| Final Action (Granular Psyllium). | 03/29/07 | 72 FR 14669 |
| NPRM (Professional Labeling—Sodium Phosphate). | 02/11/11 | 76 FR 7743 |

| Action | Date | FR Cite |
|--------------------------|------------------|---------|
| NPRM Comment Period End. | 03/14/11 | |
| Final Rule | To Be Determined | |

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-AF38

270. Over-the-Counter (OTC) Drug Review—Weight Control Products

E.O. 13771 Designation: Regulatory.
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 final action finalizes the 2005 proposed rule for weight control products containing phenylpropanolamine.

Timetable:

| Action | Date | FR Cite |
|-------------------------------------|------------------|-------------|
| NPRM (Phenylpropanolamine). | 12/22/05 | 70 FR 75988 |
| NPRM Comment Period End. | 03/22/06 | |
| NPRM (Benzocaine). | 03/09/11 | 76 FR 12916 |
| NPRM Comment Period End. | 06/07/11 | |
| Final Action (Phenylpropanolamine). | To Be Determined | |

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Janice Adams-King, Regulatory 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, Email: janice.adams-king@fda.hhs.gov.
RIN: 0910-AF45

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

E.O. 13771 Designation: Regulatory.

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 | To Be Determined | |

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-AG12

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

E.O. 13771 Designation: Other.

Legal Authority: 21 U.S.C. 321; 21 U.S.C. 331; 21 U.S.C. 351 to 353; 21 U.S.C. 355; 21 U.S.C. 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 Rule | To Be Determined | |

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Michael Bernstein, Supervisory Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 51, Room 6240, 10903 New Hampshire Avenue, Silver Spring, MD 20993-0002, *Phone:* 301 796-3478, *Email:* michael.bernstein@fda.hhs.gov.

RIN: 0910-AG18

273. Sunlamp Products; Amendment to the Performance Standard

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

Legal Authority: 21 U.S.C. 360ii; 21 U.S.C. 360kk; 21 U.S.C. 393; 21 U.S.C. 371

Abstract: FDA is updating the performance standard for sunlamp products to improve safety, reflect new scientific information, and work towards harmonization with international standards. By harmonizing with the International Electrotechnical Commission, this rule will decrease the regulatory burden on industry and allow the Agency to take advantage of the expertise of the international committees, thereby also saving resources.

Timetable:

| Action | Date | FR Cite |
|--------------------------|----------|-------------|
| NPRM | 12/22/15 | 80 FR 79505 |
| NPRM Comment Period End. | 03/21/16 | |
| Final Rule | 06/00/20 | |

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Ian Ostermiller, Regulatory Counsel, Center for Devices and Radiological Health, Department of Health and Human Services, Food and Drug Administration, 10903 New Hampshire Avenue, WO 66, Room 5454, Silver Spring, MD 20993, *Phone:* 301 796-5678, *Email:* ian.ostermiller@fda.hhs.gov.

RIN: 0910-AG30

274. General and Plastic Surgery Devices: Sunlamp Products

E.O. 13771 Designation: Regulatory.

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

Abstract: This rule would apply device restrictions to sunlamp products. Sunlamp products include ultraviolet (UV) lamps and UV tanning beds and booths. The incidence of skin cancer, including melanoma, has been increasing, and a large number of skin cancer cases are attributable to the use of sunlamp products. The devices may cause about 400,000 cases of skin cancer per year, and 6,000 of which are melanoma. Beginning use of sunlamp products at young ages, as well as frequently using sunlamp products, both increases the risk of developing skin cancers and other illnesses, and sustaining other injuries. Even infrequent use, particularly at younger ages, can significantly increase these risks. This rule would apply device restrictions to sunlamp products.

Timetable:

| Action | Date | FR Cite |
|--------------------------|----------|-------------|
| NPRM | 12/22/15 | 80 FR 79493 |
| NPRM Comment Period End. | 03/21/16 | |
| Final Rule | 06/00/20 | |

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Ian Ostermiller, Regulatory Counsel, Center for Devices and Radiological Health, Department of Health and Human Services, Food and Drug Administration, 10903 New Hampshire Avenue, WO 66, Room 5454, Silver Spring, MD 20993, *Phone:* 301 796-5678, *Email:* ian.ostermiller@fda.hhs.gov.

