DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

21 CFR Ch. I

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 semi-annual issuance of an inventory of rulemaking actions under development throughout the Department with a view to offering summarized information about forthcoming regulatory actions for public review.

FOR FURTHER INFORMATION CONTACT: Dawn L. Smalls, Executive Secretary, Department of Health and Human Services, Washington, DC 20201.

SUPPLEMENTARY INFORMATION: The information provided in the Agenda presents a forecast of the rulemaking activities that the Department of Health and Human Services (HHS) expects to undertake in the foreseeable future. Rulemakings are grouped according to pre-rulemaking actions, proposed rules, final rules, long-term actions, and rulemaking actions completed since the Spring 2009 Agenda was published.

Please note that the rulemaking abstracts included in this paper issue of the **Federal Register** relate strictly to those prospective rulemakings that are likely to have a significant economic impact on a substantial number of small entities, as required by the Regulatory Flexibility Act of 1980. Also available in this issue of the **Register** is the Department's submission to the Fiscal Year 2011 Regulatory Plan, as required under Executive Order 12866.

The purpose of the Agenda is to encourage more effective public participation in the regulatory process, and HHS invites all interested members of the public to comment on the rulemaking actions included in this issuance of the Agenda. The complete Regulatory Agenda of the Department is accessible online at www.reginfo.gov in an interactive format that offers users enhanced capabilities to obtain information from the Agenda's database.

Dated: September 21, 2010.

NAME: Dawn L. Smalls,
Executive Secretary,
Department of Health and Human Services.

The 312 Regulatory Agendas

Health Resources and Services Administration - PreRule

Title	Regulation Identifier Number
340B Drug Pricing Program; Manufacturer Civil Monetary Penalties	0906-AA89
340B Drug Pricing Program; Administrative Dispute Resolution Process	0906-AA90

Health Resources and Services Administration - Proposed Rule

Title	Regulation Identifier Number
Add Vascularized Composite Allografts to the Definition of Organs Covered by the Rule Governing the Operation of the Organ Procurement and Transplantation Network (OPTN)	0906-AA73
National Vaccine Injury Compensation Program; Separate Category for Hepatitis A, Influenza, Meningococcal, Human Papillomavirus Vaccines	0906-AA74
Health Center Federal Tort Claims Act (FTCA) Medical Malpractice Program Regulations--Clarification of FTCA Coverage for Services Provided to Non-Health Center Patients	0906-AA77
Countermeasures Injury Compensation Program; Pandemic Influenza Countermeasure Injury Table Amendment for Influenza Vaccines, Antiviral Drugs, Respiratory Protection/Support Devices, and Diagnostics	0906-AA79
Countermeasures Injury Compensation Program; Radiation Injury Table Amendment	0906-AA81
Countermeasures Injury Compensation Program; Botulism Injury Table Amendment	0906-AA82
Countermeasures Injury Compensation Program; Smallpox Injury Table Amendment	0906-AA84
Countermeasures Injury Compensation Program; Anthrax Injury Table Amendment	0906-AA85
Elimination of Duplication Between the Healthcare Integrity and Protection Data Bank and the National Practitioner Data Bank	0906-AA87
Children's Hospitals Graduate Medical Education (CHGME) Payment Program	0906-AA88
Privacy Act; Exempt Record System	0906-AA91

Health Resources and Services Administration - Final Rule

Title	Regulation Identifier Number
Designation of Medically Underserved Populations and Health Professional Shortage Areas	0906-AA44
Countermeasures Injury Compensation Program; Administrative Implementation	0906-AA83

Health Resources and Services Administration - Long-term Action

Title	Regulation Identifier Number
Health Center Program Regs--Consolidation With Migrant Health Center Program Regulations and Extension of Applicability to Health Care for the Homeless and Public Housing Primary Care Health Program	0906-AA76

Health Resources and Services Administration - Completed Action

Title	Regulation Identifier Number
Public Health Service Act, Rural Physician Training Grant Program, Definition of "Underserved Rural Community"	0906-AA86

Food and Drug Administration - PreRule

Title	Regulation Identifier Number

Food Labeling: Safe Handling Statements, Labeling of Shell Eggs; Refrigeration of Shell Eggs Held for Retail Distribution	0910-AG06
Good Laboratory Practice for Nonclinical Laboratory Studies	0910-AG47

Food and Drug Administration - Proposed Rule

Title	Regulation Identifier Number
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Over-the-Counter (OTC) Drug Review--Poison Treatment Drug Products	0910-AF68
Over-the-Counter (OTC) Drug Review--Topical Antimicrobial Drug Products	0910-AF69
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Ingredient Standards and Definitions for Animal Foods	0910-AG08
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Over-the-Counter (OTC) Drug Review—Pediatric Dosing for Cough/Cold Products	0910-AG12
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Food and Drug Administration - Final Rule

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Food and Drug Administration - Long-term Action

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Food and Drug Administration - Completed Action

Title	Regulation Identifier Number
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Indian Health Service - Long-term Action

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Centers for Disease Control and Prevention - PreRule

Title	Regulation Identifier Number
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Centers for Disease Control and Prevention - Proposed Rule

Title	Regulation Identifier Number

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Centers for Disease Control and Prevention - Final Rule

Title	Regulation Identifier Number
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Centers for Disease Control and Prevention - Long-term Action

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Centers for Disease Control and Prevention - Completed Action

Title	Regulation Identifier Number
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National Institutes of Health - Proposed Rule

Title	Regulation Identifier Number
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National Institutes of Health - Final Rule

Title	Regulation Identifier

	Number
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Substance Abuse and Mental Health Services Administration - Proposed Rule

Title	Regulation Identifier Number
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Substance Abuse and Mental Health Services Administration - Long-term Action

Title	Regulation Identifier Number
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Centers for Medicare & Medicaid Services - PreRule

Title	Regulation Identifier Number
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Centers for Medicare & Medicaid Services - Proposed Rule

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Centers for Medicare & Medicaid Services - Final Rule

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Centers for Medicare & Medicaid Services - Long-term Action

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Centers for Medicare & Medicaid Services - Completed Action

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Home Health Prospective Payment System Refinements and Rate Update for CY 2011 (CMS-1510-F)	0938-AP88
Prospective Payment System for Inpatient Rehabilitation Facilities for FY 2011 (CMS-1344-N)	0938-AP89
Qualifying Individual (QI) Allotments (CMS-2309-N)	0938-AP90
Hospital IPPS for Acute Care Hospitals and Fiscal Year 2010 Rates and to the Long-Term Care Hospital PPS and	0938-AQ03

Rate Year 2010 Rates (CMS-1406-N)	
Medicare Coverage Gap Discount Program Model Manufacturer Agreement (CMS-4151-NC)	0938-AQ04
Proposed Changes to the Hospital and Critical Access Hospital Conditions of Participation to Ensure Visitation Rights for All Patients (CMS-3228-F)	0938-AQ06
Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act	0938-AQ07
Medicare Program; Changes to the Hospital Outpatient Prospective Payment System for CY 2010, Changes to the Ambulatory Surgical Center Payment System for CY 2010, and Extension of Payment Under Part B	0938-AQ08
Establishment of Special Payment Rules, Provisions and Standards for Providers and Suppliers of Prosthetics and Certain Custom Fabricated Orthotics (CMS-6012-P)	0938-AQ18

Office of Public Health and Science - Long-term Action

Title	Regulation Identifier Number
Public Health Service Standards for the Protection of Research Misconduct Whistleblowers	0940-AA01

Office of Consumer Information and Insurance Oversight - Proposed Rule

Title	Regulation Identifier Number
Requirements To Implement American Health Benefit Exchanges and Other Provisions of the Affordable Care Act	0950-AA02
Public Use Files of Health Plan Data	0950-AA04
Transparency Reporting	0950-AA07
Affordable Care Act Waiver for State Innovation; Review and Approval Process	0950-AA10

Office of Consumer Information and Insurance Oversight - Final Rule

Title	Regulation Identifier Number
Rate Review	0950-AA03
Medical Loss Ratios	0950-AA06
Uniform Explanation of Benefits, Coverage Facts, and Standardized Definitions	0950-AA08
Health Care Reform Insurance Web Portal Requirements	0950-AA11

Office of Consumer Information and Insurance Oversight - Long-term Action

Title	Regulation Identifier Number
Preexisting Condition Exclusions, Lifetime and Annual Limits, Prohibition on Discrimination and Patient Protections	0950-AA00
Internal Claims, Appeals, and External Review Processes Under the Affordable Care Act	0950-AA01
Pre-Existing Condition Insurance Plan	0950-AA05
Preventive Services Under the Affordable Care Act	0950-AA09
Early Retiree Reinsurance Program	0950-AA12
Dependent Coverage of Children to Age 26 Under the Patient Protection and Affordable Care Act	0950-AA14
Status as a Grandfathered Health Plan Under the Affordable Care Act	0950-AA17

Administration for Children and Families - Proposed Rule

Title	Regulation Identifier Number
Revised Head Start Performance Standards, Target Population, and Slot Conversion	0970-AC36
Interim Assistance for Trafficking Victims Under the Trafficking Victims Reauthorization Act of 2008	0970-AC39
Implementation of the Unaccompanied Alien Children (UAC) Provisions of the Trafficking Victims Reauthorization Act of 2008	0970-AC42
Performance Standards for Runaway and Homeless Youth Grantees	0970-AC43
Designation Renewal of Head Start Grantees	0970-AC44

Adoption and Foster Care Analysis and Reporting System (AFCARS)	0970-AC47
Strengthen Medical Support in the Child Support Program	0970-AC48
Improving Payment Processing in the Child Support Enforcement Program	0970-AC49
Case Closure Improvements for State IV-D Programs	0970-AC50
Case Closure Improvements for Tribal IV-D Programs	0970-AC51

Administration for Children and Families - Final Rule

Title	Regulation Identifier Number
Advance Planning Document Reform	0970-AC33
Tribal Child Welfare	0970-AC41
Safeguarding Child Support Information	0970-AC45
Head Start Eligibility Determinations	0970-AC46

Administration for Children and Families - Completed Action

Title	Regulation Identifier Number
Intergovernmental Child Support Enforcement	0970-AC37
Use of TANF Funds Carried Over From Prior Year	0970-AC40

Administration on Aging - Proposed Rule

Title	Regulation Identifier Number
Community Living Assistance Services and Supports Enrollment and Eligibility Rules Under the Affordable Care Act	0985-AA07

Office of the Secretary - Proposed Rule

Title	Regulation Identifier Number
Revisions to Regulations Addressing the OIG's Authority To Impose Civil Money Penalties and Assessments	0991-AB03
Revisions to the Office of Inspector General's (OIG) Exclusion Authorities	0991-AB33
Revisions to OIG Regulations Governing State Medicaid Fraud Control Units	0991-AB41
Establishment of the Permanent Certification Program for Health Information Technology	0991-AB59
Revision to Prohibition on FFP for "Data Mining" by Medicaid Fraud Control Units	0991-AB61
HIPAA Privacy Rule Accounting of Disclosures Under the Health Information Technology for Economic and Clinical Health Act	0991-AB62
Safe Harbors to the Anti-Kickback Statute for Certain Arrangements	0991-AB72
Exceptions to the Beneficiary Inducement Prohibition for Certain Arrangements	0991-AB73
Individual Access to Protected Health Information Held by CLIA Laboratories	0991-AB74
Nondiscrimination Under the Patient Protection and Affordable Care Act	0991-AB75

Office of the Secretary - Final Rule

Title	Regulation Identifier Number
Standards for Privacy of Individually Identifiable Health Information; Modifications to the HIPAA Privacy Rule Required by the Genetic Information Nondiscrimination Act of 2008	0991-AB54
HIPAA Administrative Simplification; Modifications to the HIPAA Enforcement Rule	0991-AB55
HIPAA Administrative Simplification; Notification in the Case of Breach	0991-AB56
Modifications to the HIPAA Privacy, Security, and Enforcement Rules Under the Health Information Technology for Economic and Clinical Health Act	0991-AB57

Office of the Secretary - Long-term Action

Title	Regulation Identifier Number
Shared Risk Exception to the Safe Harbor Provisions	0991-AA91
Rescission of the Regulation Entitled Ensuring That Department of Health and Human Services Funds Do Not Support Coercive of Discriminatory Policies or Practices in Violation of Federal Law	0991-AB49
Principles for Determining Costs at Hospitals Under Federal Grants, Contracts, and Cooperative Agreements	0991-AB51
Rescission of Interest Prohibition in the Principles for Determining Costs at Hospitals Under Federal Grants, Contracts, and Cooperative Agreements	0991-AB52

Office of the Secretary - Completed Action

Title	Regulation Identifier Number
Safe Harbor for Waiver of Beneficiary Co-Insurance and Deductible Amounts for a Medicare SELECT Policy	0991-AB16
Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology	0991-AB58
Requirements for Group Health Plans and Health Insurance Issuers Relating to Preexisting Condition Exclusions, Lifetime and Annual Limits, Rescissions and Patient Protections	0991-AB69
Group Health Plans and Health Insurance Issuers Relating to Internal Claims and Appeals and External Review Processes Under the Patient Protection and Affordable Care Act	0991-AB70
Pre-Existing Condition Insurance Plan Program	0991-AB71

Department of Health and Human Services (HHS)
Health Resources and Services Administration (HRSA) RIN: 0906-AA89

View Related Documents

Title: 340B Drug Pricing Program; Manufacturer Civil Monetary Penalties

Abstract: This rulemaking is required under the Affordable Care Act (Pub. L. 111-148). The purpose is to implement one of two enhancements to the 340B Program. It amends section 340B of the Public Health Service Act to impose monetary sanctions (not to exceed $5,000 per instance) on drug manufacturers who intentionally charge a covered entity (aka “safety net provider”) a price above the ceiling price established under the procedures of the 340B Program.

Priority: Other Significant
Agenda Stage of Rulemaking: PreRule
Major: No
Unfunded Mandates: No
CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: Sec 7102 of the Affordable Care Act; PL 111-148 amending subsec.(d); sec 340B PHS Act
Legal Deadline:

Action	Source	Description	Date
Other	Statutory	ANPRM met deadline	09/20/2010

Timetable:

Action	Date	FR Cite
ANPRM	12/00/2010	
ANPRM Comment Period End	01/00/2011	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: No
Federalism: No
Energy Affected: No

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Department of Health and Human Services (HHS)
Health Resources and Services Administration (HRSA) RIN: 0906-AA90

View Related Documents

Title: 340B Drug Pricing Program; Administrative Dispute Resolution Process

Abstract: This rulemaking is required under the Affordbale Care Act (P.L. 111-148). The purpose is to implement one of two enhancements to the 340B Program. This rulemaking establishes an involuntary and binding administrative dispute resolution process to resolve claims raised by covered entities (aka “safety net providers”) that they have been overcharged for drugs purchased under the 340B Program. This administrative dispute resolution process also is available to drug manufacturers.

