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 (EO) 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.

NAME: Ann C. Agnew,

Executive Secretary to the Department

Office of the Secretary—Completed Actions

Sequence Number	Title	Regulation Identifier Number
92	Removal of 2 CFR Subsection 376.147 **(Rulemaking Resulting From a Section 610 Review)**	0991–AC08
93	Uniform Administrative Requirements, Costs Principles and Adult	0991–AC09

	Requirements (45 CFR 75) **(Rulemaking Resulting From a Section 610 Review)**	

Substance Abuse and Mental Health Services Administration—Completed Actions

Sequence Number	Title	Regulation Identifier Number
94	Requirements Governing the Use of Seclusion and Restraint in Certain Nonmedical Community-Based Facilities for Children and Youth	0930–AA10
95	Medication Assisted Treatment for Opioid Use Disorders Reporting Requirements	0930–AA22

Centers for Disease Control and Prevention—Completed Actions

Sequence Number	Title	Regulation Identifier Number
96	Establishment of Minimum Standards for Birth Certificates	0920–AA46

Food and Drug Administration—Final Rule Stage

Sequence	Title	Regulation Identifier

Number		Number
97	Human Subject Protection; Acceptance of Data From Clinical Investigations for Medical Devices	0910–AG48
98	Food Labeling; Gluten-Free Labeling of Fermented, Hydrolyzed, or Distilled Foods	0910–AH00
99	Safety and Effectiveness of Consumer Antiseptics; Topical Antimicrobial Drug Products for Over-the-Counter Human Use (Healthcare Antiseptic)	0910–AH40

Food and Drug Administration—Long-Term Actions

Sequence Number	Title	Regulation Identifier Number
100	Postmarketing Safety Reporting Requirements for Human Drug and Biological Products	0910–AA97
101	Over-the-Counter (OTC) Drug Review—Cough/Cold (Antihistamine) Products	0910–AF31
102	Laser Products; Amendment to Performance Standard	0910–AF87
103	Updated Standards for Labeling of Pet Food	0910–AG09
104	Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products	0910–AG94
105	Radiology Devices; Designation of Special Controls for the	0910–AH03

	Computed Tomography X-Ray System	
106	General and Plastic Surgery Devices: Sunlamp Products	0910–AH14

Food and Drug Administration—Completed Actions

Sequence Number	Title	Regulation Identifier Number
107	Medical Gas Containers and Closures; Current Good Manufacturing Practice Requirements	0910–AC53
108	Amendment to the Current Good Manufacturing Practice Regulations for Finished Pharmaceuticals—Second Phase	0910–AG20
109	Requirements for the Testing and Reporting of Tobacco Product Constituents, Ingredients, and Additives	0910–AG59
110	Amendments to the Current Good Manufacturing Practice Regulations for Finished Pharmaceuticals—Components	0910–AG70
111	Format and Content of Reports Intended To Demonstrate Substantial Equivalence	0910–AG96
112	Investigational New Drug Application Annual Reporting	0910–AH07
113	Requirements for Tobacco Product Manufacturing Practice	0910–AH22
114	Use of Ozone Depleting Substances **(Section 610 Review)**	0910–AH36

Centers for Medicare & Medicaid Services—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
115	CY 2018 Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Medicare Part B (CMS-1676-P) **(Section 610 Review)**	0938–AT02
116	CY 2018 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates (CMS-1678-P) **(Section 610 Review)**	0938–AT03
117	CY 2019 Notice of Benefit and Payment Parameters (CMS-9930-P) **(Section 610 Review)**	0938–AT12

Centers for Medicare & Medicaid Services—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
118	Hospital Inpatient Prospective Payment System for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and FY 2018 Rates (CMS-1677-P) **(Section 610 Review)**	0938–AS98

Centers for Medicare & Medicaid Services—Long-Term Actions

Sequence Number	Title	Regulation Identifier Number
119	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