RIN: 0910-AH14

275. Combinations of Bronchodilators With Expectorants; Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use

E.O. 13771 Designation: Regulatory.

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. These actions address cough/cold drug products containing an oral bronchodilator (ephedrine and its salts) in combination with any expectorant.

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 Rule | To Be Determined | |

*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-AH16

276. Acute Nicotine Toxicity Warnings for E-Liquids*E.O. 13771 Designation:* Regulatory.

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

Abstract: This rule would establish nicotine exposure warning requirements for liquid nicotine and nicotine-containing e-liquid(s) that are made or derived from tobacco and intended for human consumption, and potentially for other tobacco products including, but not limited to, novel tobacco products such as dissolvables, lotions, gels, and drinks. This action is intended to protect users and non-users from accidental exposures to nicotine-containing e-liquids in tobacco products.

Timetable:

| Action | Date | FR Cite |
|------------|----------|---------|
| NPRM | 12/00/20 | |

*Regulatory Flexibility Analysis**Required:* Yes.

Agency Contact: Courtney Smith, 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:* 301 595-1426, *Email:* ctpregulations@fda.hhs.gov.
RIN: 0910-AH24

277. Administration Detention of Tobacco Products*E.O. 13771 Designation:* Other.

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

Abstract: The Food and Drug Administration (FDA) is proposing regulations to establish requirements for the administrative detention of tobacco products. This action, if finalized, would allow FDA to administratively detain tobacco products encountered during inspections that an officer or employee conducting the inspection has reason to believe are adulterated or misbranded. The intent of administrative detention is to protect public health by preventing the distribution or use of violative tobacco products until FDA has had time to consider the appropriate action to take and, where appropriate, to initiate a regulatory action.

Timetable:

| Action | Date | FR Cite |
|------------|----------|---------|
| NPRM | 08/00/20 | |

*Regulatory Flexibility Analysis**Required:* Yes.

Agency Contact: Darin Achilles, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Tobacco Products, 10903 New Hampshire Avenue, Document Control Center, Building 71, Room G335, Silver Spring, MD 20993, *Phone:* 877 287-1373, *Fax:* 301 595-1426, *Email:* ctpregulations@fda.hhs.gov.
RIN: 0910-AI05

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)*Centers for Medicare & Medicaid Services (CMS)*

Proposed Rule Stage

278. Requirements for Long-Term Care Facilities: Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction (CMS-3347-P) (Section 610 Review)

Regulatory Plan: This entry is Seq. No. 55 in part II of this issue of the **Federal Register**.

RIN: 0938-AT36**279. • CY 2020 Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Medicare Part B (CMS-1715-P) (Section 610 Review)***E.O. 13771 Designation:* Other.

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

Abstract: This annual proposed rule would revise payment policies under the Medicare physician fee schedule, and

make other policy changes to payment under Medicare Part B. These changes would apply to services furnished beginning January 1, 2020. Additionally, this rule proposes updates to the Quality Payment Program.

Timetable:

| Action | Date | FR Cite |
|------------|----------|---------|
| NPRM | 06/00/19 | |

*Regulatory Flexibility Analysis**Required:* Yes.

Agency Contact: Marge Watchorn, Deputy Director, Division of Practitioner Services, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, MS: C4-01-15, 7500 Security Boulevard, Baltimore, MD 21244, *Phone:* 410 786-4361, *Email:* marge.watchorn@cms.hhs.gov.
RIN: 0938-AT72

280. • Hospital Inpatient Prospective Payment System for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and FY 2020 Rates (CMS-1716-P) (Section 610 Review)*E.O. 13771 Designation:* Other.

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

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

Timetable:

| Action | Date | FR Cite |
|------------|----------|---------|
| NPRM | 04/00/19 | |

*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: C4-08-06, 7500 Security Boulevard, Baltimore, MD 21244, *Phone:* 410 786-6504, *Email:* donald.thompson@cms.hhs.gov.
RIN: 0938-AT73

281. • CY 2020 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates (CMS-1717-P) (Section 610 Review)

E.O. 13771 Designation: Other.

