
# FEDERAL REGISTER

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Part VII

## Department of Health and Human Services

Semiannual Regulatory Agenda

## 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 agencywide effort to support the Agenda's purpose of encouraging more effective public participation in the regulatory process. For example, to encourage public participation, we regularly update our regulatory web page (*http://www.HHS.gov/regulations*), which includes links to HHS rules currently open for public comment, and also provides a ''regulations toolkit'' with background information on regulations, the commenting process, how public comments influence the development of a rule, and how the public can provide effective comments.

The rulemaking abstracts included in this paper issue of the **Federal Register** cover, as required by the Regulatory Flexibility Act of 1980, those prospective HHS rulemakings likely to have a significant economic impact on a substantial number of small entities. The Department's complete Regulatory Agenda is accessible online at *http://www.RegInfo.gov.*

**Ann C. Agnew,**

*Executive Secretary to the Department.*

OFFICE FOR CIVIL RIGHTS—FINAL RULE STAGE

| Sequence No. | Title | Regulation Identifier No. |
|---|---|---|
| 230 | Nondiscrimination in Health and Health Education Programs or Activities **(Reg Plan Seq No. 44)** | 0945–AA11 |

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

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

| Sequence No. | Title | Regulation Identifier No. |
|---|---|---|
| 231 | 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program **(Reg Plan Seq No. 45)**. | 0955–AA01 |

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

FOOD AND DRUG ADMINISTRATION—PROPOSED RULE STAGE

| Sequence No. | Title | Regulation Identifier No. |
|---|---|---|
| 232 | Postmarketing Safety Reporting Requirements for Human Drug and Biological Products | 0910–AA97 |
| 233 | Over-the-Counter (OTC) Drug Review—Cough/Cold (Antihistamine) Products | 0910–AF31 |
| 234 | Medication Guide; Patient Medication Information | 0910–AH68 |
| 235 | Testing Standards for Batteries and Battery Management Systems in Battery-Operated Tobacco Products | 0910–AH90 |
| 236 | Requirements for Tobacco Product Manufacturing Practice **(Reg Plan Seq No. 47)** | 0910–AH91 |
| 237 | Nutrient Content Claims, Definition of Term: Healthy **(Reg Plan Seq No. 48)** | 0910–AI13 |
| 238 | Revocation of 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. |
|---|---|---|
| 239 | Sunscreen Drug Products For Over-The-Counter-Human Use; Final Monograph | 0910–AF43 |
| 240 | Sunlamp Products; Amendment to the Performance Standard | 0910–AG30 |
| 241 | Food Labeling; Gluten-Free Labeling of Fermented or Hydrolyzed Foods | 0910–AH00 |
| 242 | Mammography Quality Standards Act; Amendments to Part 900 Regulations | 0910–AH04 |
| 243 | General and Plastic Surgery Devices: Sunlamp Products | 0910–AH14 |
| 244 | Required Warnings for Cigarette Packages and Advertisements | 0910–AI39 |

FOOD AND DRUG ADMINISTRATION—FINAL RULE STAGE—Continued

| Sequence No. | Title | Regulation Identifier No. |
|---|---|---|
| 245 | Milk and Cream Product and Yogurt Products, Final Rule to Revoke the Standards for Lowfat Yogurt and Nonfat Yogurt and to Amend the Standard for Yogurt. | 0910–AI40 |

FOOD AND DRUG ADMINISTRATION—LONG-TERM ACTIONS

| Sequence No. | Title | Regulation Identifier No. |
|---|---|---|
| 246 | Acute Nicotine Toxicity Warnings for E-Liquids | 0910–AH24 |
| 247 | Adminstrative Detention of Tobacco Products | 0910–AI05 |

FOOD AND DRUG ADMINISTRATION—COMPLETED ACTIONS

| Sequence No. | Title | Regulation Identifier No. |
|---|---|---|
| 248 | Over-the-Counter (OTC) Drug Review—Laxative Drug Products | 0910–AF38 |
| 249 | Over-the-Counter (OTC) Drug Review—Weight Control Products | 0910–AF45 |
| 250 | Electronic Distribution of Prescribing Information for Human Prescription Drugs Including Biological Products. | 0910–AG18 |
| 251 | Combinations of Bronchodilators With Expectorants; Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use. | 0910–AH16 |
| 252 | Topical Antimicrobial Drug Products for Over-the-Counter Human Use: Final Monograph for Consumer Antiseptic Rub Products. | 0910–AH97 |