Sequence Number	Title	Regulation Identifier Number
120	Imaging Accreditation (CMS-3309-P)	0938–AS62
121	Merit-Based Incentive Payment System (MIPS) and Alternative Payment Models (APMs) in Medicare Fee-for-Service (CMS-5517-FC) **(Completion of a Section 610 Review)**	0938–AS69
122	CY 2017 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model; and Home Health Quality Reporting Requirements (CMS-1648-F) **(Completion of a Section 610 Review)**	0938–AS80
123	CY 2017 Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Medicare Part B (CMS-1654-F) **(Completion of a Section 610 Review)**	0938–AS81
124	CY 2017 Hospital Outpatient PPS Policy Changes and Payment	0938–AS82

	Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates (CMS-1656-FC) **(Completion of a Section 610 Review)**	

Department of Health and Human Services (HHS)	**Completed Actions**
Office of the Secretary (OS)	

92. REMOVAL OF 2 CFR SUBSECTION 376.147 (RULEMAKING RESULTING FROM A SECTION 610 REVIEW)

Legal Authority: 5 U.S.C. 301; 31 U.S.C. 6101

Abstract: HHS is amending its adoption of the Office of the Management and Budget's Nonprocurement Common Rule, found at 2 CFR part 180. This will remove 2 CFR subsection 376.147, which provides information about the scope of HHS OIG exclusions under title XI of the Social Security Act.

Timetable:

Action	**Date**	**FR Cite**
Withdrawn	06/08/17	

Regulatory Flexibility Analysis Required: Undetermined

Agency Contact: Tiffani Redding, Program Analyst, Department of Health and Human Services, Office of the Secretary, 200 Independence Avenue, SW., Washington, DC 20201

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RIN: 0991–AC08

93. UNIFORM ADMINISTRATIVE REQUIREMENTS, COSTS PRINCIPLES AND ADULT REQUIREMENTS (45 CFR 75) (RULEMAKING RESULTING FROM A SECTION 610 REVIEW)

Legal Authority: 5 U.S.C. 301

Abstract: This will address the comments of the NPRM to 45 CFR 75 and to include additional provision that are not in conflict with OMB's language, and provide additional guidance regulated community.

Timetable:

Action	Date	FR Cite
Final Rule	12/12/16	81 FR 89393
Final Rule Effective	01/17/17	

Regulatory Flexibility Analysis Required: No

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Phone: 202 260–6825

RIN: 0991–AC09

Department of Health and Human Services (HHS)	Completed Actions
Substance Abuse and Mental Health Services Administration (SAMHSA)	

94. REQUIREMENTS GOVERNING THE USE OF SECLUSION AND RESTRAINT IN CERTAIN NONMEDICAL COMMUNITY–BASED FACILITIES FOR CHILDREN AND YOUTH

Legal Authority: Pub. L. 106–310; 42 U.S.C. 290jj to 290jj–2

Abstract: The Secretary is required by statute to publish regulations governing States that license nonmedical, community-based residential facilities for children and youth. The regulation would require States to develop licensing rules and monitoring requirements concerning behavior management practice that will ensure compliance; requires States to develop and implement such licensing rules and implementation requirements within one year; and ensures that States require such facilities to have adequate staff, and that the States provide training for professional staff.

Timetable:

Action	Date	FR Cite
Withdrawn	06/08/17	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0930–AA10

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95. MEDICATION ASSISTED TREATMENT FOR OPIOID USE DISORDERS REPORTING REQUIREMENTS

Legal Authority: 21 U.S.C. 823(g)(2)

Abstract: On July 8, 2016, SAMHSA finalized a rule to increase access to buprenorphine and the combination buprenorphine/naloxone (Medication Assisted Treatment for Opioid Use Disorders). Concurrently with this final rule, SAMHSA issued a Supplemental Notice of Proposed Rulemaking seeking further comment on reporting provisions that would apply to physicians prescribing buprenorphine for up to 275 patients.