Priority: Other Significant
Agenda Stage of Rulemaking: PreRule
Major: No
Unfunded Mandates: No
CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: Sec 7102 of the Affordable Care Act, Pub L 111-148, amending subsection (d) of sec 340B of the Public Health Service Act
Legal Deadline:

Action	Source	Description	Date
Other	Statutory	ANPRM	09/20/2010

Timetable:

Action	Date	FR Cite
ANPRM	12/00/2010	
ANPRM Comment Period End	01/00/2011	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Health Resources and Services Administration (HRSA) RIN: 0906-AA73

View Related Documents

Title: Add Vascularized Composite Allografts to the Definition of Organs Covered by the Rule Governing the Operation of the Organ Procurement and Transplantation Network (OPTN)

Abstract: This notice of proposed rulemaking will add vascularized composite allografts (VCA) to the definition of "organs" for purpose of coverage under NOTA and the OPTN final rule. NOTA authorizes the Secretary to include by regulation, additional organs under the definition of organ. Currently, the OPTN final rule defines covered organs as "a human kidney, liver, heart, lung, pancreas, or intestine (including the esophagus, stomach, small and/or large intestine, or any portion of the gastrointestinal tract)." VCA transplantation comprises transplants of a variety of body parts (i.e. hand and face transplants) that are not currently regulated and which share common characteristics.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 121 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: sec 301 of the National Organ Transplant Act (NOTA) of 1984, as amended; sec 371 to 376 of the Public Health Service Act; sec 1138 of the Social Security Act
Legal Deadline: None

Timetable:

Action	Date	FR Cite

NPRM	02/00/2011	

Regulatory Flexibility Analysis Required: No
Small Entities Affected: No
Government Levels Affected: No
Federalism: No

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Department of Health and Human Services (HHS)
Health Resources and Services Administration (HRSA) RIN: 0906-AA74

View Related Documents

Title: National Vaccine Injury Compensation Program; Separate Category for Hepatitis A, Influenza, Meningococcal, Human Papillomavirus Vaccines

Abstract: This notice of proposed rulemaking proposes to change the Vaccine Injury Table (Table) to create separate categories for hepatitis A, trivalent influenza, meningococcal, and human papillomavirus (HPV) vaccines. When a vaccine is recommended for routine administration to children by the Centers for Disease Control and Prevention (CDC), and after an excise tax is imposed on it by Congress, a vaccine is added to the Table under the new vaccines category (Category XIII). These four vaccines have been recommended for routine administration to children by the CDC and have had an excise tax imposed on them. Notices were published informing the public that these four vaccines have been added to the Table under Category XIII. The next step is that new vaccines are added as their own separate categories, with associated injuries/conditions, including the time periods in which the first symptoms or significant aggravation of such injuries/conditions must occur, if applicable, once the Secretary goes through the rulemaking process. In the past, such injuries/conditions have been added based on extensive scientific reviews of medical literature for adverse events following vaccination. Because reviews for these vaccines are not expected until 2011 at the earliest, we are proceeding with rulemaking to add these four vaccines as their own separate categories in order to make clear the four vaccines are covered by the National Vaccine Injury Compensation Program. Once results of the scientific reviews are published, additional rulemaking may be necessary, if certain conditions are viewed by the Department as appropriate for inclusion on the Table, including the relevant time periods of onset.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 100.3(c)(5) (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: sec 2114(e)(2) of the Public Health Service Act, 42 USC 300ea-14(e)(2); sec 13632(a)(3) PL 103-66, 42 USC CFR 100.3(c)(5)
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	12/00/2010	
NPRM Comment Period End	03/00/2011	

Regulatory Flexibility Analysis Required: No
Small Entities Affected: No
Government Levels Affected: No
Federalism: No
Energy Affected: No

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Department of Health and Human Services (HHS)
Health Resources and Services Administration (HRSA) RIN: 0906-AA77

View Related Documents

Title: Health Center Federal Tort Claims Act (FTCA) Medical Malpractice Program Regulations--Clarification of FTCA Coverage for Services Provided to Non-Health Center Patients

Abstract: This notice of proposed rulemaking proposes to amend regulations at 42 CFR part 6 (FTCA Coverage of Certain Grantees and Individuals) to include additional examples of FTCA covered activities. Recently, questions have arisen regarding the scope of FTCA regulations as they affect medical malpractice coverage for FTCA deemed health centers and non-health center patients. Section 6.6(e) of the Health Center FTCA Program regulations provides examples of situations within the scope of section 6.6(d), which authorizes FTCA medical malpractice coverage for non-health center patients. These examples include certain community-wide interventions and hospital-related activities where the health center's health care practitioners will be covered for services provided to non-health center patients.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 6 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 233
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	02/00/2011	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No

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Department of Health and Human Services (HHS)
Health Resources and Services Administration (HRSA) RIN: 0906-AA79

View Related Documents

Title: Countermeasures Injury Compensation Program; Pandemic Influenza Countermeasure Injury Table Amendment for Influenza Vaccines, Antiviral Drugs, Respiratory Protection/Support Devices, and Diagnostics

Abstract: This proposed rule establishes the Pandemic Influenza Countermeasure Injury Table for Influenza Vaccines, Antiviral Medications, Respiratory Protection Devices, Respiratory Support Devices, and Diagnostics for the Countermeasure Injury Compensation Program (CICP). The Public Readiness and Emergency Preparedness Act (PREP Act) authorized the Secretary of HHS to establish the CICP to provide benefits to certain persons who sustain serious physical injury or death as a direct result of the administration or use of covered countermeasures identified by the Secretary in declarations issued under the PREP Act. In addition, the Secretary may provide death benefits to certain survivors of individuals who died as a direct result of covered injuries or their health complications. One way that an individual who was administered or used a covered countermeasure can show that they sustained a covered injury is by demonstrating that they sustained an injury listed on a Countermeasures Injury Table (Table) within the time interval set forth on the Table. This rule will be an amendment to the CICP Administrative Interim Final Rule and will list and explain injuries that, based on compelling, reliable, valid, medical, and scientific evidence, are presumed to be caused by covered Pandemic Influenza Vaccines, Antiviral Medications, Respiratory Protection Devices, Respiratory Support Devices, and Diagnostics, and set forth the time periods in which the onset of these injuries must occur after the administration or use of these covered Pandemic influenza countermeasures.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule

Major: Undetermined Unfunded Mandates: No
CFR Citation: 42 CFR 110 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL109-148; sec 31F-3 and 319F-4 of the PHS Act
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	01/00/2011	

Regulatory Flexibility Analysis Required: No Government Levels Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Health Resources and Services Administration (HRSA) RIN: 0906-AA81

View Related Documents

Title: Countermeasures Injury Compensation Program; Radiation Injury Table Amendment
Abstract: This proposed rule establishes the Radiation Injury Table for the Countermeasures Injury Compensation Program (CICP). The Public Readiness and Emergency Preparedness Act (PREP Act) authorized the Secretary of HHS to establish the CICP to provide benefits to certain persons who sustain serious physical injury or death as a direct result of the administration or use of covered countermeasures identified by the Secretary in declarations issued under the PREP Act. In addition, the Secretary may provide death benefits to certain survivors of individuals who died as a direct result of covered injuries or their health complications. One way that an individual who was administered or used a covered countermeasure can show that they sustained a covered injury is by demonstrating that they sustained an injury listed on a Countermeasures Injury Table (Table) within the time interval set forth on the Table. This rule will be an amendment to the CICP Administrative Interim Final Rule and will list and explain injuries that, based on compelling, reliable, valid, medical, and scientific evidence, are presumed to be caused by covered radiation countermeasures and set forth the time periods in which the onset of these injuries must occur after the administration or use of these covered radiation countermeasures.

Priority: Other Significant Agenda Stage of Rulemaking: Proposed Rule
Major: Undetermined Unfunded Mandates: No
CFR Citation: 42 CFR 110 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 109-148 secs 31F-3 and 319F-4; PHSA 42, USC 247d-6d and 247d-6e
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	03/00/2011	

Regulatory Flexibility Analysis Required: No Government Levels Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Health Resources and Services Administration (HRSA) RIN: 0906-AA82

View Related Documents

Title: Countermeasures Injury Compensation Program; Botulism Injury Table Amendment

Abstract: This proposed rule establishes the Botulism Injury Table for the Countermeasures Injury Compensation Program (CICP). The Public Readiness and Emergency Preparedness Act (PREP Act) authorized the Secretary of HHS to establish the CICP to provide benefits to certain persons who sustain serious physical injury or death as a direct result of the administration or use of covered countermeasures identified by the Secretary in declarations issued under the PREP Act. In addition, the Secretary may provide death benefits to certain survivors of individuals who died as a direct result of covered injuries or their health complications. One way that an individual who was administered or used a covered countermeasure can show that they sustain a covered injury is by demonstrating that they sustained an injury listed on a Countermeasures Injury Table (Table) within the time interval set forth on the Table. This rule will be an amendment to the CICP Administrative Interim Final Rule and will list and explain injuries that, based on compelling, reliable, valid, medical, and scientific evidence, are presumed to be caused by covered botulism countermeasures, and the time periods in which the onset of these injuries must occur after the administration or use of these covered botulism countermeasures.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 110 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: P L 109-148; sec 31F-3 and 319F-4 of PHS Act as amended; 42 USC 247d-6d and 247d-6e
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	04/00/2011	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No

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Department of Health and Human Services (HHS)
Health Resources and Services Administration (HRSA) RIN: 0906-AA84

View Related Documents

Title: Countermeasures Injury Compensation Program; Smallpox Injury Table Amendment

Abstract: This rule will establish the Smallpox Injury Table for the Countermeasures Injury Compensation Program (CICP). The Public Readiness and Emergency Preparedness Act (PREP Act) authorized the Secretary of HHS to establish the CICP to provide benefits to certain persons who sustain serious physical injury or death as a direct result of the administration or use of covered countermeasures identified by the Secretary in declarations issued under the PREP Act. In addition, the Secretary may provide death benefits to certain survivors of individuals who died as a direct result of such covered injuries or their health complications. One way that an individual who was administered or used a covered countermeasure can show that they sustain a covered injury is by demonstrating that they sustained an injury listed on a Countermeasures Injury Table (Table) within the time interval set forth on the Table. This rule will be an amendment to the CICP Administrative Interim Final Rule and will list and explain injuries that, based on compelling, reliable, valid, medical and scientific evidence, are presumed to be caused by covered smallpox countermeasures, and the time periods in which the onset of these injuries must occur after the administration or use of these covered smallpox countermeasures.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 110 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 109-148, sec 31F-3 and 319F-4 of PHS Act as amended; 42 USC 247d-6d and 247d-6e
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	03/00/2011	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Health Resources and Services Administration (HRSA)
RIN: 0906-AA85

View Related Documents

Title: Countermeasures Injury Compensation Program; Anthrax Injury Table Amendment

Abstract: This rule will establish the Anthrax Injury Table for the Countermeasures Injury Compensation Program (CICP). The Public Readiness and Emergency Preparedness Act (PREP Act) authorized the Secretary of HHS to establish the CICP to provide benefits to certain persons who sustain serious physical injury or death as a direct result of the administration or use of covered countermeasures identified by the Secretary in declarations issued under the PREP Act. In addition, the Secretary may provide death benefits to certain survivors of individuals who died as a direct result of such covered injuries or their health complications. One way that an individual who was administered or used a covered countermeasure can show that they sustain a covered injury is by demonstrating that they sustained an injury listed on a Countermeasures Injury Table (Table) within the time interval set forth on the Table. This rule will be an amendment to the CICP Administrative Interim Final Rule and will list and explain injuries that, based on compelling, reliable, valid, medical and scientific evidence, are presumed to be caused by covered anthrax countermeasures, and the time periods in which the onset of these injuries must occur after the administration or use of these covered anthrax countermeasures.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 110 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 109-148 sec 31F-3 and319F-4 PHA; 42 USC 247d-6e
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	04/00/2011	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Federalism: Undetermined
Energy Affected: No
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Department of Health and Human Services (HHS)
Health Resources and Services Administration (HRSA) RIN: 0906-AA87

View Related Documents

Title: Elimination of Duplication Between the Healthcare Integrity and Protection Data Bank and the National Practitioner Data Bank

Abstract: This rule is required under the Patient Protection and Affordable Care Act of 2010 (Pub L. 111-148). The purpose is to eliminate the redundant reporting requirements for two closely related national health care data banks. This rule terminates the Healthcare Integrity and Protection Databank (HIPDB) and transfers all data collected in the HIPDB to the National Practitioner Data Bank (NPDB) established pursuant to the Health Care Quality Improvement Act of 1986. This rule will also provides for the disclosure of information, fee collection, establishment of dispute procedures, and an effective date of no later than one year after enactment or when regulations are published.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: Undetermined
Unfunded Mandates: No
CFR Citation: 45 CFR 60; 45 CFR 61 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: Sec 6403 PPAC Act; PL 111-148, 42 USC 1320a-7e,; 42 USC 11101
Legal Deadline:

Action	Source	Description	Date
NPRM	Statutory	PL 111-148, sec 6403	

Timetable:

Action	Date	FR Cite
NPRM	05/00/2011	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: No
Federalism: No
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Department of Health and Human Services (HHS)
Health Resources and Services Administration (HRSA) RIN: 0906-AA88

View Related Documents

Title: Children's Hospitals Graduate Medical Education (CHGME) Payment Program

Abstract: Under Section 340E of the Public Health Service Act and as amended by the Children's Health Act of 2000 (Pub. L. 106-310), "The Secretary shall promulgate regulations pursuant to the rulemaking requirements of title 5, United States Code, which shall govern payments made under this subpart." This mandates a Notice of Proposed Rulemaking that codifies policies guiding the administration of the Children's Hospital Graduate Medical Education (CHGME) Payment Program. The CHGME Payment Program policies codified in the Notice of Proposed Rulemaking will cover eligibility criteria, funding allocation between Direct Medical Education (DME) and Indirect Medical Education (IME) payments, application and payment processes, payment determination, counting methodology of full time equivalent (FTE) residents, methodologies for determination of DME and IME payments, data dissemination, and the appeals process.