CENTERS FOR MEDICARE & MEDICAID SERVICES—PROPOSED RULE STAGE

| Sequence No. | Title | Regulation Identifier No. |
|---|---|---|
| 253 | CY 2021 Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Medicare Part B (CMS–1734–P) **(Section 610 Review)**. | 0938–AU10 |
| 254 | Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals; the Long-Term Care Hospital Prospective Payment System; and FY 2021 Rates (CMS–1735–P) **(Section 610 Review)**. | 0938–AU11 |
| 255 | CY 2021 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates (CMS–1736–P) **(Section 610 Review)**. | 0938–AU12 |

CENTERS FOR MEDICARE & MEDICAID SERVICES—FINAL RULE STAGE

| Sequence No. | Title | Regulation Identifier No. |
|---|---|---|
| 256 | CY 2020 Home Health Prospective Payment System Rate Update and Quality Reporting Requirements (CMS–1711–F) **(Section 610 Review)**. | 0938–AT68 |
| 257 | CY 2020 Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Medicare Part B (CMS–1715–F) **(Section 610 Review)**. | 0938–AT72 |
| 258 | CY 2020 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates (CMS–1717–F) **(Section 610 Review)**. | 0938–AT74 |

CENTERS FOR MEDICARE & MEDICAID SERVICES—LONG-TERM ACTIONS

| Sequence No. | Title | Regulation Identifier No. |
|---|---|---|
| 259 | 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 |
| 260 | Requirements for Long-Term Care Facilities: Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction (CMS–3347–F) **(Section 610 Review)**. | 0938–AT36 |

CENTERS FOR MEDICARE & MEDICAID SERVICES—COMPLETED ACTIONS

| Sequence No. | Title | Regulation Identifier No. |
|---|---|---|
| 261 | 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 |

CENTERS FOR MEDICARE & MEDICAID SERVICES—COMPLETED ACTIONS—Continued

| Sequence No. | Title | Regulation Identifier No. |
|---|---|---|
| 262 | FY 2020 Inpatient Psychiatric Facilities Prospective Payment System Rate and Quality Reporting Updates (CMS–1712–F). | 0938–AT69 |
| 263 | Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals; the Long-Term Care Hospital Prospective Payment System; and FY 2020 Rates (CMS–1716–F) **(Section 610 Review)**. | 0938–AT73 |

## DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

*Office for Civil Rights (OCR)*

Final Rule Stage

### 230. Nondiscrimination in Health and Health Education Programs or Activities

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

*RIN:* 0945–AA11

## DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

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

Final Rule Stage

### 231. 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program

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

*RIN:* 0955–AA01

## DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

*Food and Drug Administration (FDA)*

Proposed Rule Stage

### 232. Postmarketing Safety Reporting Requirements for Human Drug and Biological Products

*E.O. 13771 Designation:* Regulatory.

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

*Abstract:* The 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 | |
| NPRM Comment Period End. | 07/14/03 | |
| NPRM Comment Period Extension End. | 10/14/03 | |
| Reproposing NPRM. | 06/00/20 | |

*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

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

*E.O. 13771 Designation:* Deregulatory.

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

*Abstract:* FDA will be proposing a rule to add the common cold indication to certain over-the-counter (OTC) antihistamine active ingredients. This proposed rule is the result of collaboration under the U.S. Canada Regulatory Cooperation Council as part of efforts to reduce unnecessary duplication and differences. This pilot exercise will help determine the feasibility of developing an ongoing mechanism for alignment in review and adoption of 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). | 12/00/19 | |

*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

### 234. Medication Guide; Patient Medication Information

*E.O. 13771 Designation:* Regulatory.

*Legal Authority:* 21 U.S.C. 321 *et seq.;* 42 U.S.C. 262; 42 U.S.C. 264; 21 U.S.C. 371

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

*Timetable:*

| Action | Date | FR Cite |
|---|---|---|
| NPRM ..... | 06/00/20 | |

*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

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

*E.O. 13771 Designation:* Regulatory.