Timetable:

Action	Date	FR Cite
NPRM	03/30/16	81 FR 17639
NPRM Comment Period End	05/31/16	
Final Action	09/27/16	81 FR 66191
Final Action Effective	10/27/16	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0930–AA22

Department of Health and Human Services	Completed Actions

(HHS)	
Centers for Disease Control and Prevention (CDC)	

96. ESTABLISHMENT OF MINIMUM STANDARDS FOR BIRTH CERTIFICATES

Legal Authority: 42 U.S.C. 264

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

Timetable:

Action	Date	FR Cite
Withdrawn	06/08/17	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0920–AA46

Department of Health and Human Services (HHS)	**Final Rule Stage**
Food and Drug Administration (FDA)	

97. HUMAN SUBJECT PROTECTION; ACCEPTANCE OF DATA FROM CLINICAL INVESTIGATIONS FOR MEDICAL DEVICES

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

Abstract: This rule updates FDA's requirements for accepting clinical data used to bring new medical devices to market as part of fulfilling FDA's mission. While helping to ensure the quality and integrity of clinical trial data and the protection of study participants, this rule should reduce burden on industry by avoiding the need for on-site inspections. This rule parallels the drug regulation, which should further reduce burden by having a harmonized approach. Under this new rule, a device applicant would provide FDA with information about the conduct of their study such as, the research sites where the study was conducted, the investigators who conducted the study, a summary of the protocol, information about how informed consent from the study participants was obtained, and information about the ethics committee that reviewed the study. (If such information is not available, the sponsor may explain why and request a waiver.)

Timetable:

Action	Date	FR Cite
NPRM	02/25/13	78 FR 12664
NPRM Comment Period End	05/28/13	
Final Action	12/00/17	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AG48

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98. FOOD LABELING; GLUTEN–FREE LABELING OF FERMENTED, HYDROLYZED, OR DISTILLED FOODS

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

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

Timetable:

Action	Date	FR Cite
NPRM	11/18/15	80 FR 71990
NPRM Comment Period Reopened	01/22/16	81 FR 3751
NPRM Comment Period End	02/16/16	
NPRM Comment Period Reopened	02/22/16	81 FR 8869
NPRM Comment Period Reopened End	04/25/16	

Final Rule	10/00/18	

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, 5100 Paint Branch Parkway, College Park, MD 20740

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RIN: 0910–AH00

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99. SAFETY AND EFFECTIVENESS OF CONSUMER ANTISEPTICS; TOPICAL ANTIMICROBIAL DRUG PRODUCTS FOR OVER–THE–COUNTER HUMAN USE (HEALTHCARE ANTISEPTIC)

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 to 361; 21 U.S.C. 371; 21 U.S.C. 374 to 375; 21 U.S.C. 379; 42 U.S.C. 216; 42 U.S.C. 241; 42 U.S.C. 262

Abstract: This rulemaking addresses whether FDA considers certain active ingredients in over the counter (OTC) consumer antiseptic hand wash and health care antiseptic products to be generally recognized as safe and effective. If FDA determines that the ingredient is not generally recognized as safe and effective, a manufacturer will not be able to market the product unless it submits and receives approval of a new drug application.

Timetable:

Action	Date	FR Cite

NPRM	12/17/13	78 FR 764444
NPRM Comment Period End	06/16/14	
Final Action	01/00/18	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AH40

Department of Health and Human Services (HHS)	**Long-Term Actions**
Food and Drug Administration (FDA)	

100. POSTMARKETING SAFETY REPORTING REQUIREMENTS FOR HUMAN DRUG AND BIOLOGICAL PRODUCTS

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 expedited and periodic safety reporting regulations for human drugs and biological products to revise certain definitions and reporting formats as

recommended by the International Council on Harmonisation and to define new terms; to add to or revise current reporting requirements; to revise certain reporting time frames; and to propose other revisions to these regulations to 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). This final rule applies to postmarketing safety reporting requirements.

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	
Final Rule	10/00/18	

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

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RIN: 0910–AA97

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101. OVER–THE–COUNTER (OTC) DRUG REVIEW—COUGH/COLD (ANTIHISTAMINE) PRODUCTS

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

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

Timetable:

Action	Date	FR Cite
Reopening of Administrative Record	08/25/00	65 FR 51780
Comment Period End	11/24/00	
NPRM (Amendment) (Common Cold)	10/00/18	

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

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RIN: 0910–AF31

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102. LASER PRODUCTS; AMENDMENT TO PERFORMANCE STANDARD

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

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

Timetable:

Action	Date	FR Cite
NPRM	06/24/13	78 FR 37723
NPRM Comment Period End	09/23/13	
NPRM (Reproposal)	10/00/18	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Erica Blake–Payne, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, WO 66, Room 4426, 10903 New Hampshire Avenue, Silver Spring, MD 20993

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RIN: 0910–AF87

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103. UPDATED STANDARDS FOR LABELING OF PET FOOD

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

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

Timetable: Next Action Undetermined

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AG09

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104. SUPPLEMENTAL APPLICATIONS PROPOSING LABELING CHANGES FOR APPROVED DRUGS AND BIOLOGICAL PRODUCTS

Legal Authority: 21 U.S.C. 321; 21 U.S.C. 331; 21 U.S.C. 352; 21 U.S.C. 353; 21 U.S.C. 355; 21 U.S.C. 371; 42 U.S.C. 262; ...