Priority: Routine and Frequent
Agenda Stage of Rulemaking: Proposed Rule
Major: Undetermined
Unfunded Mandates: No
CFR Citation: 42 CFR 122 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: Sec 340E PHSA

Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	05/00/2011	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Federalism: No
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Department of Health and Human Services (HHS)
Health Resources and Services Administration (HRSA)
RIN: 0906-AA91

View Related Documents

Title: Privacy Act; Exempt Record System
Abstract: The purpose of this proposed rule is to exempt the system of records for the National Practitioner Data Bank (NPDB) from certain provisions of the Privacy Act (5 U.S.C. 552a). Currently the system of records for the Healthcare Integrity and Protection Data Bank (HIPDB) has an exemption from certain provisions of the Privacy Act. In order to maintain this exemption for the HIPDB materials, which are now under the NPDB due to implementation of section 1921 of the Social Security Act (42 U.S.C. 1396r-2), it is necessary to expand the same privacy act exemptions for the HIPDB to the NPDB.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: Undetermined
Unfunded Mandates: No
CFR Citation: 45 CFR 5b (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 1396r-2 and 5 USC 552a
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	04/00/2011	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: Undetermined
Federalism: Undetermined
Energy Affected: Undetermined
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Department of Health and Human Services (HHS)
Health Resources and Services Administration (HRSA)
RIN: 0906-AA44

View Related Documents

Title: Designation of Medically Underserved Populations and Health Professional Shortage Areas
Abstract: This rulemaking is mandated under the Patient Protection and Affordable Care Act of 2010 (P.L. 111-148). It requires the Secretary to establish a committee to draft an interim final rule for designation of Medically Underserved Populations (MUPs) and Primary Care Health Professions Shortage Areas (HPSAs). A notice of intent to form the negotiated

rulemaking committee was published on May 21, 2010 (75 FR 26167) and the Secretary announced committee membership on July 21, 2010. The rulemaking committee consists of technical experts representing stakeholders that will be significantly affected by this rule. A variety of federal and state programs target resources to underserved populations using MUP and HPSA designations. These designations have not been updated in many cases for over 20 years and may not reflect current conditions in many areas. The task of the rulemaking committee is to update the designations, which will likely involve revisions to the current methodologies to reflect changes in the prevailing values of the indicators and availability of data on other indicators of underservice. Prior to passage of the Patient Protection and Affordable Care Act, the Department made several attempts to revise the designations. An initial NPRM was published on September 1, 1998, but due to the extensive comments received, another notice was published on June 3, 1999 announcing a decision to develop and publish a revised NPRM for public comment. The second NPRM was published on February 29, 2008, with the comment period extended twice (first on April 21, 2008, and again on June 2, 2008). Substantial comments were received. A Federal Register Notice published on July 23, 2008, announcing an Agency decision to carefully review these comments, develop a modified proposal, and publish another NPRM at a future date.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 5; 42 CFR 51c (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 254b; 42 USC 254e
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	09/01/1998	63 FR 46538
NPRM Comment Period End	11/02/1998	
Second NPRM	02/29/2008	73 FR 11232
Second NPRM Comment Period Extended	04/21/2008	73 FR 21300
Second NPRM Initial Comment Period End	04/29/2008	
Second NPRM Extended Comment Period End	05/29/2008	
Second NPRM Second Comment Period Extended	06/02/2008	73 FR 31418
Second NPRM Second Extension of Comment Period End	06/30/2008	
NPRM Status	07/23/2008	73 FR 42743
Interim Final Rule	11/00/2011	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Federalism: No
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Department of Health and Human Services (HHS)
Health Resources and Services Administration (HRSA)
RIN: 0906-AA83

View Related Documents

Title: Countermeasures Injury Compensation Program; Administrative Implementation
Abstract: This interim final rule with request for comments establishes the administrative policies, procedures, and requirements for the Countermeasures Injury Compensation Program (CICP). The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the Secretary of HHS to establish the CICP to provide benefits to certain persons who sustain serious physical injury or death as a direct result of the administration or use of covered countermeasures identified by the Secretary in declarations issued under the PREP Act. In addition, the Secretary may provide death benefits to certain survivors of individuals who died as a direct result of such covered injuries or their health complications.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 110 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: Authorized by the Public Readiness and Emergency Preparedness Act PL 109-148, secs 31F-3 and 319F-4 of the Public Health Service Act, as amended; 42 USC 247d to 6d, 247d to 6e

Legal Deadline: None

Timetable:

Action	Date	FR Cite
Interim Final Rule	12/00/2010	
Interim Final Rule Effective	01/00/2011	
Interim Final Rule Comment Period End	11/00/2011	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: No

Small Entities Affected: Business

Federalism: No

Energy Affected: No

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Department of Health and Human Services (HHS)
Health Resources and Services Administration (HRSA) RIN: 0906-AA76

View Related Documents

Title: Health Center Program Regs--Consolidation With Migrant Health Center Program Regulations and Extension of Applicability to Health Care for the Homeless and Public Housing Primary Care Health Program

Abstract: HRSA proposes to amend its regulations at 42 CFR part 51c (the community health center regulations) to increase the consistency and improve the clarity of requirements across all health center types within the Health Center Program.

Priority: Other Significant

Agenda Stage of Rulemaking: Long-term Action

Major: Undetermined

Unfunded Mandates: Undetermined

CFR Citation: 42 CFR 51c; 42 CFR 56 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: 42 USC 254b

Legal Deadline: None

Timetable:

Action	Date	FR Cite
Next Action Undetermined		

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: No

Energy Affected: No

Related RINs: Merge with 0906-AA72

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Department of Health and Human Services (HHS)
Health Resources and Services Administration (HRSA) RIN: 0906-AA86

View Related Documents

Title: Public Health Service Act, Rural Physician Training Grant Program, Definition of "Underserved Rural Community"

Abstract: This regulation is required by the Patient Protection and Affordable Care Act of 2010 (P.L. 111-148). The purpose is to define the term “underserved rural community,” with respect to the Rural Physician Training Grant Program. For purposes of the Rural Physician Training Grant program only, HRSA combined existing definitions of “underserved” and “rural” by using the definition of “rural” utilized by the ORHP Rural Health Grant programs and the definition of “underserved” established by HRSA’s Office of Shortage Designation in the Bureau of Health Professions.

Priority: Other Significant
Agenda Stage of Rulemaking: Completed Action
Major: No
Unfunded Mandates: No
CFR Citation: None (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 111-148
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Interim Final Rule	05/26/2010	75 FR 29447

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Federalism: No
Energy Affected: Undetermined

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
RIN: 0910-AG06

View Related Documents

Title: Food Labeling: Safe Handling Statements, Labeling of Shell Eggs; Refrigeration of Shell Eggs Held for Retail Distribution

Abstract: Section 101.17(h) (21 CFR 101.17(h)) describes requirements for the labeling of the cartons of shell eggs that have not been treated to destroy Salmonella microorganisms. Section 115. 50 (21 CFR 115.50) describes requirements for refrigeration of shell eggs held for retail distribution. Section 16.5(a)(4) (21 CFR 16.5(a)(4)) provides that part 16 does not apply to a hearing on an order for relabeling, diversion, or destruction of shell eggs under section 361 of the Public Health Service Act (42 U.S.C. 264) and sections 101.17(h) and 115.50. FDA amended 21 CFR 101.17(h) on August 20, 2007 (72 FR 46375) to permit the safe handling statement to appear on the inside lid of egg cartons to provide the industry greater flexibility in the placement of the statement, provided the words "keep refrigerated" appear on the principal display panel or information panel. FDA is undertaking a review of 21 CFR sections 101.17(h), 115.50, and 16.5(a)(4) under section 610 of the Regulatory Flexibility Act. The purpose of this review is to determine whether the regulations in sections 101.17(h), 115.50 and 16.5(a)(4) should be continued without change, or whether they should be amended or rescinded, consistent with the stated objectives of applicable statutes, to minimize any significant economic impact on a substantial number of small entities. FDA will consider, and is soliciting comments on, the following: (1) The continued need for the rule; (2) the nature of complaints or comments received concerning the rule from the public; (3) the complexity of the rule; (4) the extent to which the rule overlaps, duplicates, or conflicts with other Federal rules, and, to the extent feasible, with State and local governmental rules; and (5) the length of time since the rule has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the rule.

Priority: Routine and Frequent
Agenda Stage of Rulemaking: PreRule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 101.17; 21 CFR 115.50; 21 CFR 16.5(a)(4) (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 15 USC 1453 to 1455; 21 USC 321; 21 USC 331; 21 USC 342 and 343; 21 USC 348; 21 USC 371; 42

USC 243; 42 USC 264; 42 USC 271
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Begin Review	12/15/2009	
End Review	12/00/2010	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: Undetermined
Federalism: Undetermined
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AG47

View Related Documents

Title: Good Laboratory Practice for Nonclinical Laboratory Studies

Abstract: The Food and Drug Administration (FDA) is seeking comment on whether to amend the regulation governing good laboratory practices (GLPs) (21 CFR part 58--Good Laboratory Practice for Nonclinical Laboratory Studies). The GLP regulation was finalized in December 1978 and prescribes GLPs for conducting nonclinical laboratory studies that support or are intended to support applications for research or marketing permits for FDA-regulated products. Since this regulation was published, nonclinical laboratory studies have changed markedly. To help ensure the integrity of data in nonclinical laboratory studies submitted to FDA, the agency is seeking comment about whether to propose that nonclinical facilities/laboratories follow a GLP quality system. While many of the requirements of the existing regulation are consistent with a GLP quality system, FDA is considering modifications to incorporate all basic elements needed for a GLP quality system consistent with internationally recognized quality systems. FDA believes that implementation of a GLP quality system may reduce regulatory burden and encourage science-based technology.

Priority: Other Significant
Agenda Stage of Rulemaking: PreRule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 58 (revision) (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 342; 21 USC 346 and 346a; 21 USC 348; 21 USC 351 to 353; 21 USC 355; ...
Legal Deadline: None

Timetable:

Action	Date	FR Cite
ANPRM	12/00/2010	
ANPRM Comment Period End	04/00/2011	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: Undetermined
Small Entities Affected: Business
Federalism: No
International Impacts: This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AC52

View Related Documents

Title: Electronic Submission of Data From Studies Evaluating Human Drugs and Biologics

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

Priority: Economically Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: Yes
Unfunded Mandates: Private Sector
CFR Citation: 21 CFR 314.50; 21 CFR 601.12; 21 CFR 314.94; 21 CFR 314.96 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 355; 21 USC 371; 42 USC 262
Legal Deadline: None

Regulatory Plan:

Statement of Need: Before a drug is approved for marketing, FDA must determine that the drug is safe and effective for its intended use. This determination is based in part on clinical study data and bioequivalence data that are submitted as part of the marketing application. Study data submitted to FDA in electronic format have generally been more efficient to process and review. FDA's proposed rule would address the submission of study data in a standardized electronic format. Electronic submission of study data would improve patient safety and enhance health care delivery by enabling FDA to process, review, and archive data more efficiently. Standardization would also enhance the ability to share study data and communicate results. Investigators and industry would benefit from the use of standards throughout the lifecycle of a study--in data collection, reporting, and analysis. The proposal would work in concert with ongoing Agency and national initiatives to support increased use of electronic technology as a means to improve patient safety and enhance health care delivery.

Legal Basis: Our legal authority to amend our regulations governing the submission and format of clinical study data and bioequivalence data for human drugs and biologics derives from sections 505 and 701 of the Act (U.S.C. 355 and 371) and section 351 of the Public Health Service Act (42 U.S.C. 262).

Alternatives: FDA considered issuing a guidance document outlining the electronic submission and the standardization of study data, but not requiring electronic submission of the data in the standardized format. This alternative was rejected because the Agency would not fully benefit from standardization until it became the industry standard, which could take up to 20 years. We also considered a number of different implementation scenarios, from shorter to longer time-periods. The 2-year time-period was selected because the Agency believes it would provide ample time for applicants to comply without too long a delay in the effective date. A longer time-period would delay the benefit from the increased efficiencies, such as standardization of review tools across applications, and the incremental cost savings to industry would be small.

Costs and Benefits: Standardization of clinical data structure, terminology, and code sets will increase the efficiency of the Agency review process. FDA estimates that the costs resulting from the proposal would include substantial one-time costs, additional waves of one-time costs as standards mature, and possibly some annual recurring costs. One-time costs would include, among other things, the cost of converting data to standard structures, terminology, and cost sets (i.e., purchase of software to convert data); the cost of submitting electronic data (i.e., purchase of file transfer programs); and the cost of installing and validating the software and training personnel. Additional annual recurring costs may result from software purchases and licensing agreements for use of proprietary terminologies. The proposal could result in many long-term benefits associated with reduced time for preparing applications, including reduced preparation costs and faster time to market for beneficial products. In addition, the proposed rule would improve patient safety through faster, more efficient, comprehensive and accurate data review, as well as enhanced communication among sponsors and clinicians.

Risks: None.

Timetable:

Action	Date	FR Cite
NPRM	06/00/2011	

Regulatory Flexibility Analysis Required: Business Government Levels Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF31

View Related Documents

Title: Over-the-Counter (OTC) Drug Review--Cough/Cold (Antihistamine) Products
Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action addresses antihistamine labeling claims for the common cold.