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

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

*Timetable:*

| Action | Date | FR Cite |
|---|---|---|
| NPRM ..... | 05/00/20 | |

*Regulatory Flexibility Analysis Required:* Yes.

*Agency Contact:* Nathan Mease, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, 10903 New Hampshire Avenue, WO 71, Room G335, Silver Spring, MD 20993, *Phone:* 877 287–1373, *Email: ctpregulations@fda.hhs.gov.*

*RIN:* 0910–AH90

**236. Requirements for Tobacco Product Manufacturing Practice**

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

*RIN:* 0910–AH91

**237. Nutrient Content Claims, Definition of Term: Healthy**

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

*RIN:* 0910–AI13

**238. Revocation of Uses of Partially Hydrogenated Oils in Foods**

*E.O. 13771 Designation:* Regulatory.

*Legal Authority:* 21 U.S.C. 321; 21 U.S.C. 341; 21 U.S.C. 342; 21 U.S.C. 343; 21 U.S.C. 348; 21 U.S.C. 371; 21 U.S.C. 379e

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

*Timetable:*

| Action | Date | FR Cite |
|---|---|---|
| NPRM ..... | 03/00/20 | |

*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

**239. Sunscreen Drug Products for Over-the-Counter—Human Use; 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 final rule will describe the conditions of use under which OTC sunscreen monograph products are generally recognized as safe and effective (GRASE) and not misbranded. Consistent with the Sunscreen Innovation Act, we expect that these conditions will include sunscreen dosage forms and maximum SPF values. The preamble of the final rule will also indicate which sunscreen active ingredients FDA has deferred further rulemaking on while data supporting the GRASE status of those ingredients is developed.

*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 ..... | 02/26/19 | 84 FR 6204 |
| NPRM Comment Period End. | 06/27/19 | |
| NPRM Extension of Comment Period. | 04/18/19 | 84 FR 16222 |
| NPRM Extension of Comment Period End. | 06/27/19 | |
| Final Rule ..... | 09/00/20 | |

*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

**240. 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

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

*E.O. 13771 Designation:* Regulatory.

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

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

*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 | 12/00/19 | |

*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

**242. Mammography Quality Standards Act; Amendments to Part 900 Regulations**

*E.O. 13771 Designation:* Regulatory.

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

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

*Timetable:*

| Action | Date | FR Cite |
|---|---|---|
| NPRM | 03/28/19 | 84 FR 11669 |
| NPRM Comment Period End. | 06/26/19 | |
| Final Rule | 09/00/20 | |

*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–AH04

**243. General and Plastic Surgery Devices: Sunlamp Products**

*E.O. 13771 Designation:* Regulatory.

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

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

**244. Required Warnings for Cigarette Packages and Advertisements**

*E.O. 13771 Designation:* Regulatory.

*Legal Authority:* 15 U.S.C. 1333; 21 U.S.C. 371; 21 U.S.C. 374; 21 U.S.C. 387c; 21 U.S.C. 387e; 21 U.S.C. 387i; Pub. L. 111–31, secs. 201 and 202, 123 Stat. 1776

*Abstract:* This rule will require color graphics depicting the negative health consequences of smoking to accompany textual warning statements on cigarette packages and in cigarette advertisements. As directed by Congress in the Family Smoking Prevention and Tobacco Control Act, which amends the Federal Cigarette Labeling and Advertising Act, the rule will require these new cigarette health warnings to occupy the top 50 percent of the area of the front and rear panels of cigarette packages and at least 20 percent of the area of cigarette advertisements. The original rule FDA issued in 2011 was vacated by the U.S. Court of Appeals for the District of Columbia Circuit in August 2012 (*R.J. Reynolds Tobacco Co.* v. *United States Food & Drug Admin.,* 696 F.3d 1205 D.C. Cir. 2012).

*Timetable:*

| Action | Date | FR Cite |
|---|---|---|
| NPRM | 08/16/19 | 84 FR 42754 |
| NPRM Comment Period End. | 10/15/19 | |
| Final Rule | 03/00/20 | |

*Regulatory Flexibility Analysis Required:* Yes.