Abstract: This rule would amend the regulations regarding new drug applications (NDAs), abbreviated new drug applications (ANDAs), and biologics license application (BLAs) to revise and clarify procedures for changes to the labeling of an approved drug to reflect certain types of newly acquired information in advance of FDA's review of such change.

Timetable:

Action	Date	FR Cite
NPRM	11/13/13	78 FR 67985
NPRM Comment Period Extended	12/27/13	78 FR 78796
NPRM Comment Period End	01/13/14	
NPRM Comment Period Extended End	03/13/14	
NPRM Comment Period Reopened	02/18/15	80 FR 8577
NPRM Comment Period Reopened End	04/27/15	
Next Action Undetermined		

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AG94

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105. RADIOLOGY DEVICES; DESIGNATION OF SPECIAL CONTROLS FOR THE COMPUTED TOMOGRAPHY X–RAY SYSTEM

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

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

Timetable:

Action	Date	FR Cite
NPRM	10/00/18	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Erica Blake–Payne, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, WO 66, Room 4426, 10903 New Hampshire Avenue, Silver Spring, MD 20993

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RIN: 0910–AH03

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106. GENERAL AND PLASTIC SURGERY DEVICES: SUNLAMP PRODUCTS

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

Abstract: This rule would apply device restrictions to sunlamp products. 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 sunlamp product use at young ages, as well as frequently using sunlamp products, both increase 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.

Sunlamp products incorporate ultraviolet (UV) lamps and include devices such as UV tanning beds and booths. People who use sunlamp products are at increased risk of developing skin cancer and other illnesses, and sustaining injuries.

Timetable:

Action	Date	FR Cite
NPRM	12/22/15	80 FR 79493
NPRM Comment Period End	03/21/16	
Final Rule	10/00/18	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AH14

Department of Health and Human Services (HHS)	**Completed Actions**
Food and Drug Administration (FDA)	

107. MEDICAL GAS CONTAINERS AND CLOSURES; CURRENT GOOD MANUFACTURING PRACTICE REQUIREMENTS

Legal Authority: 21 U.S.C. 321; 21 U.S.C. 351 to 21 U.S.C. 353

Abstract: The Food and Drug Administration is amending its current good manufacturing practice regulations and other regulations to clarify and strengthen requirements for the label, color, dedication, and design of medical gas containers and closures. Despite existing regulatory requirements and industry standards for medical gases, there have been repeated incidents in which cryogenic containers of harmful industrial gases have been connected to medical oxygen supply systems in hospitals and nursing homes and subsequently administered to patients. These incidents have resulted in death and serious injury. There have also been several incidents involving high-pressure medical gas cylinders that have resulted in death and injuries to patients. These amendments, together with existing regulations, are intended to ensure that the types of incidents that have occurred in the past, as well as other types of foreseeable and potentially deadly medical gas accidents, do not occur in the future. FDA has described

a number of proposals in the proposed rule including requiring that gas use outlet connections on portable cryogenic medical gas containers be securely attached to the valve body.

Timetable:

Action	Date	FR Cite
NPRM	04/10/06	71 FR 18039
NPRM Comment Period End	07/10/06	
Final Action	11/18/16	81 FR 81685
Final Action Effective	01/17/17	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AC53

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108. AMENDMENT TO THE CURRENT GOOD MANUFACTURING PRACTICE REGULATIONS FOR FINISHED PHARMACEUTICALS—SECOND PHASE

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

Abstract: FDA will revise regulations for "current good manufacturing practice" for oversight and controls over the manufacture of drugs to ensure quality, including managing the risk of and establishing the safety of raw materials, materials used in the manufacturing of drugs, and finished drug products. This revision will update and harmonize requirements and improve detection and response to emerging product safety and quality signals.