Priority: Substantive, Nonsignificant Agenda Stage of Rulemaking: Proposed Rule
Major: No Unfunded Mandates: No
CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Reopening of Administrative Record	08/25/2000	65 FR 51780
NPRM (Amendment) (Common Cold)	10/00/2011	

Regulatory Flexibility Analysis Required: Business Government Levels Affected: Local; State
Federalism: Yes
Related RINs: Split From 0910-AA01
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF36

View Related Documents

Title: Over-the-Counter (OTC) Drug Review--Internal Analgesic Products
Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. The first action addresses products labeled to relieve upset stomach associated with overindulgence in food and drink and to relieve symptoms associated with a hangover. The second action addresses acetaminophen safety. The third action addresses products marketed for children under 2 years old and weight- and age-based dosing for children's products. The fourth action addresses combination products

containing the analgesic acetaminophen or aspirin and sodium bicarbonate used as an antacid ingredient. The last document finalizes the internal analgesic products monograph.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371; 21 USC 374; 21 USC 379e
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Final Action (Internal Analgesics)	00/00/0000	
NPRM (Amendment) (Sodium Bicarbonate)	00/00/0000	
NPRM (Amendment) (Pediatric)	00/00/0000	
NPRM (Overindulgence/Hangover)	00/00/0000	
NPRM (Amendment) (Required Warnings and Other Labeling)	12/26/2006	71 FR 77314
NPRM Comment Period End	05/25/2007	
Final Action (Required Warnings and Other Labeling)	04/29/2009	74 FR 19385
Final Action (Correction)	06/30/2009	74 FR 31177
Final Action (Technical Amendment)	11/25/2009	74 FR 61512
NPRM (Acetaminophen)	03/00/2011	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: Local; State
Federalism: Yes
Related RINs: Split From 0910-AA01
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
RIN: 0910-AF38

View Related Documents

Title: Over-the-Counter (OTC) Drug Review--Laxative Drug Products
Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. The first NPRM listed will address the professional labeling for sodium phosphate drug products. The second NPRM listed will address all other professional labeling requirements for laxative drug products. The final action will address laxative drug products.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360 to 360a; 21 USC 371 to 371a
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM (Professional Labeling)	00/00/0000	
Final Action (Laxative Drug Products)	00/00/0000	

Final Action (Granular Psyllium)	03/29/2007	72 FR 14669
NPRM (Professional Labeling--Sodium Phosphate)	12/00/2010	

Regulatory Flexibility Analysis Required: Business Government Levels Affected: Local; State
Federalism: Yes
Related RINs: Split From 0910-AA01
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF43

View Related Documents

Title: Over-the-Counter (OTC) Drug Review--Sunscreen Products

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. The first action addresses active ingredients reviewed under Time and Extent Applications. The second action addresses other safety and effectiveness issues for OTC sunscreen drug products. The third action finalizes sunscreen labeling and testing requirements for both ultraviolet B and ultraviolet A radiation protection. The fourth action addresses the safety of sunscreen products. The last action addresses combination products containing sunscreen and insect repellent ingredients.

Priority: Economically Significant Agenda Stage of Rulemaking: Proposed Rule
Major: Yes Unfunded Mandates: No
CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM (Sunscreen and Insect Repellent)	00/00/0000	
ANPRM (Sunscreen and Insect Repellent)	02/22/2007	72 FR 7941
ANPRM Comment Period End	05/23/2007	
NPRM (UVA/UVB)	08/27/2007	72 FR 49070
NPRM Comment Period End	12/26/2007	
NPRM (Safety and Effectiveness)	12/00/2010	
Final Action (UVA/UVB)	12/00/2010	
ANPRM (Safety)	04/00/2011	
NPRM (Time and Extent Applications)	04/00/2011	

Additional Information: The proposed rule is economically significant and a major rule (reviewed under 0910-ZA39). The final rule is not economically significant nor a major rule.

Regulatory Flexibility Analysis Required: Business Government Levels Affected: Local; State
Federalism: Yes
Related RINs: Split From 0910-AA01
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF68

View Related Documents

Title: Over-the-Counter (OTC) Drug Review--Poison Treatment Drug Products

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

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM (Ipecac)	03/00/2011	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: Local; State
Federalism: Yes
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF69

View Related Documents

Title: Over-the-Counter (OTC) Drug Review--Topical Antimicrobial Drug Products

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. The first action addresses food handler products. The second action addresses testing requirements for healthcare professional products. The third action addresses the safety and effectiveness of consumer products. The final actions listed will address the healthcare, consumer, food handlers, and first aid antiseptic drug products respectively.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371
Legal Deadline: None

Timetable:

Action	Date	FR Cite

Final Action (Food Handlers)	00/00/0000	
Final Action (First Aid Antiseptic)	00/00/0000	
Final Action (Consumer)	00/00/0000	
Final Action (Healthcare)	00/00/0000	
NPRM (Testing -- Healthcare Professional Products)	00/00/0000	
NPRM (Food Handlers)	00/00/0000	
NPRM (Healthcare)	06/17/1994	59 FR 31402
NPRM (Consumer)	03/00/2011	

Regulatory Flexibility Analysis Required: Business Government Levels Affected: Local; State
Federalism: Yes
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF78

View Related Documents

Title: Import Tolerances for Residues of Unapproved New Animal Drugs in Food
Abstract: The Food and Drug Administration (FDA) plans to publish a proposed rule related to the implementation of the import tolerances provision of the Animal Drug Availability Act of 1996 (ADAA). The ADAA authorizes FDA to establish tolerances for unapproved new animal drugs where edible portions of animals imported into the United States may contain residues of such drugs (import tolerances). It is unlawful to import animal-derived food that bears or contains residues of a new animal drug that is not approved in the United States, unless FDA has established an import tolerance for that new animal drug and the residue of the new animal drug in the animal-derived food does not exceed that tolerance.

Priority: Substantive, Nonsignificant Agenda Stage of Rulemaking: Proposed Rule
Major: No Unfunded Mandates: No
CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 360b(a)(6); 21 USC 371
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	03/00/2011	
NPRM Comment Period End	06/00/2011	

Regulatory Flexibility Analysis Required: Business Government Levels Affected: No
Federalism: No
Energy Affected: No
International Impacts: This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF87

View Related Documents

Title: Laser Products; Amendment to Performance Standard

Abstract: FDA is proposing to amend the performance standard for laser products to achieve closer harmonization between the current standard and the International Electrotechnical Commission (IEC) standard for laser products and medical laser products. The proposed amendment is intended to update FDA's performance standard to reflect advancements in technology. The proposal would adopt portions of an IEC standard to achieve greater harmonization and reflect current science. In addition, the proposal would include an alternative mechanism for providing certification and identification, address novelty laser products, and clarify the military exemption for laser products.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 1002; 21 CFR 1010; 21 CFR 1040 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 360hh to 360ss; 21 USC 371; 21 USC 393
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	06/00/2011	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: No
Federalism: No
Energy Affected: Undetermined
International Impacts: This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF89

View Related Documents

Title: Regulations on Fixed-Dose Combination and Co-Packaged Drug and/or Biological Products

Abstract: The proposed rule would amend FDA regulations on fixed-combination prescription and over-the-counter (OTC) drugs. The current regulations require, among other things, that the sponsor of a fixed-combination drug demonstrate that each of the components makes a contribution to the drug's claimed effects. The proposed rule would create a single set of regulations for prescription and OTC combination drugs, and codify existing policy on what kinds of studies are needed to show that the combination drug requirements are met. The proposed rule also would: Apply these regulations to combinations of biological drug products and to drug-biological product combinations; clarify application of FDA's requirements regarding fixed-dose combinations to certain natural source drugs and certain synthetic drugs; establish circumstances under which the agency might waive the combination requirements for a particular drug or biological product; and address the issue of co-packaging.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 300.50; 21 CFR 330.10; 21 CFR 610.17 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 331; 21 USC 351 and 352; 21 USC 355; 21 USC 371; 42 USC 262; 42 USC 264

Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	01/00/2011	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF97

View Related Documents

Title: Proposed Revisions To Implement Portions of Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and Other Changes

Abstract: Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108-173) (MMA) amended provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that govern the approval of new drug applications (NDAs), described by section 505(b)(2) of the Act (505(b)(2) applications); and abbreviated new drug applications (ANDAs), described by section 505(j) of the Act. This proposed rule would implement portions of title XI of the MMA that pertain to: (1) Provision of notice to each patent owner and the NDA holder of certain patent certifications made by applicants submitting 505(b)(2) applications or ANDAs; (2) the availability of 30-month stays of approval on 505(b)(2) applications and ANDAs that are otherwise ready to be approved; (3) submission of amendments and supplements to 505(b)(2) applications and ANDAs; and (4) the types of bioavailability and bioequivalence data that can be used to support these applications. This proposed rule also would amend certain regulations regarding 505(b)(2) applications and ANDAs to facilitate compliance with and efficient enforcement of the Act. This proposed rule also would amend certain regulations regarding 505(b)(2) applications and ANDAs, including regulations related to certain patent certification requirements, identification of the listed drug relied upon, and suitability petitions, to facilitate compliance with and efficient enforcement of the Act.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: Undetermined
Unfunded Mandates: No

CFR Citation: 21 CFR 314.3; 21 CFR 314.50; 21 CFR 314.52; 21 CFR 314.53; 21 CFR 314.54; 21 CFR 314.60; 21 CFR 314.70; 21 CFR 314.90; 21 CFR 314.93; 21 CFR 314.94; 21 CFR 314.95; 21 CFR 314.96; 21 CFR 314.97; 21 CFR 314.99; 21 CFR 314.101; 21 CFR 314.105; 21 CFR 314.107; 21 CFR 314.108; 21 CFR 314.125; 21 CFR 314.127; 21 CFR 320.1; 21 CFR 320.23 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: PL 108-173, title XI; 21 USC 355; 21 USC 371

Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	04/00/2011	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: No
Federalism: No

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AG07

View Related Documents

Title: Conditional Approval of New Animal Drugs for Minor Use and Minor Species

Abstract: This proposed rule implements section 571 of the Food, Drug, and Cosmetic Act. The Minor Use and Minor Species Animal Health Act of 2004 (MUMS act) added three sections to the Federal Food, Drug, and Cosmetic Act (the Act) (571, 572, and 573), and it established new regulatory procedures intended to make more medications legally available to veterinarians and animal owners for the treatment of minor animal species, as well as uncommon diseases in major animal species. Section 571 of the Act provides for animal drug conditional approval after all safety and manufacturing components of a new animal drug approval have met the standards of section 512 of the Act. For the effectiveness component of a new animal drug review, a reasonable expectation of effectiveness must be established prior to conditional approval under section 571 of the Act. Sponsors then have up to 5 years to complete the demonstration of effectiveness by the standards of section 512 of the Act and achieve a complete new animal drug approval.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 516 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 360ccc; 21 USC 371
Legal Deadline:

Action	Source	Description	Date
NPRM	Statutory		02/00/2011

Timetable:

Action	Date	FR Cite
NPRM	03/00/2011	
NPRM Comment Period End	06/00/2011	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: Business
Federalism: No
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AG08

View Related Documents

Title: Ingredient Standards and Definitions for Animal Foods

Abstract: The President signed into law the Food and Drug Administration Amendments Act of 2007 (FDAAA) on September 27, 2007. The FDAAA includes several provisions pertaining to food safety, including the safety of pet food. FDAAA section 1002(a)(1) directs FDA to promulgate regulations within 2 years to establish pet food ingredient standards and definitions. FDA plans to publish a proposed rule to establish standards for certain substances used in animal foods, to define which ingredient names shall be used on animal food labeling, and to add a new collective name for certain feed ingredients. This same provision of the law also directs that, in developing these new regulations, FDA consult with the Association of American Feed Control Officials and other relevant stakeholder groups, including veterinary medical associations, animal health organizations,

and pet food manufacturers.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 341; 21 USC 371; PL 110-85, sec 1002(a)(1)
Legal Deadline:

Action	Source	Description	Date
Other	Statutory	FDA must issue proposed and final regulations by the statutory deadline.	09/27/2009

Timetable:

Action	Date	FR Cite
NPRM	03/00/2011	
NPRM Comment Period End	06/00/2011	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: No
Federalism: No
International Impacts: This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
RIN: 0910-AG09

View Related Documents

Title: Pet Food Labeling Requirements
Abstract: The President signed into law the Food and Drug Administration Amendments Act of 2007 (FDAAA) on September 27, 2007 (Pub. L. 110-85). Title X of the FDAAA includes several provisions pertaining to food safety, including the safety of pet food. Section 1002(a) of the new law directs FDA to issue new regulations to establish updated standards for the labeling of pet food that include nutritional and ingredient information. This same provision of the law also directs that, in developing these new regulations, FDA obtain input from its stakeholders, including the Association of American Feed Control Officials, veterinary medical associations, animal health organizations, and pet food manufacturers.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 343; 21 USC 371; PL 110-85, sec 1002(a)(3)
Legal Deadline:

Action	Source	Description	Date
Other	Statutory	FDA is directed to issue proposed and final regulations by the statutory deadline.	09/27/2009

Timetable:

Action	Date	FR Cite
NPRM	03/00/2011	
NPRM Comment Period End	06/00/2011	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: No
Federalism: No
Energy Affected: No

International Impacts: This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AG10

View Related Documents

Title: Process Controls for Animal Feed Ingredients and Mixed Animal Feed

Abstract: The Food and Drug Administration (FDA) is proposing regulations for process controls for animal feed ingredients and mixed animal feed to provide greater assurance that marketed animal feed ingredients and mixed feeds intended for all animals, including pets, are safe. This action is being taken as part of the FDA's Animal Feed Safety System initiative. The proposed process controls will apply to animal feed ingredients and mixed animal feed, including pet food. This action is also being taken to carry out the requirements of the Food and Drug Administration Amendments Act of 2007. Section 1002(a) directs FDA to establish by regulation processing standards for pet food. This same provision of the law also directs that, in developing these new regulations, FDA obtain input from its stakeholders, including the Association of American Feed Control Officials, veterinary medical associations, animal health organizations, and pet food manufacturers.

Priority: Economically Significant Agenda Stage of Rulemaking: Proposed Rule
Major: Yes Unfunded Mandates: No
CFR Citation: 21 CFR 228 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 342; 21 USC 350e; 21 USC 371; 21 USC 374; 42 USC 264; PL 110-85, sec 1002(a)(2)
Legal Deadline:

Action	Source	Description	Date
Other	Statutory	FDA is directed to issue proposed and final regulations by the statutory deadline.	09/27/2009

Timetable:

Action	Date	FR Cite
NPRM	03/00/2011	
NPRM Comment Period End	06/00/2011	

Regulatory Flexibility Analysis Required: Business Government Levels Affected: No
Federalism: No
International Impacts: This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AG12

View Related Documents

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

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a monograph is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action will propose changes to the final monograph to address safety and efficacy issues associated with pediatric cough and cold products.