*Agency Contact:* Courtney Smith, Senior 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:* 301 796–3894, *Fax:* 301 595–1426, *Email: ctpregulations@fda.hhs.gov*.

*RIN:* 0910–AI39

**245. Milk and Cream Product and Yogurt Products, Final Rule To Revoke the Standards for Lowfat Yogurt and Nonfat Yogurt and To Amend the Standard for Yogurt**

*E.O. 13771 Designation:* Deregulatory.

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

*Abstract:* This final rule amends the standard of identity for yogurt and revokes the standards of identity for lowfat yogurt and nonfat yogurt. It modernizes the standard for yogurt to allow for technological advances, to preserve the basic nature and essential characteristics of yogurt, and to promote honesty and fair dealing in the interest of consumers. Section 701(e)(1), of the Federal Food, Drug, and Cosmetic Act requires that the amendment or repeal of the definition and standard of identity for a dairy product proceed under a formal rulemaking process. Such is consistent with the formal rulemaking provisions of the Administrative Procedures Act (5 U.S.C. 556 and 557). Although, standard practice is not to include formal rulemaking in the Unified Agenda, this rule is included to highlight the de-regulatory work in this space.

*Timetable:*

| Action | Date | FR Cite |
|---|---|---|
| ANPRM | 07/03/03 | 68 FR 39873 |
| ANPRM Comment Period End. | 10/01/03 | |
| NPRM | 01/15/09 | 74 FR 2443 |
| NPRM Comment Period End. | 04/29/09 | |
| Final Rule | 05/00/20 | |

*Regulatory Flexibility Analysis Required:* Yes.

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

*RIN:* 0910–AI40

## DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

*Food and Drug Administration (FDA)*

Long-Term Actions

**246. 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 | 03/00/21 | |

*Regulatory Flexibility Analysis Required:* Yes.

*Agency Contact:* Courtney Smith, Senior 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:* 301 796–3894, *Fax:* 301 595–1426, *Email: ctpregulations@fda.hhs.gov*.

*RIN:* 0910–AH24

**247. Adminstrative Detention of Tobacco Products**

*E.O. 13771 Designation:* Other.

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

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

*Timetable:*

| Action | Date | FR Cite |
|---|---|---|
| NPRM | 11/00/20 | |

*Regulatory Flexibility Analysis Required:* Yes.

*Agency Contact:* Nathan Mease, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, 10903 New Hampshire Avenue, WO 71, Room G335, Silver Spring, MD 20993, *Phone:* 877 287–1373, *Email: ctpregulations@fda.hhs.gov*.

*RIN:* 0910–AI05

## DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

*Food and Drug Administration (FDA)*

Completed Actions

**248. 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.

*Completed:*

| Action | Date | FR Cite |
|---|---|---|
| Withdrawn | 10/23/19 | |

*Regulatory Flexibility Analysis Required:* Yes.

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

*RIN:* 0910–AF38

**249. 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.

*Completed:*

| Action | Date | FR Cite |
|---|---|---|
| Withdrawn ..... | 10/23/19 | |

*Regulatory Flexibility Analysis Required:* Yes.

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

*RIN:* 0910–AF45

**250. 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.

*Completed:*

| Action | Date | FR Cite |
|---|---|---|
| Withdrawn ..... | 10/23/19 | |

*Regulatory Flexibility Analysis Required:* Yes.

*Agency Contact:* Michael Bernstein, *Phone:* 301 796–3478, *Email: michael.bernstein@fda.hhs.gov*.

*RIN:* 0910–AG18

**251. 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. 321(p); 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 will propose changes to the final monograph for Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products to address cough/cold drug products containing an oral bronchodilator (ephedrine and its salts) in combination with any expectorant.

*Completed:*

| Action | Date | FR Cite |
|---|---|---|
| Withdrawn ..... | 10/23/19 | |

*Regulatory Flexibility Analysis Required:* Yes.