Timetable:

Action	Date	FR Cite
Withdrawn	06/08/17	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AG20

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109. REQUIREMENTS FOR THE TESTING AND REPORTING OF TOBACCO PRODUCT CONSTITUENTS, INGREDIENTS, AND ADDITIVES

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

Abstract: The Federal Food, Drug, and Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Control Act, requires the Food and Drug Administration to promulgate regulations that

require the testing and reporting of tobacco product constituents, ingredients, and additives, including smoke constituents, that the Agency determines should be tested to protect the public health.

Timetable:

Action	Date	FR Cite
Withdrawn	04/05/17	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Laura Rich, Senior Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Tobacco Products, Building 71, G335, 10903 New Hampshire Avenue, Silver Spring, MD 20993

Phone: 877 287–1373

Email: ctpregulations@fda.hhs.gov

RIN: 0910–AG59

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110. AMENDMENTS TO THE CURRENT GOOD MANUFACTURING PRACTICE REGULATIONS FOR FINISHED PHARMACEUTICALS—COMPONENTS

Legal Authority: 21 U.S.C. 321; 21 U.S.C. 351; 21 U.S.C. 352; 21 U.S.C. 355; 21 U.S.C. 360b; 21 U.S.C. 360bbb–7; 21 U.S.C. 371; 21 U.S.C. 374; 42 U.S.C. 262; 42 U.S.C. 264

Abstract: FDA will revise regulations for “current good manufacturing practice” with regard to control over components used in manufacturing finished pharmaceuticals.

Timetable:

Action	Date	FR Cite

Withdrawn	06/08/17	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AG70

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111. FORMAT AND CONTENT OF REPORTS INTENDED TO DEMONSTRATE SUBSTANTIAL EQUIVALENCE

Legal Authority: 21 U.S.C. 387e(j); 21 U.S.C. 387j(a); 21 U.S.C. 371; 21 U.S.C. 374; 21 U.S.C. 387b; 21 U.S.C 387c; 21 U.S.C. 387i

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

Timetable:

Action	Date	FR Cite
Withdrawn	04/05/17	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AG96

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112. INVESTIGATIONAL NEW DRUG APPLICATION ANNUAL REPORTING

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

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

Timetable:

Action	Date	FR Cite

Withdrawn	04/05/17	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AH07

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113. REQUIREMENTS FOR TOBACCO PRODUCT MANUFACTURING PRACTICE

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

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

Timetable:

Action	Date	FR Cite
ANPRM	03/19/13	78 FR 16824
ANPRM Comment Period End	05/20/13	
ANPRM Withdrawn	08/01/17	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AH22

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114. USE OF OZONE DEPLETING SUBSTANCES (SECTION 610 REVIEW)

Legal Authority: 21 U.S.C. 321; 21 U.S.C. 331; 21 U.S.C. 335; 21 U.S.C. 342; 21 U.S.C. 346a; 21 U.S.C. 348; 21 U.S.C. 351; 21 U.S.C. 352; 21 U.S.C. 355; 21 U.S.C. 360b; 21 U.S.C. 361; 21 U.S.C. 371; 21 U.S.C. 372; 21 U.S.C. 374; 15 U.S.C. 402; 15 U.S.C. 409

Abstract: The Food and Drug Administration (FDA or the Agency) is proposing to amend its regulation (21 CFR 2.125) on uses of ozone-depleting substances (ODSs), including chlorofluorocarbons (CFCs), to remove designations for certain products as essential uses under the Clean Air Act. Essential-use products are exempt from FDA's ban on the use of CFC propellants in FDA-regulated products and the Environmental Protection Agency's (EPA's) ban on the use of CFCs and other ODSs in pressurized dispensers. This action, if finalized, will remove essential use exemptions for sterile aerosol talc administered intrapleurally by thoracoscopy for human use, metered-dose atropine sulfate aerosol human drugs administered by oral inhalation, and anesthetic drugs for topical use on accessible mucous membranes of humans where a cannula is used for application. FDA is proposing this action because alternative products that do not use ODSs are now available and because these products are no longer being marketed in approved versions that contain ODSs. On June 29, 2015, FDA published a notice and request for comment concerning its tentative conclusion that these products are no longer an essential use under the Clean Air Act (80 FR 36937). The Agency received no comments concerning removal of

essential use designations for sterile aerosol talc and metered-dose atropine sulfate, and is proposing to remove these designations by direct final rule and a companion proposed rule in the event adverse comments are received. FDA received one comment concerning removal of anesthetic drugs for topical use in response to its 2015 notice and request for comment, and is proposing to remove this exemption through a separate notice. Because these products are not currently sold in the approved form, no significant economic impact is anticipated.