Priority: Economically Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: Yes
Unfunded Mandates: Private Sector
CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	06/00/2011	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: Local; State
Federalism: Yes
Energy Affected: No
International Impacts: This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.
Related RINs: Related to 0910-AF31; Related to 0910-AF32; Related to 0910-AF33; Related to 0910-AF34
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
RIN: 0910-AG16

View Related Documents

Title: Amendments to Sterility Testing Requirements for Biological Products
Abstract: The Food and Drug Administration (FDA) is issuing a proposed rule to amend the sterility testing requirements for biological products. This proposed rule is intended to provide manufacturers of biological products greater flexibility and to encourage use of the most appropriate and state-of-the-art methodologies to ensure the safety of biological products.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 600; 21 CFR 610; 21 CFR 680 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351; 21 USC 352; 21 USC 353; 21 USC 355; 21 USC 360; 21 USC 360c; 21 USC 360d; 21 USC 360h; 21 USC 360i; 21 USC 371; 21 USC 372; 21 USC 374; 21 USC 381; 42 USC 216; 42 USC 262; 42 USC 263; 42 USC 263a; 42 USC 264; ...
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	09/00/2011	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Federalism: No
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AG17

View Related Documents

Title: New Animal Drugs: Updating Tolerances for Residues in New Animal Drugs in Food

Abstract: FDA is proposing to revise 21 CFR 556 to reformat the listings of tolerances for residues of approved new animal drugs in food. Currently, part 556 employs a patchwork of various styles for listing tolerances that have evolved over the past 40 years as each additional animal drug has been approved. The listings in part 556 are not uniform in format, and FDA does not always provide relevant information in a clear and straightforward manner. For example, FDA provides the acceptable daily intake (ADI) and safe concentrations for some, but not all drugs; FDA lists some tolerances as being for "negligible" residues; and FDA presents some listings in a text paragraph format while others are presented in outline form. Moreover, sometimes FDA specifies "no residue," "zero tolerance," or tolerance "not required," but does not define or make distinction between these important terms. This revision will standardize, simplify, and clarify these listings and improve the readability of the regulations.

Priority: Routine and Frequent
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 556 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 342; 21 USC 360b; 21 USC 371
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	03/00/2011	
NPRM Comment Period End	06/00/2011	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AG18

View Related Documents

Title: Electronic Distribution of Content of Labeling for Human Prescription Drug and Biological Products

Abstract: This rule would require electronic package inserts for human drug and biological prescription products, 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.

Priority: Economically Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: Yes
Unfunded Mandates: Private Sector
CFR Citation: 21 CFR 201.100; 21 CFR 201.306; 21 CFR 201.310 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351; 21 USC 352; 21 USC 353; 21 USC 355; 21 USC 358; 21 USC

360; 21 USC 360b; 21 USC 360gg to 360ss; 21 USC 371; 21 USC 374; 21 USC 379e; 42 USC 216; 42 USC 241; 42 USC 262; 42 USC 264

Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	04/00/2011	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: No
Federalism: No
Energy Affected: No

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AG20

View Related Documents

Title: Amendment to the Current Good Manufacturing Practice Regulations for Finished Pharmaceuticals

Abstract: The Food and Drug Administration (FDA) periodically reassesses and revises the cGMP regulations to accommodate advances in technology and other scientific knowledge that further safeguard the drug manufacturing process and the public health. In August 2002, FDA announced the Pharmaceutical cGMPs for the 21st Century Initiative. As part of the Initiative, FDA created a cGMP Harmonization Analysis Working Group to analyze related cGMP requirements in the United States and internationally. The cGMP working group compared 21 CFR parts 210 and 211 with the cGMPs of the European Union, as well as other FDA regulations (such as the Quality Systems Regulation in 21 CFR part 820) to identify differences and consider the value of supplementing or changing the current regulations. Based on the cGMP Working Group's analysis, FDA decided to take an incremental approach to modifying 21 CFR parts 210 and 211. In September of 2008, FDA published a final rule revising the cGMP regulations primarily in the areas of aseptic processing, use of asbestos filters, and verification of operations by a second individual; this final rule represented the culmination of the first increment of modifications to the cGMP regulations. The proposed rule identified on this Unified Agenda would begin the second increment of modifications to the cGMP regulations.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Proposed Rule
Major: Undetermined
Unfunded Mandates: Undetermined
CFR Citation: 21 CFR 210; 21 CFR 211 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321; 21 USC 351; 21 USC 352; 21 USC 355; 21 USC 360b; 21 USC 371; 21 USC 374; 42 USC 216; 42 USC 262; 42 USC 263a; 42 USC 264
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	10/00/2011	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: Undetermined
Small Entities Affected: Business
Federalism: No
Energy Affected: Undetermined

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AG26

View Related Documents

Title: Amendments to Regulations on Citizen Petitions, Petitions for Stay of Action, and Submission of Documents to Dockets; Implementation of Section 505(q) of the Federal Food, Drug, and Cosmetic Act

Abstract: The Food and Drug Administration (FDA) is proposing to amend certain regulations relating to citizen petitions, petitions for stay of action, and the submission of documents to the agency. We are making these changes to implement certain provisions of section 914 of title IX of the Food and Drug Administration Amendments Act, which added section 505(q) to the Federal Food, Drug, and Cosmetic Act (the Act). In particular, the proposed rule would establish new regulations to implement section 505(q) of the Act, which concerns certain citizen petitions and petitions for stay of action that involve a request for FDA to take any form of action relating to a pending application submitted under section 505(b)(2) or (j) of the Act. In particular, this proposal would codify the certification specified in section 505(q)(1)(H) that applies to initial citizen petitions and petitions for stay of action. In addition, the proposal would codify the verification specified in section 505(q)(1)(I) that applies to supplemental information or comments on a citizen petition or petition for stay of action. To avoid altering the meaning of the certification and verification specified in 505(q)(1)(H) and 505(q)(1)(I), respectively, we are proposing to require that petitioners submit the exact statutory language of the certification and verification.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 10.20; 21 CFR 10.30 and 10.31; 21 CFR 10.35; ... (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 505
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	03/00/2011	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: No
Federalism: No
Energy Affected: No

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AG28

View Related Documents

Title: Animal Drugs, Feeds, and Related Products; Regulation of Carcinogenic Compounds in Food-Producing Animals

Abstract: The Food and Drug Administration (FDA) plans to publish a proposed rule to amend the regulations regarding compounds of carcinogenic concern used in food-producing animals. No food additive or drug can be deemed safe for use in a food if it is found to induce cancer in man or animals. An exception can be made if it can be found that (1) an animal feed additive or veterinary drug will not adversely affect the animal and (2) no residue of the animal feed additive or veterinary drug will be found in any edible portion of that animal. The approach permits the determination of the quantity of residues of

carcinogenic concern in edible tissues (e.g. meat) that may be consumed daily by the human consumer with no significant increase in the risk of cancer. This quantity is termed the So. The So quantity is expressed as the concentration of residue of carcinogenic concern in the total diet that can safely be consumed by humans over a lifetime. The total diet refers to the daily 1500g typically consumed, of which 500g is assumed to come from meat. The So is typically presented as mg per person per day, or mg per kg body weight per day. The So is currently defined by regulation primarily as the concentration of the carcinogenic compound that corresponds to a maximum lifetime risk to the test animals of 1 in 1 million, and secondarily as corresponding to the concentration of residue of carcinogenic concern in the total human diet that represents no significant increase in the risk of cancer to people. FDA believes that a careful reading of the December 31, 1987, final rule (52 FR 49586) suggests that an emphasis on no significant increase in the risk of cancer to the human consumer, rather than on the specific 1 in 1 million approach, reflects the original intent of the regulation. Specifically, FDA is proposing a revision to the definition of So for clarification purposes so that the term primarily means the concentration of residue of carcinogenic concern in the total human diet that represents no significant increase in the risk of cancer to the human consumer and secondarily corresponds to the concentration of test compound in the total diet of test animals that corresponds to a maximum lifetime risk of cancer in the test animals of 1 in 1 million. FDA is also proposing a redefinition of Sm to conform to the revised definition of So. The total quantity of residues of carcinogenic concern in edible tissues derived from the So is termed the Sm. The Sm quantity is expressed as the total concentration of residues of carcinogenic concern in food which, when eaten at a given consumption rate, would not exceed the So. Specifically, FDA is proposing that Sm would mean the concentration of a residue of carcinogenic concern in a specific edible tissue corresponding to no significant increase in the risk of cancer to the human consumer, thus aligning more closely with the primary definition of So. These changes reflect advances in scientific technology. Other clarifying and conforming changes are also being proposed.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 500.82 and 500.84 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 360b(d)(1)(I)
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	03/00/2011	
NPRM Comment Period End	06/00/2011	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Federalism: No

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
RIN: 0910-AG30

View Related Documents

Title: Sunlamp Products; Proposed Amendment to the Performance Standard

Abstract: The Food and Drug Aministration's (FDA's) Center for Devices and Radiological Health (CDRH) intends to amend its standard for sunlamp products (21 CFR 1040.20). The sunlamp standard was promulgated in 1979, and FDA has not issued any amendments since 1985. CDRH issued two “Policy Letters” in 1985 and 1986, outlining FDA policy and providing a recommended exposure schedule. In 1999, FDA published an advanced notice of proposed rulemaking (ANPRM) that sought input on several proposed changes to the FDA performance standard for sunlamp products. The agency received 27 comments to the ANPRM. A summary is available on request. FDA plans to update the performance standard for sunlamp products to improve safety, reflect new scientific information, and work towards harmonization with international standards. FDA scientists have participated in amendments to the International Electrotechnical Commission's (IEC) international standard, IEC 60335-2-27, over the past 10 years. There are many elements of the IEC standard which FDA is considering adopting in our standard. Adopting specific elements of the IEC standard by reference would allow the agency to take advantage of the expertise of the international committees involved in the modernization of the international standard, and thus save agency resources. FDA also

plans to include changes to the required warning label.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 1040.20 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: Not Yet Determined
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	09/00/2011	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: Undetermined
Federalism: Undetermined
Energy Affected: No
International Impacts: This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
RIN: 0910-AG31

View Related Documents

Title: Unique Device Identification

Abstract: The Food and Drug Administration Amendments Act of 2007, amended the Federal Food, Drug, and Cosmetic Act by adding section 519(f) (21 U.S.C. 360i(f)). This section requires FDA to promulgate regulations establishing a unique identification system for medical devices requiring the label of medical devices to bear a unique identifier, unless FDA specifies an alternative placement or provides for exceptions. The unique identifier must adequately identify the device through distribution and use, and may include information on the lot or serial number.

Priority: Economically Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: Yes
Unfunded Mandates: Undetermined
CFR Citation: 21 CFR 16, 801, 803, 806, 810, 814, 820, 821, (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 15 USC 1451 to 1461; 21 USC 141 to 149, 321 to 394, 467f, 679, 821, 1034; 28 USC 2112; 42 USC 201 to 262, 263a and 263b, 264, 271, 364
Legal Deadline: None

Regulatory Plan:

Statement of Need: A unique device identification system will help reduce medical errors; will allow FDA, the healthcare community, and industry to more rapidly review and organize adverse event reports; identify problems relating to a particular device (even down to a particular lot or batch, range of serial numbers, or range of manufacturing or expiration dates); and thereby allow for more rapid, effective, corrective actions that focus sharply on the specific devices that are of concern.

Legal Basis: This rule is provided for/mandated by FDAAA. Section 519(f) of the FD&C Act (added by sec. 226 of the Food and Drug Administration Amendments Act of 2007) directs the Secretary to promulgate regulations establishing a unique device identification (UDI) system for medical devices, requiring the label of devices to bear a unique identifier that will adequately identify the device through its distribution and use.

Alternatives: FDA considered several alternatives that allow certain requirements of the proposed rule to vary, such as the

required elements of a UDI and the scope of affected devices.

Costs and Benefits: FDA estimates that the affected industry would incur one-time and recurring costs, including administrative costs, to change and print labels that include the required elements of a UDI, costs to purchase equipment to print and verify the UDI, and costs to purchase software, integrate and validate the UDI into existing IT systems. Certain entities would be required to submit information about each UDI and the relevant medical device into a database, FDA would incur costs to develop, implement, and administer a database that would serve as a repository of information to facilitate the identification of medical devices through their distribution and use. FDA anticipates that implementation of a UDI system would help improve the efficiency of recalled medical devices and medical device adverse event reporting. The proposed rule would also standardize how medical devices are identified and contribute to future potential public health benefits of initiatives aimed at optimizing the use of automated systems in healthcare. Most of these benefits, however, require complementary developments and innovations in the private and public sectors.

Risks: This rule is intended to substantially eliminate existing obstacles to the adequate identification of medical devices used in the Unites States. By providing the means to rapidly and definitely identify a device and key attributes that affect its safe and effective use, the rule would reduce medical errors that result from misidentification of a device or confusion concerning its appropriate use. The rule will fulfill a statutory directive to establish a unique device identification system.

Timetable:

Action	Date	FR Cite
NPRM	06/00/2011	

Regulatory Flexibility Analysis Required: Business Government Levels Affected: Undetermined

Federalism: Undetermined

Energy Affected: No

International Impacts: This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AG37

View Related Documents

Title: Additions to the List of Tropical Diseases in Section 524 of the Federal Food, Drug, and Cosmetic Act

Abstract: Section 524 of the Federal Food, Drug, and Cosmetic Act (21 USC 360n), “Priority Review to Encourage Treatments for Tropical Diseases,” provides authority for the Food and Drug Administration to award to the sponsor of a tropical disease product application, defined in section 524(a)(4), a priority review voucher, entitling the sponsor to priority review of a single human drug application that is unrelated to the tropical disease product application. The term “tropical disease” means any of the diseases listed in section 524(a)(3), and “any other infectious disease for which there is no significant market in developed nations and that disproportionately affects poor and marginalized populations, designated by regulation by the Secretary.” The proposed rule will designate tropical diseases to be added to the list in accordance with section 524(a)(3)(Q).

Priority: Other Significant Agenda Stage of Rulemaking: Proposed Rule

Major: No Unfunded Mandates: No

CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: 21 USC 360n

Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	03/00/2011	

Regulatory Flexibility Analysis Required: No Government Levels Affected: No

Small Entities Affected: No
Federalism: No
Energy Affected: No
International Impacts: This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
RIN: 0910-AG38

View Related Documents

Title: Cigars Subject to the Family Smoking Prevention and Tobacco Control Act
Abstract: The Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act) provides FDA authority to regulate cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. Section 901 of the Federal Food, Drug, and Cosmetic Act, as amended by the Tobacco Control Act, permits FDA to issue regulations deeming other tobacco products to be subject to the Tobacco Control Act. This proposed rule would deem cigars to be subject to the Tobacco Control Act and include provisions to address public health concerns raised by cigars.