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

*RIN:* 0910–AH16

**252. Topical Antimicrobial Drug Products for Over-the-Counter Human Use: Final Monograph for Consumer Antiseptic Rub 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. 360 and 361; 21 U.S.C. 371; 21 U.S.C. 374 and 375; 21 U.S.C. 379; 42 U.S.C. 216; 42 U.S.C. 241 and 242; 42 U.S.C. 262

*Abstract:* This final rule finalizes part of the 1994 tentative final monograph (TFM) for over-the-counter (OTC) antiseptic drug products that published in the **Federal Register** of June 17, 1994, (the 1994 TFM). The final rule is part of the ongoing review of OTC drug products conducted by FDA. In this final rule, we address whether certain active ingredients used in OTC consumer antiseptic products intended for use without water (referred to as consumer antiseptic rubs) are eligible for evaluation under the OTC Drug Review for use in consumer antiseptic rub products.

*Completed:*

| Action | Date | FR Cite |
|---|---|---|
| Final Rule ..... | 04/12/19 | 84 FR 14847 |
| Final Rule Effective. | 04/13/20 | |

*Regulatory Flexibility Analysis Required:* Yes.

*Agency Contact:* Anita Kumar, *Phone:* 301 796–1032, *Email: anita.kumar@fda.hhs.gov*.

*RIN:* 0910–AH97

## DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

*Centers for Medicare & Medicaid Services (CMS)*

Proposed Rule Stage

**253. • CY 2021 Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Medicare Part B (CMS–1734–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 polices under the Medicare physician fee schedule, and make other policy changes to payment under Medicare Part B. These changes would apply to services furnished beginning January 1, 2021. Additionally, this rule proposes updates to the Quality Payment Program.

*Timetable:*

| Action | Date | FR Cite |
|---|---|---|
| NPRM ..... | 06/00/20 | |

*Regulatory Flexibility Analysis Required:* Yes.

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

*RIN:* 0938–AU10

**254. • Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals; the Long-Term Care Hospital Prospective Payment System; and FY 2021 Rates (CMS–1735–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 ..... | 04/00/20 | |

*Regulatory Flexibility Analysis Required:* Yes.

*Agency Contact:* Donald Thompson, Director, Division of Acute Care, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, MS: C4–08–06, 7500 Security Boulevard, Baltimore, MD 21244, *Phone:* 410 786–6504, *Email: donald.thompson@cms.hhs.gov*.

*RIN:* 0938–AU11

**255. • CY 2021 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates (CMS–1736–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 ..... | 06/00/20 | |

*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–AU12

## DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

*Centers for Medicare & Medicaid Services (CMS)*

Final Rule Stage

**256. CY 2020 Home Health Prospective Payment System Rate Update and Quality Reporting Requirements (CMS–1711–F) (Section 610 Review)**

*E.O. 13771 Designation:* Regulatory.

*Legal Authority:* 42 U.S.C. 1302; 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 ..... | 07/18/19 | 84 FR 34598 |
| NPRM Comment Period End. | 09/09/19 | |
| Final Action ..... | 11/00/19 | |

*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: C5–07–22, 7500 Security Boulevard, Baltimore, MD 21244, *Phone:* 410 786–0456, *Email: hillary.loeffler@cms.hhs.gov*.

*RIN:* 0938–AT68

**257. CY 2020 Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Medicare Part B (CMS–1715–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 polices under the Medicare physician fee schedule, and makes other policy changes to payment under Medicare Part B. These changes apply to services furnished beginning January 1, 2020. Additionally, this rule finalizes updates to the Quality Payment Program.

*Timetable:*

| Action | Date | FR Cite |
|---|---|---|
| NPRM ..... | 08/14/19 | 84 FR 40482 |
| NPRM Comment Period End. | 09/27/19 | |
| Final Action ..... | 11/00/19 | |

*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

**258. CY 2020 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates (CMS–1717–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 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 also updates and refines the requirements for the Hospital Outpatient Quality Reporting (OQR) Program and the ASC Quality Reporting (ASCQR) Program.

*Timetable:*

| Action | Date | FR Cite |
|---|---|---|
| NPRM ..... | 08/09/19 | 84 FR 39398 |
| NPRM Comment Period End. | 09/27/19 | |
| Final Action ..... | 11/00/19 | |

*Regulatory Flexibility Analysis Required:* Yes.