Timetable:

Action	**Date**	**FR Cite**
Withdrawn	06/30/17	

Regulatory Flexibility Analysis Required: No

Agency Contact: Daniel Orr, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Building 51, Room 5199, 10993 New Hampshire Avenue, Silver Spring, MD 20993

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RIN: 0910–AH36

Department of Health and Human Services (HHS)	**Proposed Rule Stage**
Centers for Medicare & Medicaid Services (CMS)	

115. CY 2018 REVISIONS TO PAYMENT POLICIES UNDER THE PHYSICIAN FEE SCHEDULE AND OTHER REVISIONS TO MEDICARE PART B (CMS–1676–P) (SECTION 610 REVIEW)

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, 2018.

Timetable:

Action	Date	FR Cite
NPRM	06/00/17	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Ryan Howe, Director, Division of Practitioner Services, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, MS: C4–01–15, 7500 Security Boulevard, Baltimore, MD 21244

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RIN: 0938–AT02

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116. CY 2018 HOSPITAL OUTPATIENT PPS POLICY CHANGES AND PAYMENT RATES AND AMBULATORY SURGICAL CENTER PAYMENT SYSTEM POLICY CHANGES AND PAYMENT RATES (CMS–1678–P) (SECTION 610 REVIEW)

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.

Timetable:

Action	Date	FR Cite
NPRM	06/00/17	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Lela Strong, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, MS: C4–05–13, 7500 Security Boulevard, Baltimore, MD 21244

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RIN: 0938–AT03

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117. • CY 2019 NOTICE OF BENEFIT AND PAYMENT PARAMETERS (CMS–9930–P) (SECTION 610 REVIEW)

Legal Authority: Pub. L. 111–148

Abstract: This proposed rule would set forth payment parameters and provisions related to the risk adjustment programs; cost sharing parameters and cost-sharing reductions; and user fees for Federally-Facilitated Exchanges. It would also provide additional standards for several other Affordable Care Act programs.

Timetable:

Action	Date	FR Cite
NPRM	09/00/17	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Lindsey Murtagh, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Consumer Information and Insurance Oversight, 7500 Security Boulevard, Baltimore, MD 21244

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RIN: 0938–AT12

Department of Health and Human Services (HHS)	Final Rule Stage
Centers for Medicare & Medicaid Services (CMS)	

118. HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEM FOR ACUTE CARE HOSPITALS AND THE LONG–TERM CARE HOSPITAL PROSPECTIVE PAYMENT SYSTEM AND FY 2018 RATES (CMS–1677–P) (SECTION 610 REVIEW)

Legal Authority: 42 U.S.C. 1302; 42 U.S.C. 1395hh; Pub. L. 114–255

Abstract: This annual final rule would revise the Medicare hospital inpatient and long-term care hospital prospective payment systems for operating and capital-related costs. This rule implements changes arising from our continuing experience with these systems.

Timetable:

Action	Date	FR Cite
NPRM	04/28/17	82 FR 19796
NPRM Comment Period End	06/13/17	
Final Action	08/00/17	

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

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RIN: 0938–AS98

Department of Health and Human Services (HHS)	Long-Term Actions
Centers for Medicare & Medicaid Services (CMS)	

119. 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)

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	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

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RIN: 0938–AS21

Department of Health and Human Services (HHS)	Completed Actions
Centers for Medicare & Medicaid Services (CMS)	

120. IMAGING ACCREDITATION (CMS–3309–P)

Legal Authority: 42 U.S.C. 1395hh; 42 U.S.C. 1102

Abstract: This proposed rule would establish standards for imaging accreditation for advanced diagnostic imaging services. These proposed standards would address qualifications for clinical personnel, standards to ensure that suppliers have established policies and procedures governing the use of equipment in furnishing the technical component of advanced diagnostic imaging, and the establishment and maintenance of a quality assurance and quality control program to ensure reliability, clarity and accuracy of the diagnostic images. This proposed rule would also address oversight of CMS approved accrediting organizations with imaging accreditation programs.