Priority: Economically Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: Yes
Unfunded Mandates: Undetermined
CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 301 et seq, The Federal Food, Drug, and Cosmetic Act; PL 111-31, The Family Smoking Prevention and Tobacco Control Act
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	06/00/2011	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: Undetermined
Federalism: Undetermined
International Impacts: This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
RIN: 0910-AG39

View Related Documents

Title: Tobacco Product Substantial Equivalence Exemptions
Abstract: This rule implements the substantial equivalence exemption provision of the Family Smoking Prevention and Tobacco Control Act. The Secretary may exempt from the requirements relating to demonstration that a tobacco product is

substantially equivalent, tobacco products that are modified by adding or deleting a tobacco additive or increasing or decreasing the quantity of an existing tobacco additive, if the Secretary determines the modification would be a minor modification of a tobacco product that can be sold under the law, a report is not necessary to ensure that permitting the tobacco product to be marketed would be appropriate for protection of the public health, and an exemption is otherwise appropriate.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: Undetermined
Unfunded Mandates: Undetermined
CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 111-31, sec 101(b)(3), The Family Smoking Prevention and Tobacco Control Act
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		07/01/2011

Timetable:

Action	Date	FR Cite
NPRM	12/00/2010	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: Undetermined
Small Entities Affected: Business
Federalism: Undetermined
International Impacts: This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
RIN: 0910-AG40

View Related Documents

Title: Amendment to Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents

Abstract: Section 102 of the Family Smoking Prevention and Tobacco Control Act (FSPTCA) requires the Secretary to publish a final rule regarding cigarettes and smokeless tobacco identical in its provisions to the regulations promulgated by FDA in 1996 (61 FR 44396, August 28, 1996) (1996 final rule), with certain specified exceptions. In the re-issued 1996 rule, 21 CFR 1140.16(a) is identical to section 897.16(a) in the 1996 final rule. Section 102(a)(3) and (4) of the FSPTCA give FDA the authority to amend the rule in accordance with the Administrative Procedure Act (5 U.S.C. Chapter 5). FDA is proposing to amend 21 CFR 1140.16(a), which became effective June 22, 2010, to allow the manufacturer of a cigarette or smokeless tobacco product with a trade or brand name that is also the trade or brand name of a nontobacco product to continue to use the name if the tobacco product was sold in the United States on or before June 22, 2009. FDA is evaluating whether further changes to 21 CFR 1140.16(a) are warranted.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 1140 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 301 et seq, The Federal Food, Drug, and Cosmetic Act; PL 111-31, The Family Smoking Prevention and Tobacco Control Act
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	05/00/2011	
NPRM Comment Period End	08/00/2011	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: No

Federalism: No

Related RINs: Related to 0910-AG33

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AG41

View Related Documents

Title: Cigarette Warning Label Statements

Abstract: Section 4 of the FCLAA, as amended by section 201 of the Tobacco Control Act, requires FDA to issue regulations that require color graphics depicting the negative health consequences of smoking to accompany required warning statements. FDA also may adjust the type size, text and format of the required label statements on product packaging and advertising if FDA determines that it is appropriate so that both the graphics and the accompanying label statements are clear, conspicuous, legible and appear within the specified area.

Priority: Economically Significant

Agenda Stage of Rulemaking: Proposed Rule

Major: Yes

Unfunded Mandates: Private Sector

CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: PL 111-31, The Family Smoking Prevention and Tobacco Control Act, sec 201

Legal Deadline: Section 4 of the Federal Cigarette Labeling and Advertising Act (FCLAA), as amended by section 201 of the Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act), requires FDA to issue regulations no later than 24 months after the date of enactment of the Tobacco Control Act that require color graphics depicting the negative health consequences of smoking.

Action	Source	Description	Date
Other	Statutory		06/22/2011

Regulatory Plan:

Statement of Need: This proposed rule is necessary to amend FDA's regulations to add a new requirement for the display of health warnings on cigarette packages and in cigarette advertisements and to specify the color graphics that must accompany each textual warning statement.

Legal Basis: The proposed rule would implement a provision of the Tobacco Control Act that requires FDA to issue regulations requiring color graphics depicting the negative health consequences of smoking to accompany the nine new textual warning statements that will be required under the Tobacco Control Act. The Tobacco Control Act amends the FCLAA to require each cigarette package and advertisement to bear one of nine new textual warning statements.

Alternatives: The Agency will compare the proposed rule to two hypothetical alternatives: An otherwise identical rule with a 24-month compliance period and an otherwise identical rule with a 6-month compliance period. Although we will compare the rule to two hypothetical alternatives, they are not viable regulatory options as they are inconsistent with FDA’s statutory mandate.

Costs and Benefits: The largest benefits of this proposed rule stem from increased life expectancies for individuals who are induced not to smoke. Other quantifiable benefits come from reductions in cases of non-fatal emphysema, reductions in fire losses, and reductions in medical expenditures. Unquantifiable benefits come from reductions in smokers' non-fatal illnesses other than emphysema, reductions in passive smoking, and reductions in infant and child health effects due to mothers' smoking during pregnancy. Large, one-time costs will arise from the need to change cigarette package labels and remove point-of-sale promotions that do not comply with the new advertising restrictions. Additionally, there will be smaller ongoing FDA enforcement costs.

Risks: This proposed rule would reduce the risk to the public by helping to clearly and effectively convey the negative health consequences of smoking on cigarette packages and in cigarette advertisements, which would help both to discourage non-

smokers, including minor children, from initiating cigarette use and to encourage current smokers to consider cessation.

Timetable:

Action	Date	FR Cite
NPRM	11/12/2010	75 FR 69524
NPRM Comment Period End	01/11/2011	
Final Action	06/00/2011	

Regulatory Flexibility Analysis Required: Business Government Levels Affected: Undetermined

Federalism: No

Energy Affected: Undetermined

International Impacts: This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AG43

View Related Documents

Title: Sale and Distribution of Tobacco Products That Occur or Are Conducted Through a Means Other Than a Direct, Face-to-Face Exchange Between a Retailer and Consumer

Abstract: This rulemaking will address sale and distribution of tobacco products involving Internet and mail-order transactions, and other transactions that involve a means “other than a direct, face-to-face exchange between the retailer and consumer.” Examples of these types of transactions include: (1) Mail-order—e.g., a print ad in a magazine that includes a phone number and/or web address for ordering a tobacco product; and (2) Internet—e.g., standard websites, such as an official website of cigarette brand or company/firm websites.

Priority: Other Significant Agenda Stage of Rulemaking: Proposed Rule

Major: Undetermined Unfunded Mandates: Undetermined

CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: PL 111-31, section 906,The Family Smoking Prevention and Tobacco Control Act; 21 USC 301 et seq, section 387f, The Federal Food Drug and Cosmetic Act

Legal Deadline:

Action	Source	Description	Date
Other	Statutory	sec. 906(d)(4)(A)(i) of the Family Smoking Prevention and Tobacco Control Act	10/01/2011

Timetable:

Action	Date	FR Cite
NPRM	05/00/2011	

Regulatory Flexibility Analysis Required: Undetermined Government Levels Affected: Undetermined

Federalism: Undetermined

Energy Affected: Undetermined

International Impacts: This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AG44

View Related Documents

Title: Antimicrobial Active Ingredient Distribution Reports Under Section 105 of the Animal Drug User Fee Amendments of 2008

Abstract: Section 105 of the Animal Drug User Fee Amendments of 2008 (ADUFA) amended section 512 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360b) to require that the sponsor of each new animal drug that contains an antimicrobial agent submit an annual report to the Food and Drug Administration on the amount of each antimicrobial active ingredient in the drug that is sold or distributed for use in food-producing animals, including information on any distributor-labeled product. FDA recognizes the need for standardized reporting; thus, this direct final rule, with its companion proposal, is to mandate the use of an FDA form.

Priority: Info./Admin./Other
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 514.80 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 360b(1)(3)
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM/Direct Final Rule	03/00/2011	
NPRM Comment Period End	06/00/2011	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: No
Small Entities Affected: Business
Federalism: No

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AG45

View Related Documents

Title: Reports of Distribution and Sales Information for Antimicrobial Active Ingredients Used in Food-Producing Animals

Abstract: Section 105 of the Animal Drug User Fee Amendments of 2008 (ADUFA) amended section 512 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 USC 360b) to require that the sponsor of each new animal drug product that contains an antimicrobial agent submit an annual report to the Food and Drug Administration on the amount of each antimicrobial active ingredient in the drug product that is sold or distributed for use in food-producing animals, including information on any distributor-labeled product. This rulemaking is intended to establish the implementing regulations for this statutory provision. In addition, FDA is exploring the establishment of other requirements to provide for the collection of more useful drug distribution data.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No

CFR Citation: 21 CFR 514.80 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 360b(1)(3)
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	03/00/2011	
NPRM Comment Period End	07/00/2011	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: No
Small Entities Affected: Business
Federalism: No

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AG46

View Related Documents

Title: Abbreviated New Animal Drug Regulation

Abstract: The Generic Animal Drug and Patent Restoration Act (GADPTRA) amended section 512 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360b) to authorize abbreviated applications for the approval of a new animal drug. This rulemaking is intended to establish the implementing regulations for GADPTRA by proposing procedural requirements for the submission and approval of generic new animal drug applications.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 514 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351; 21 USC 352; 21 USC 356a; 21 USC 360b; 21 USC 371; 21 USC 379e; 21 USC 381
Legal Deadline:

Action	Source	Description	Date
NPRM	Statutory		11/16/1989

Timetable:

Action	Date	FR Cite
NPRM	03/00/2011	
NPRM Comment Period End	07/00/2011	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: No
Small Entities Affected: Business
Federalism: No

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AG48

View Related Documents

Title: Human Subject Protection; Acceptance of Clinical Studies Conducted Outside the United States

Abstract: The Food and Drug Administration (FDA) is proposing to amend its regulations on acceptance of data from clinical studies conducted outside the United States in support of a premarket approval application or a humanitarian device exemption application for a medical device. FDA is proposing to require that these studies be conducted in accordance with good clinical practice (GCP). FDA proposes to define GCP as a standard for the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials in a way that provides assurance that the data and reported results are credible and accurate, and that the rights, safety, and well-being of trial subjects are protected. GCP also would include review and approval by an independent ethics committee (IEC) before initiating a study, continuing IEC review of ongoing studies, and obtaining and documenting freely given informed consent of study subjects. FDA is also proposing to include requirements for the submission of clinical data in support of an investigational device exemption application and a premarket notification submission. The proposed changes will require a statement regarding compliance with FDA regulations for studies conducted in the United States and compliance with GCP for studies conducted outside the United States. With the above described changes, the proposed rule is intended to update the standards for the acceptance of clinical studies and to help to continue to ensure the protection of human subjects and the quality and integrity of data obtained from these studies.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: Not Yet Determined
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	09/00/2011	
NPRM Comment Period End	12/00/2011	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: Business
Federalism: No
International Impacts: This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AG49

View Related Documents

Title: Disqualification of a Clinical Investigator

Abstract: The Food and Drug Administration (FDA) is proposing to amend the regulations to expand the scope of clinical investigator disqualification. Under this proposal, when the Commissioner of Food and Drugs determines that an investigator is ineligible to receive certain investigational products such as drugs (including biologics), new animal drugs, or devices, the investigator also will be ineligible to conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by the FDA. This proposal is based in part upon recommendations from the Government Accountability Office. Also, this proposal harmonizes existing FDA investigator disqualification regulations. This proposal is intended to help ensure adequate protection of research subjects and the quality and integrity of data submitted to FDA.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No

CFR Citation: 21 CFR 16.1; 21 CFR 312.70; 21 CFR 511.1; 21 CFR 511.3 (new); 21 CFR 812.119 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 28 USC 2112; 42 USC 201 to 262; 21 USC 321 to 394; 42 USC 263b to 263n; ...
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	01/00/2011	
NPRM Comment Period End	04/00/2011	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Federalism: No

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AG50

View Related Documents

Title: Food Labeling; Dietary Guidance Statements

Abstract: This proposed rule would define dietary guidance statements as statements in food labeling about the usefulness of a food, or a category of foods in maintaining healthy dietary practices. Dietary guidance statements focus on general dietary patterns, practices, and recommendations that promote health. They may highlight the presence or amount of a food or category of foods in relation to a general health benefit or healthful diet or recommend the substitution of a food or food category that is consistent with current dietary recommendations for a food or food category that is less beneficial to health. The proposed rule would also establish requirements for making dietary guidance statements in food labeling. In addition, the proposed rule provides guidance on how dietary guidance statements differ from other types of food labeling claims.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: Undetermined
CFR Citation: 21 CFR 101.16 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321 and 331; 21 USC 343 and 371
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	03/00/2011	
NPRM Comment Period End	06/00/2011	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: Undetermined
Federalism: No

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AG52

View Related Documents

Title: Implementation of Sanitary Food Transportation Act of 2005

Abstract: The Food and Drug Administration (FDA) is issuing an advance notice of proposed rulemaking (ANPRM) to request data and information on the food transportation industry and its practices. FDA also is requesting data and information on the contamination of transported foods and any associated outbreaks. FDA is taking this action as part of its implementation of the Sanitary Food Transportation Act of 2005 (2005 SFTA), which requires the Secretary of Health and Human Services (HHS) to issue regulations setting forth sanitary transportation practices to be followed by shippers, carriers by motor vehicle or rail vehicle, receivers, and others engaged in food transport. This action is also part of a larger agency effort to focus on prevention of food safety problems throughout the food chain. The regulations would address the risks to human or animal health associated with the transportation of food.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 1 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 331; 21 USC 342; 21 USC 350e; 21 USC 371
Legal Deadline: None

Timetable:

Action	Date	FR Cite
ANPRM	04/30/2010	75 FR 22713
ANPRM Comment Period End	08/30/2010	
NPRM	09/00/2011	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AG53

View Related Documents

Title: Amendment to the CGTPs to Create Urgent Medical Need Exception for Distribution of Certain HCT/Ps That May Not Meet Release Criteria

Abstract: The Food and Drug Administration (FDA) is proposing to amend the current good tissue practice (CGTP) regulations to provide an exception in situations of documented urgent medical need for distribution of certain minimally manipulated human cells, tissues, and tissue-based products (HCT/Ps) for homologous use, which may not meet release criteria because of the potential or actual presence of bacteria or fungi. As part of this rulemaking, FDA also is proposing amendments to the CGTP regulations in connection with labeling and physician notification as to these HCT/Ps. This action is intended to enhance access to medically necessary products in cases of documented urgent medical need where there is no comparable HCT/P available and the treating physician has determined that the recipient is likely to suffer death or serious morbidity without the HCT/P.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 1271 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 243 and 264; 42 USC 262 and 271
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	09/00/2011	

Regulatory Flexibility Analysis Required: No Government Levels Affected: No
Federalism: No
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AG54

View Related Documents

Title: General Hospital and Personal Use Devices: Designation of Special Controls for Infusion Pumps
Abstract: Since 2003, FDA has seen a dramatic increase in the number of device recalls, as well as an increase in the number of death and serious injury reports submitted regarding infusion pumps. An analysis of the reports reveals that a majority of the recalls and failures were caused by user error and/or device design flaw. As a result of these incidents, FDA is proposing to designate a special controls guidance document as the special controls for infusion pumps. The agency believes that establishing these special controls for infusion pumps is necessary to provide reasonable assurance of the safety and effectiveness of these devices.