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

Abstract: This annual proposed rule would revise the Medicare hospital outpatient prospective payment system to implement statutory requirements and changes arising from our continuing experience with this system. The proposed rule describes changes to the amounts and factors used to determine payment rates for services. In addition, the rule proposes changes to the ambulatory surgical center payment system list of services and rates. This proposed rule would also update and refine the requirements for the Hospital Outpatient Quality Reporting (OQR) Program and the ASC Quality Reporting (ASCQR) Program.

Timetable:

| Action | Date | FR Cite |
|------------|----------|---------|
| NPRM | 06/00/19 | |

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-AT74

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Centers for Medicare & Medicaid Services (CMS)

Final Rule Stage

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

E.O. 13771 Designation: Regulatory.

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

Abstract: This final rule updates the requirements that hospitals and critical access hospitals (CAHs) must meet to participate in the Medicare and Medicaid programs. These final requirements are intended to conform the requirements to current standards of

practice and 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 | 06/16/16 | 81 FR 39447 |
| NPRM Comment Period End. | 08/15/16 | |
| Final Action—To Be Merged With 0938-AS59 and 0938-AT23. | 06/00/19 | |

Regulatory Flexibility Analysis Required: No.

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

283. CY 2019 Changes to the End-Stage Renal Disease (ESRD) Prospective Payment System, Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) (CMS-1691-F) (Section 610 Review)

E.O. 13771 Designation: Regulatory.

Legal Authority: 42 U.S.C. 1302; 42 U.S.C. 1395d(d); 42 U.S.C. 1395f(b); 42 U.S.C. 1395g

Abstract: This annual final rule updates the bundled payment system for ESRD facilities by January 1, 2019. The rule also updates the quality incentives in the ESRD program and implements changes to the DMEPOS competitive bidding program.

Timetable:

| Action | Date | FR Cite |
|--------------------------|----------|-------------|
| NPRM | 07/19/18 | 83 FR 34304 |
| NPRM Comment Period End. | 09/10/18 | |
| Final Action | 11/00/18 | |

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Janae James, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, MS: C5-05-27, 7500 Security Boulevard, Baltimore, MD 21244, *Phone:* 410 786-0801, *Email:* janae.james@cms.hhs.gov.

RIN: 0938-AT28

284. CY 2019 Home Health Prospective Payment System Rate Update and CY 2020 Case-Mix Adjustment Methodology Refinements; Value-Based Purchasing Model; Quality Reporting Requirements (CMS-1689-F) (Section 610 Review)

E.O. 13771 Designation: Other.

Legal Authority: 42 U.S.C. 1302; 42 U.S.C. 1315a; 42 U.S.C. 1395(hh)

Abstract: This annual final rule updates the payment rates under the Medicare prospective payment system for home health agencies. In addition, this rule finalizes changes to the Home Health Value-Based Purchasing (HHVBP) Model and to the Home Health Quality Reporting Program (HH QRP).

Timetable:

| Action | Date | FR Cite |
|--------------------------|----------|-------------|
| NPRM | 07/12/18 | 83 FR 32340 |
| NPRM Comment Period End. | 08/31/18 | |
| Final Action | 11/00/18 | |

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Hillary Loeffler, Director, Division of Home Health and Hospice, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, MS: C5-08-28, 7500 Security Boulevard, Baltimore, MD 21244, *Phone:* 410 786-0456, *Email:* hillary.loeffler@cms.hhs.gov.

RIN: 0938-AT29

285. CY 2019 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates (CMS-1695-F) (Section 610 Review)

E.O. 13771 Designation: Deregulatory.

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

Abstract: This annual final rule would revise the Medicare hospital outpatient prospective payment system to implement statutory requirements and changes arising from our continuing experience with this system. The rule describes changes to the amounts and factors used to determine payment rates for services. In addition, the rule finalizes changes to the ambulatory surgical center payment system list of services and rates. This rule updates and refines the requirements for the Hospital Outpatient Quality Reporting (OQR) Program and the ASC Quality Reporting (ASCQR) Program.