*Agency Contact:* Elise Barringer, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, MS: C4–03–06, 7500 Security Boulevard, Baltimore, MD 21244, *Phone:* 410 786–9222, *Email: elise.barringer@cms.hhs.gov*.

*RIN:* 0938–AT74

## DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

*Centers for Medicare & Medicaid Services (CMS)*

Long-Term Actions

### 259. 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:* Other.

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

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

*Timetable:*

| Action | Date | FR Cite |
|---|---|---|
| Interim Final Rule | 05/11/18 | 83 FR 21912 |
| Interim Final Rule Comment Period End. | 07/09/18 | |
| Final Action to be Merged With 0938–AU17. | 05/00/21 | |

*Regulatory Flexibility Analysis Required:* Yes.

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

*RIN:* 0938–AT21

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

*E.O. 13771 Designation:* Deregulatory.

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

*Abstract:* This final rule reforms the requirements that long-term care facilities must meet to participate in the Medicare and Medicaid programs that CMS has identified as unnecessary, obsolete, or excessively burdensome on facilities. This rule increases the ability of healthcare professionals to devote resources to improving resident care by eliminating or reducing requirements that impede quality care or that divert resources away from providing high-quality care.

*Timetable:*

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

*Regulatory Flexibility Analysis Required:* Yes.

*Agency Contact:* Ronisha Blackstone, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Clinical Standards and Quality, MS: S3–02–01, 7500 Security Boulevard, Baltimore, MD 21244, *Phone:* 410 786–6882, *Email: ronisha.blackstone@cms.hhs.gov*.

*RIN:* 0938–AT36

## DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

*Centers for Medicare & Medicaid Services (CMS)*

Completed Actions

### 261. 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.

*Completed:*

| Reason | Date | FR Cite |
|---|---|---|
| Continuation Notice. | 06/11/19 | 84 FR 27069 |
| Final Action—Merged With 0938–AT23. | 09/30/19 | 84 FR 51732 |
| Final Action Effective. | 11/29/19 | |
| Final Action—Merged With 0938–AS59. | 09/30/19 | 84 FR 51836 |
| Final Action Effective. | 11/29/19 | |

*Regulatory Flexibility Analysis Required:* No.

*Agency Contact:* Scott Cooper, *Phone:* 410 786–9465, *Email: scott.cooper@cms.hhs.gov*.

*RIN:* 0938–AS21

### 262. FY 2020 Inpatient Psychiatric Facilities Prospective Payment System Rate and Quality Reporting Updates (CMS–1712–F)

*E.O. 13771 Designation:* Other.

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

*Abstract:* This annual final rule updates the prospective payment rates for inpatient psychiatric facilities (IPF) with discharges beginning on October 1, 2019. The rule also includes updates to the IPF Quality Reporting Program.

*Completed:*

| Reason | Date | FR Cite |
|---|---|---|
| NPRM | 04/23/19 | 84 FR 16948 |
| Final Action | 08/06/19 | 84 FR 38424 |
| Final Action Effective. | 10/01/19 | |

*Regulatory Flexibility Analysis Required:* Yes.

*Agency Contact:* Sherlene Jacques, *Phone:* 410 786–0510, *Email: sherlene.jacques@cms.hhs.gov.*

*RIN:* 0938–AT69

### 263. Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals; The Long-Term Care Hospital Prospective Payment System; and FY 2020 Rates (CMS–1716–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 the Medicare hospital inpatient and long-term care hospital prospective payment systems for operating and capital-related costs. This rule would implements changes arising from our continuing experience with these systems. In addition, the rule establishes new requirements or revises existing

requirements for quality reporting by specific Medicare providers.

*Completed:*

| Reason | Date | FR Cite |
|---|---|---|
| NPRM | 05/03/19 | 84 FR 19158 |
| Final Action | 08/16/19 | 84 FR 42044 |
| Final Action Effective. | 10/01/19 | |

*Regulatory Flexibility Analysis Required:* Yes.

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

*RIN:* 0938–AT73

[FR Doc. 2019–26539 Filed 12–23–19; 8:45 am]

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