Priority: Substantive, Nonsignificant Agenda Stage of Rulemaking: Proposed Rule
Major: Undetermined Unfunded Mandates: No
CFR Citation: None (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 351 371; 21 USC 360 and 360c; 21 USC 360e and 360j; 21 USC 371
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	09/00/2011	
NPRM Comment Period End	12/00/2011	

Regulatory Flexibility Analysis Required: Business Government Levels Affected: Undetermined
Federalism: Undetermined
Energy Affected: No
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AG55

View Related Documents

Title: Amendments to the General Regulations of the Food and Drug Administration
Abstract: The Food and Drug Administration is seeking to amend certain of its general regulations to include tobacco products, where appropriate, in light of FDA's authority to regulate these products under the Family Smoking Prevention and Tobacco Control Act.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 1.1(b); 21 CFR 1.1(c); 21 CFR 7.3(f); 21 CFR 14.55(f) (New); 21 CFR 14.100(h) (New); 21 CFR 17.1(j) (New); 21 CFR 17.2 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321; 21 USC 331; 21 USC 333; 21 USC 387; 21 USC 387q
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Direct Final Rule	12/00/2010	
NPRM -- Companion to Direct Final Rule	12/00/2010	
NPRM Comment Period End	03/00/2011	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
RIN: 0910-AG56

View Related Documents

Title: Food Labeling: Nutrition Labeling for Food Sold in Vending Machines

Abstract: The Food and Drug Administration (FDA) is proposing regulations to establish requirements for nutrition labeling of food sold in vending machines. FDA is also proposing the terms and conditions for registering to voluntarily be subject to the requirements of section 4205. FDA is taking this action to carry out the provisions of section 4205 of the Patient Protection and Affordable Care Act ("Affordable Care Act" or "ACA"), which was signed into law on March 23, 2010.

Priority: Economically Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: Yes
Unfunded Mandates: Undetermined
CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 343; 21 USC 371
Legal Deadline:

Action	Source	Description	Date
NPRM	Statutory	Proposed rule to be published 1 year after enactment.	03/23/2011

Regulatory Plan:

Statement of Need: This proposed rule was mandated by section 4205 of the Affordable Care Act.

Legal Basis: On March 23, 2010, the Affordable Care Act (Pub. L. 111-148) was signed into law. Section 4205 amended 403(q)(5) of the Federal Food, Drug, and Cosmetic Act by creating new clause (H) to require that vending machine operators, who own or operate 20 or more machines, disclose calories for food items. FDA has the authority to issue this proposed rule under section 403(q)(5)(H) and 701(a) (21 U.S.C. 343(q)(5)(H), and 371(a)). Section 701(a) of the act vests the Secretary (and, by delegation, the FDA) with the authority to issue regulations for the efficient enforcement of the act.

Alternatives: Section 4205 requires the Secretary (and, by delegation, the FDA) to establish, by regulation, requirements for calorie disclosure of food items for vending machine operators, who own or operate 20 or more machines. Therefore, there are no alternatives to rulemaking.

Costs and Benefits: The bulk of the costs associated with this rule will be in managing the actual disclosure of calories at the machine. Since almost all vending machines sell food that is previously manufactured and packaged, most vended foods

are subject to the Nutrition Labeling Education Act, which means that calorie content is already collected. A likely scenario for response to vending machine labeling is that food manufacturers include a set of calorie label stickers in each case of product. Since consumers of vended foods do not generally have access to nutrition information prior to purchase, requiring that operators make that information available should benefit consumers. Consumers may ignore future costs of overeating, relative to the current gains from eating, even when they understand the connection. Therefore, consumers do not generally demand calorie and other nutrition information for food away from home, even when they do, given a wider frame of reference, value that information. Given the costs and the uncertain reception for calorie information that many consumers appear not to care about, most vending machine operators have chosen not to display calorie information. The requirements of the proposed rule, specifically, that calorie and other nutrition information appear at the point of purchase, solves the apparent market failure in providing information provision stemming from present-biased preferences.

Risks: For some vending machine foods, consumers cannot view the nutrition facts panel or otherwise see nutrition information prior to purchasing the item. Completion of this rulemaking will provide consumers information about the nutritional content of food to empower them to make healthier food choices from vending machines.

Timetable:

Action	Date	FR Cite
NPRM	03/00/2011	
NPRM Comment Period End	06/00/2011	

Regulatory Flexibility Analysis Required: Business; Governmental Jurisdictions

Government Levels Affected: Federal; Local; State

Federalism: Undetermined

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

RIN: 0910-AG57

View Related Documents

Title: Food Labeling: Nutrition Labeling of Standard Menu Items in Chain Restaurants

Abstract: The Food and Drug Administration (FDA) is proposing regulations to establish requirements for nutrition labeling of standard menu items for chain restaurants and similar retail food establishments. FDA is also proposing the terms and conditions for registering to voluntarily be subject to the requirements of section 4205. FDA is taking this action to carry out the provisions of section 4205 of the Patient Protection and Affordable Care Act ("Affordable Care Act" or "ACA"), which was signed into law on March 23, 2010.

Priority: Economically Significant

Agenda Stage of Rulemaking: Proposed Rule

Major: Yes

Unfunded Mandates: Undetermined

CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: 21 USC 343; 21 USC 371

Legal Deadline:

Action	Source	Description	Date
NPRM	Statutory	Proposed rule to be published 1 year after enactment.	03/23/2011

Regulatory Plan:

Statement of Need: This proposed rule was mandated by section 4205 of the Affordable Care Act.

Legal Basis: On March 23, 2010, the Affordable Care Act (Pub. L. 111-148) was signed into law. Section 4205 amended 403(q)(5) of the Federal Food, Drug, and Cosmetic Act by creating new clause (H) to require that chain restaurants, with 20 or more locations, require certain nutrient disclosure. Specifically, section 4205 required the Secretary of Health and Human Services to issue a proposed regulation to carry out clause (H) of the ACA no later than 1 year of enactment of this clause (i.e., Mar. 23, 2011). FDA has the authority to issue this proposed rule under section 403(q)(5)(H) and 701(a) (21 U.S.C. 343(q)(5)(H), and 371(a)). Section 701(a) of the act vests the Secretary (and, by delegation, the FDA) with the authority to issue

regulations for the efficient enforcement of the act. As directed by section 4205, FDA is proposing requirements for menu calorie declaration, as well as other nutrition information declaration to implement the provisions of 403(q)(5)(H). FDA is also proposing the terms and conditions for registering to voluntarily be subject to the requirements of section 4205.

Alternatives: Section 4205 requires the Secretary (and, by delegation, the FDA) to establish, by regulation, requirements for nutrition labeling of standard menu items for chain restaurants and similar retail food establishments. Therefore, there are no alternatives to rulemaking.

Costs and Benefits: Chain restaurants operating in local jurisdictions that impose different nutrition labeling requirements will benefit from having a uniform national standard. Any restaurant, with fewer than 20 locations, may opt in to the national standard to receive this benefit. Many chain restaurants, with 20 or more locations, will bear costs for adding nutrition information to menus and menu boards. Consumers will benefit from having important nutrition information for the approximately 30 per cent of calories consumed away from home.

Risks: Americans now consume an estimated one-third of their total calories on foods prepared outside the home and spend almost half of their food dollars on such foods. Unlike packaged foods that are labeled with nutrition information, foods in restaurants, for the most part, do not have nutrition information. Completion of this rulemaking will provide consumers information about the nutritional content of food to empower them to make healthier food choices.

Timetable:

Action	Date	FR Cite
NPRM	03/00/2011	
NPRM Comment Period End	06/00/2011	

Regulatory Flexibility Analysis Required: Business; Governmental Jurisdictions

Government Levels Affected: Federal; Local; State

Federalism: Undetermined

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AG58

View Related Documents

Title: New Animal Drugs for Minor Use and Minor Species

Abstract: The Minor Use and Minor Species Animal Health Act of 2004 (MUMS Act) amended the Federal Food, Drug, and Cosmetic Act (the Act) to establish new regulatory procedures that provide incentives intended to make more drugs legally available to veterinarians and animal owners for the treatment of minor animal species and uncommon diseases in major animal species. FDA published the final rule to implement these regulations (21 CFR part 516) on July 26, 2007 (72 FR 41010). FDA is issuing this direct final rule to amend its regulations regarding new animal drugs for minor use and minor species (MUMS) in part 516 to update language and clarify the intent of the regulations consistent with the preambles to the proposed and final rules. In sectiom 516.3(b), FDA is amending the definition of “same dosage form” to make it clearer that the six dosage form categories listed in the regulations under numbers (i) through (vi) are the “categories” of dosage forms that the preamble to the proposed rule referenced as follows: “The second test of sameness which the statute establishes to determine eligibility of an animal drug for designation is 'same dosage form.' The Agency proposes to use the long-established dosage form categories listed in title 21 of the Code of Federal Regulations to implement this statutory requirement.” (70 FR 56394 at 56398). To accomplish this clarification, the amendment will add the word “categories” after the phrase “dosage forms” and remove the “s” from “forms” in the first sentence of the definition. Section 516.20(b)(2) requires that requests for MUMS designation include “the generic and trade name, if any, of the drug” intended to be designated and FDA is amending this language to replace the terms “generic” and “trade” with the terms “established” and “proprietary”, respectively, because the latter are the terms used in the Act. See section 502(e) of the act (21 U.S.C. section 352(e)). FDA is also revising this language to clarify that “drug” in the context of paragraph (b)(2) refers to the “active pharmaceutical ingredient (API)” name rather than to a formulated drug product name. The purpose of the information required in this provision of the regulation is to permit the Agency to determine whether a drug is eligible for designation on the basis that it is not the “same drug” as a drug that is already designated, conditionally approved, or approved (see section 573(a)(2)(B) of the Act) and, since the definition of “same drug” in section 516.3(b) requires

a knowledge of the drug's "active moiety" in order to make this determination, a request for MUMS designation needs to include the API name. This is because the API name includes the active moiety and the drug product name normally does not. FDA is also clarifying the relationship between established and proprietary names in this context with the use of parentheses.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 516 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 360ccc-1; 21 USC 360ccc-2; 21 USC 371(a)
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Direct Final Rule	11/15/2010	75 FR 69586
NPRM	11/15/2010	75 FR 69614
NPRM Comment Period End	01/31/2011	
Confirmation of Effective Date	03/00/2011	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
RIN: 0910-AA97

View Related Documents

Title: Postmarketing Safety Reporting Requirements for Human Drug and Biological Products

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 Conference 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. FDA plans to finalize the premarket and postmarket safety reporting requirements in separate final rules.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: Yes
Unfunded Mandates: No
CFR Citation: 21 CFR 310; 21 CFR 314; 21 CFR 600 and 601; 21 CFR 606 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 216; 42 USC 241; 42 USC 242a; 42 USC 262 and 263; 42 USC 263a to 263n; 42 USC 264; 42 USC 300aa; 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 360b to 360j; 21 USC 361a; 21 USC 371; 21 USC 374; 21 USC 375; 21 USC 379e; 21 USC 381
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	03/14/2003	68 FR 12406
NPRM Comment Period Extended	06/18/2003	
NPRM Comment Period End	07/14/2003	
NPRM Comment Period Extension End	10/14/2003	
Final Action	08/00/2011	

Regulatory Flexibility Analysis Required: Business Government Levels Affected: No
Federalism: No

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AC25

View Related Documents

Title: Medical Devices; Exception From General Requirements for Informed Consent

Abstract: This final rule will affirm the interim final rule's exception from the general requirement for informed consent in certain circumstances involving the use of investigational in vitro diagnostic devices to identify chemical, biological, radiological, or nuclear agents in a potential terrorist event or other public health emergency. Informed consent will be required unless the clinical investigator determines in writing that: 1) There exists a life-threatening situation involving the human subject of such testing which necessitates the use of the investigational device; 2) it is not feasible to obtain informed consent from the subject; and 3) there is not sufficient time to obtain such consent from his or her representative. Further, a licensed physician uninvolved in the testing must agree in writing with this three-part determination before the product is used unless immediate use of the device is required to save the life of the human subject of such testing and there is not sufficient time to get such concurrence. This final rule adds a requirement that the investigator submit the required documentation to FDA in addition to submitting the documentation to the Institutional Review Board (IRB).