Timetable:

| Action | Date | FR Cite |
|------------|----------|-------------|
| NPRM | 07/31/18 | 83 FR 37046 |

| Action | Date | FR Cite |
|--------------------------|----------|---------|
| NPRM Comment Period End. | 09/24/18 | |
| Final Action | 11/00/18 | |

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-AT30

286. CY 2019 Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Medicare Part B and the Quality Payment Program (CMS-1693-F) (Section 610 Review)

E.O. 13771 Designation: Regulatory.

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

Abstract: This annual final rule revises payment policies 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, 2019. Additionally, this rule updates the Quality Payment Program.

Timetable:

| Action | Date | FR Cite |
|--------------------------|----------|-------------|
| NPRM | 07/27/18 | 83 FR 35704 |
| NPRM Comment Period End. | 09/10/18 | |
| Final Action | 11/00/18 | |

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Marge Watchorn, Deputy Director, Division of Practitioner Services, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, MS: C4-01-15, 7500 Security Boulevard, Baltimore, MD 21244, Phone: 410 786-4361, Email: marge.watchorn@cms.hhs.gov.

RIN: 0938-AT31

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Centers for Medicare & Medicaid Services (CMS)

Long-Term Actions

287. Durable Medical Equipment Fee Schedule, Adjustments To Resume the Transitional 50/50 Blended Rates To Provide Relief in Non-Competitive Bidding Areas (CMS-1687-F) (Section 610 Review)

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

Legal Authority: 42 U.S.C. 1302, 1395hh, and 1395rr(b)(1); Pub. L. 114-255, sec. 5004(b), 16007(a) and 16008

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

Timetable:

| Action | Date | FR Cite |
|--|----------|-------------|
| Interim Final Rule | 05/11/18 | 83 FR 21912 |
| Interim Final Rule Comment Period End. | 07/09/18 | |
| Final Action | 05/00/21 | |

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Alexander Ullman, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, MS: C5-07-26, 7500 Security Boulevard, Baltimore, MD 21244, Phone: 410 786-9671, Email: alexander.ullman@cms.hhs.gov.

RIN: 0938-AT21

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Centers for Medicare & Medicaid Services (CMS)

Completed Actions

288. Hospital Inpatient Prospective Payment System for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and FY 2019 Rates (CMS-1694-F) (Completion of a Section 610 Review)

E.O. 13771 Designation: Deregulatory.

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

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

Timetable:

| Action | Date | FR Cite |
|--------------------------|----------|-------------|
| NPRM | 05/07/18 | 83 FR 20164 |
| NPRM Comment Period End. | 06/25/18 | |
| Final Action | 08/17/18 | 83 FR 41144 |
| Final Action Effective. | 10/01/18 | |

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

RIN: 0938-AT27

289. FY 2019 Inpatient Psychiatric Facilities Prospective Payment System—Rate and Quality Reporting Updates (CMS-1690-F) (Completion of a Section 610 Review)

E.O. 13771 Designation: Deregulatory.

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

Abstract: This annual final rule updates the prospective payment rates and quality reporting requirements for inpatient psychiatric facilities (IPF) with discharges beginning on October 1, 2018. This rule also includes updates to the IPF Quality Reporting Program.

Timetable:

| Action | Date | FR Cite |
|-----------------------------|----------|-------------|
| NPRM | 05/08/18 | 83 FR 21104 |
| NPRM Comment Period End. | 06/26/18 | |
| Final Action | 08/06/18 | 83 FR 38576 |
| Final Action Effective. | 10/01/18 | |

*Regulatory Flexibility Analysis**Required: Yes.*

Agency Contact: Sherlene Jacques,
Health Insurance Specialist, Department
of Health and Human Services, Centers
for Medicare & Medicaid Services,
Center for Medicare, MS: C5-05-27,
7500 Security Blvd., Baltimore, MD

21244, Phone: 410 786-0510, Email:
sherlene.jacques@cms.hhs.gov.

RIN: 0938-AT32

[FR Doc. 2018-24151 Filed 11-15-18; 8:45 am]

BILLING CODE 4150-03-P