Timetable:

Action	Date	FR Cite
Withdrawn	03/23/17	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Sonia Swancy, 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

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RIN: 0938–AS62

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121. MERIT–BASED INCENTIVE PAYMENT SYSTEM (MIPS) AND ALTERNATIVE PAYMENT MODELS (APMS) IN MEDICARE FEE–FOR–SERVICE (CMS–5517–FC) (COMPLETION OF A SECTION 610 REVIEW)

Legal Authority: Pub. L. 114–10, sec. 101

Abstract: This rule implements provisions of the Medicare Access and CHIP Reauthorization Act (MACRA) related to MIPS and APMs. Section 101 of MACRA authorizes a new MIPS, which repeals the Medicare sustainable growth rate and improves Medicare payments for physician services. MACRA consolidates the current programs of the Physician Quality Reporting System, the Value-Based Modifier, and the Electronic Health Records Incentive Program into one program, MIPS, that streamlines and improves on the three distinct incentive programs. Additionally, MACRA authorizes incentive payments for providers who participate in eligible APMs.

Timetable:

Action	Date	FR Cite
NPRM	05/09/16	81 FR 28161
NPRM Comment Period End	06/27/16	
Final Action	11/04/16	81 FR 77088
Final Action Effective	01/01/17	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AS69

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122. CY 2017 HOME HEALTH PROSPECTIVE PAYMENT SYSTEM RATE UPDATE; HOME HEALTH VALUE–BASED PURCHASING MODEL; AND HOME HEALTH QUALITY REPORTING REQUIREMENTS (CMS–1648–F) (COMPLETION OF A SECTION 610 REVIEW)

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

Abstract:

This annual rule updates the 60-day national episode rate, the national per-visit rates used to calculate low utilization payment adjustments (LUPAs), and outlier payments under the Medicare prospective payment system for home health agencies. The rule also updates the provisions of the Home Health Value-Based Purchasing (HHVBP) program.

Timetable:

Action	Date	FR Cite
NPRM	07/05/16	81 FR 43714

NPRM Comment Period End	08/26/16	
Final Action	11/03/16	81 FR 76702
Final Action Effective	01/01/17	

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

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RIN: 0938–AS80

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123. CY 2017 REVISIONS TO PAYMENT POLICIES UNDER THE PHYSICIAN FEE SCHEDULE AND OTHER REVISIONS TO MEDICARE PART B (CMS–1654–F) (COMPLETION OF A SECTION 610 REVIEW)

Legal Authority: 42 U.S.C. 1302; 42 U.S.C. 1395hh; Pub. L. 114–10

Abstract:

This annual rule revises payment polices under the Medicare physician fee schedule, and make other policy changes to payment under Medicare Part B. These changes apply to services furnished beginning January 1, 2017.

Timetable:

Action	Date	FR Cite

NPRM	07/15/16	81 FR 46162
NPRM Comment Period End	09/06/16	
Final Action	11/15/16	81 FR 80170
Final Action Effective	01/01/17	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AS81

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124. CY 2017 HOSPITAL OUTPATIENT PPS POLICY CHANGES AND PAYMENT RATES AND AMBULATORY SURGICAL CENTER PAYMENT SYSTEM POLICY CHANGES AND PAYMENT RATES (CMS–1656–FC) (COMPLETION OF A SECTION 610 REVIEW)

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

Abstract:

This annual rule revises the Medicare hospital outpatient prospective payment system to implement statutory requirements and changes arising from our continuing experience with this system. The rule describes changes to the amounts and factors used to determine payment rates for services. In addition, the rule changes the ambulatory surgical center payment system list of services and rates.

Timetable:

Action	Date	FR Cite
NPRM	07/14/16	81 FR 45604
NPRM Comment Period End	09/06/16	
Final Action	11/14/16	81 FR 79562
Final Action Effective	01/01/17	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AS82

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