Priority: Other Significant Agenda Stage of Rulemaking: Final Rule
Major: No Unfunded Mandates: No
CFR Citation: 21 CFR 50.23 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321; 21 USC 343; 21 USC 346 to 346a; 21 USC 348; 21 USC 350a; 21 USC 352; 21 USC 353; 21 USC 355; 21 USC 360; 21 USC 360c to 360f; 21 USC 360h to 360j; 21 USC 371; 21 USC 379e; 21 USC 381; 42 USC 216; 42 USC 241; 42 USC 262; 42 USC 263b to 263n
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Interim Final Rule	06/07/2006	71 FR 32827
Interim Final Rule Comment Period End	08/07/2006	
Final Action	06/00/2011	

Regulatory Flexibility Analysis Required: No Government Levels Affected: State
Small Entities Affected: No Federalism: Yes

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AC30

View Related Documents

Title: Medical Devices; Anesthesiology Devices; Reclassification of Pressure Regulators for Use With Medical Oxygen; and Separate Classification of Oxygen Conserving Devices

Abstract: The Food and Drug Administration (FDA) issued a proposed rule to reclassify pressure regulators for use with medical oxygen from class I to class II, establish a separate classification for oxygen conserving devices, and establish a special control for these devices to address problems of fire and explosion associated with use of these devices. The special control discussed in the proposed rule is a guidance document that includes standardized testing, performance, and labeling guidance for industry. Under the proposed rule, oxygen pressure regulators that meet the standard identified in a special controls guidance document would be exempt from the premarket notification requirements of the Federal Food, Drug, and Cosmetic Act. FDA anticipates that the requirements of a final rule would be phased-in to minimize the cost of complying with the special control.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No

CFR Citation: 21 CFR 868.2700; 21 CFR 868.2750; 21 CFR 868.5905; 21 CFR 868.5910 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: 21 USC 351; 21 USC 360; 21 USC 360c; 21 USC 360e; 21 USC 360j; 21 USC 371

Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	02/27/2007	72 FR 8643
NPRM Comment Period End	05/29/2007	
Final Action	09/00/2011	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

Energy Affected: Undetermined

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
RIN: 0910-AC53

View Related Documents

Title: Medical Gas Containers and Closures; Current Good Manufacturing Practice Requirements

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 permanently attached to the valve body.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No

CFR Citation: 21 CFR 201.161(a); 21 CFR 211.94; 21 CFR 211.125 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: 21 USC 321; 21 USC 351 to 21 USC 353
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	04/10/2006	71 FR 18039
NPRM Comment Period End	07/10/2006	
Final Action	10/00/2011	

Regulatory Flexibility Analysis Required: Business Government Levels Affected: No
Federalism: No
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AC59

View Related Documents

Title: Reporting Information Regarding Falsification of Data
Abstract: The proposed rule would require sponsors to promptly report any information indicating that any person has or may have engaged in the falsification of data in the course of proposing, designing, performing, recording, supervising, or reviewing research, or in reporting research results.

Priority: Other Significant Agenda Stage of Rulemaking: Final Rule
Major: No Unfunded Mandates: No
CFR Citation: 21 CFR 16.1; 21 CFR 58.11 and 58.12; 21 CFR 71.1; 21 CFR 101.69 and 101.70; 21 CFR 170.101; 21 CFR 171.1; 21 CFR 190.6; 21 CFR 312.56; 21 CFR 511.1; 21 CFR 571.1; 21 CFR 812.46 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321; 21 USC 341 to 343; 21 USC 348 and 349; 21 USC 351 and 352; 21 USC 355; 21 USC 360b and 360c; 21 USC 360e; 21 USC 360i to 360k; 21 USC 361; 21 USC 371; 21 USC 379e; 42 USC 262
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	02/19/2010	75 FR 7412
NPRM Comment Period End	05/20/2010	
Final Action	05/00/2011	

Regulatory Flexibility Analysis Required: No Government Levels Affected: No
Federalism: No
Related RINs: Previously Reported as 0910-AC02
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF11

View Related Documents

Title: Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Pregnancy and Lactation Labeling

Abstract: To amend the regulations governing the format and content of labeling for human prescription drugs and biological products (21 CFR parts 201.56, 201.57, and 201.80). Under FDA's current regulations, labeling concerning the use of prescription drugs in pregnancy uses letter categories (A, B, C, D, X) to characterize the risk to the fetus of using the drug in pregnancy. One of the deficiencies of the category system is that drugs may be assigned to the same category when the severity, incidence, and types of risk are quite different. Dissatisfaction with the category system has been expressed by health care providers, medical organizations, experts in the study of birth defects, women's health researchers, and women of childbearing age. Stakeholders consulted through a public hearing, several focus groups, and several advisory committees have recommended that FDA replace the category system with a concise narrative summarizing a product's risks to pregnant women and to women of childbearing age. Therefore, the revised format and the information provided in the labeling would make it easier for health care providers to understand the risks and benefits of drug use during pregnancy and lactation.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 201.56 and 201.57; 21 CFR 201.80 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 358; 21 USC 360; 21 USC 360b; 21 USC 360gg to 360ss; 21 USC 371; 21 USC 374; 21 USC 379e; 42 USC 216; 42 USC 241; 42 USC 262; 42 USC 264
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	05/29/2008	73 FR 30831
NPRM Comment Period End	08/27/2008	
Final Action	10/00/2011	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: State
Federalism: Yes
Energy Affected: No
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF26

View Related Documents

Title: Blood Initiative--Revisions to Labeling Requirements for Blood and Blood Components, Including Source Plasma, and Technical Amendment

Abstract: The Food and Drug Administration (FDA) is amending the regulations regarding container labels and instruction circulars for certain human blood and blood components, including Source Plasma, to be more consistent with current practices and to remove unnecessary or outdated requirements. This action is based on FDA's comprehensive review of the biologics regulations. It is also based on reports by the U.S. House of Representatives Committee on Government Reform and Oversight Subcommittee on House Resources and Intergovernmental Relations, the Government Accountability Office (previously, the General Accounting Office), and the Institute of Medicine, as well as on public comments. This action is intended to help ensure the continued safety of the blood supply and to help ensure consistency in container labeling. The rule will also consolidate most of the regulations applicable to labeling standards for blood and blood components, including Source Plasma. For example, most labeling requirements for all blood and blood components, including Source Plasma, found previously in 21 CFR 606.121 and 21

CFR 640.70, will be found in 21 CFR 606.121.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 606; 21 CFR 610; 21 CFR 640 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 360d; 21 USC 360h to 360j; 21 USC 371; 21 USC 374; 21 USC 381; 42 USC 216; 42 USC 262 and 263; 42 USC 263a; 42 USC 264
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	07/30/2003	68 FR 44678
NPRM Comment Period End	10/28/2003	
Final Action	04/00/2011	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Related RINs: Split From 0910-AB26
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
RIN: 0910-AF27

View Related Documents

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

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

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 106 and 107 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321; 21 USC 350a; 21 USC 371; ...
Legal Deadline: None

Regulatory Plan:

Statement of Need: The agency published a proposed rule on July 9, 1996, that would establish current good manufacturing practice regulations, quality control procedures, quality factors, notification requirements, records and reports for the production of infant formula. This proposal was issued in response to the 1986 Amendments to the Infant Formula Act of 1980. On April 28, 2003, FDA reopened the comment period to update comments on the proposal. The comment was extended on June 27, 2003 and ended on August 26, 2003. The comment period was reopened on August 1, 2006 and ended on September 15, 2006.

Legal Basis: The Infant Formula Act of 1980 (the 1980 Act) (Pub. L. 96-359) amended the Federal Food, Drug, and Cosmetic Act (the Act) to include section 412 (21 U.S.C. 350a). This law is intended to improve protection of infants consuming infant formula products by establishing greater regulatory control over the formulation and production of infant formula. In 1982, FDA adopted infant formula recall procedures in subpart D of 21 CFR part 107 of its regulations (47 FR 18832, Apr. 30, 1982), and infant formula quality control procedures in subpart B of 21 CFR part 106 (47 FR 17016, Apr. 20, 1982). In 1985, FDA further implemented the 1980 Act by establishing subparts B, C, and D in 21 CFR part 107 regarding the labeling of infant formula, exempt infant formulas, and nutrient requirements for infant formula, respectively (50 FR 1833, Jan. 14, 1985; 50 FR

48183, Nov. 22, 1985; and 50 FR 45106, Oct. 30, 1985). In 1986, Congress, as part of the Anti-Drug Abuse Act of 1986 (Pub. L. 99-570) (the 1986 amendments), amended section 412 of the act to address concerns that had been expressed by Congress and consumers about the 1980 Act and its implementation related to the sufficiency of quality control testing, CGMP, recordkeeping, and recall requirements. The 1986 amendments: (1) State that an infant formula is deemed to be adulterated if it fails to provide certain required nutrients, fails to meet quality factor requirements established by the Secretary (and, by delegation, FDA), or if it is not processed in compliance with the CGMP and quality control procedures established by the Secretary; (2) require that the Secretary issue regulations establishing requirements for quality factors and CGMP, including quality control procedures; (3) require that infant formula manufacturers regularly audit their operations to ensure that those operations comply with CGMP and quality control procedure regulations; (4) expand the circumstances in which firms must make a submission to the Agency to include when there is a major change in an infant formula or a change that may affect whether the formula is adulterated; (5) specify the nutrient quality control testing that must be done on each batch of infant formula; (6) modify the infant formula recall requirements; and (7) give the Secretary authority to establish requirements for retention of records, including records necessary to demonstrate compliance with CGMP and quality control procedures. In 1989, the Agency implemented the provisions on recalls (secs. 412(f) and (g) of the act) by establishing subpart E in 21 CFR part 107 (54 FR 4006, Jan. 27, 1989). In 1991, the Agency implemented the provisions on record and record retention requirements by revising 21 CFR 106.100 (56 FR 66566, Dec. 24, 1991). The Agency has already promulgated regulations that respond to a number of the provisions of the 1986 amendments. The final rule would address additional provisions of these amendments.

Alternatives: The 1986 amendments require the Secretary (and, by delegation, FDA) to establish, by regulation, requirements for quality factors and CGMPs, including quality control procedures. Therefore, there are no alternatives to rulemaking.

Costs and Benefits: FDA estimates that the costs from the final rule to producers of infant formula would include first year and recurring costs (e.g., administrative costs, implementation of quality controls, records, audit plans and assurances of quality factors in new infant formulas). FDA anticipates that the primary benefits would be a reduced risk of illness due to Cronobacter sakazakii and Salmonella spp in infant formula. Additional benefits stem from the quality factors requirements that would assure the healthy growth of infants consuming infant formula. Monetized estimates of costs and benefits for this final rule are not available at this time. The analysis for the proposed rule estimated costs of less than $1 million per year. FDA was not able to quantify benefits in the analysis for the proposed rule.

Risks: Special controls for infant formula manufacturing are especially important because infant formula, particularly powdered infant formula, is an ideal medium for bacterial growth and because infants are at high risk of foodborne illness because of their immature immune systems. In addition, quality factors are of critical need to assure that the infant formula supports healthy growth in the first months of life when infant formula may be an infant's sole source of nutrition. The provisions of this rule will address weaknesses in production that may allow contamination of infant formula, including, contamination with C. sakazakii and Salmonella spp which can lead to serious illness with devastating sequelae and/or death. The provisions would also assure that new infant formulas support healthy growth in infants.

Timetable:

Action	Date	FR Cite
NPRM	07/09/1996	61 FR 36154
NPRM Comment Period End	12/06/1996	
NPRM Comment Period Reopened	04/28/2003	68 FR 22341
NPRM Comment Period Extended	06/27/2003	68 FR 38247
NPRM Comment Period End	08/26/2003	
NPRM Comment Period Reopened	08/01/2006	71 FR 43392
NPRM Comment Period End	09/15/2006	
Final Action	06/00/2011	

Regulatory Flexibility Analysis Required: Business Government Levels Affected: No

Federalism: No

Energy Affected: No

International Impacts: This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.

Related RINs: Split From 0910-AA04

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF32

View Related Documents

Title: Over-the-Counter (OTC) Drug Review--Cough/Cold (Bronchodilator) Products

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action addresses labeling for single ingredient bronchodilator products.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM (Amendment--Ephedrine Single Ingredient)	07/13/2005	70 FR 40237
NPRM Comment Period End	11/10/2005	
Final Action (Technical Amendment)	11/30/2007	72 FR 67639
Final Action (Amendment--Single Ingredient Labeling)	01/00/2011	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: Local; State
Federalism: Yes
Related RINs: Split From 0910-AA01

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF33

View Related Documents

Title: Over-the-Counter (OTC) Drug Review--Cough/Cold (Combination) Products

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action addresses cough/cold drug products containing an oral bronchodilator (ephedrine and its salts) in combination with any expectorant or any oral nasal decongestant.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM (Amendment)	07/13/2005	70 FR 40232
NPRM Comment Period End	11/10/2005	
Final Action (Technical Amendment)	03/19/2007	72 FR 12730

Final Action	10/00/2011	

Regulatory Flexibility Analysis Required: Business Government Levels Affected: Local; State
Federalism: Yes
Related RINs: Split From 0910-AA01
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF35

View Related Documents

Title: Over-the-Counter (OTC) Drug Review--External Analgesic Products
Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. The final action addresses the 2003 proposed rule on patches, plasters, and poultices. The proposed rule will address issues not addressed in previous rulemakings.

Priority: Substantive, Nonsignificant Agenda Stage of Rulemaking: Final Rule
Major: No Unfunded Mandates: No
CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM (Amendment)	00/00/0000	
Final Action (GRASE dosage forms)	10/00/2011	

Regulatory Flexibility Analysis Required: Business Government Levels Affected: Local; State
Federalism: Yes
Related RINs: Split From 0910-AA01
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF42

View Related Documents

Title: Over-the-Counter (OTC) Drug Review--Skin Protectant Products
Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. The first action identifies safe and effective skin protectant active ingredients to treat and prevent diaper rash. The second action addresses skin protectant

products used to treat fever blisters and cold sores.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Final Action (Technical Amendments)	02/01/2008	73 FR 6014
Final Action (Aluminum Acetate) (Technical Amendment)	03/06/2009	74 FR 9759
Final Action (Diaper Rash)	10/00/2011	
Final Action (Fever Blisters/Cold Sores)	10/00/2011	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: Local; State
Federalism: Yes
Related RINs: Split From 0910-AA01
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
RIN: 0910-AF47

View Related Documents

Title: Use of Materials Derived From Cattle in Human Food and Cosmetics

Abstract: On July 14, 2004, FDA issued an interim final rule (IFR), effective immediately, to prohibit the use of certain cattle material and to address the potential risk of bovine spongiform encephalopathy (BSE) in human food, including dietary supplements, and cosmetics. Prohibited cattle materials under the IFR include specified risk materials, small intestine of all cattle, material from nonambulatory disabled cattle, material from cattle not inspected and passed for human consumption, and mechanically separated (MS) beef. Specified risk materials are the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia of cattle 30 months and older; and the tonsils and distal ileum of the small intestine of all cattle. Prohibited cattle materials do not include tallow that contains no more than 0.15 percent hexane-insoluble impurities and tallow derivatives. This action minimizes human exposure to materials that scientific studies have demonstrated are highly likely to contain the BSE agent in cattle infected with the disease. Scientists believe that the human disease variant Creutzfeldt-Jakob disease (vCJD) is likely caused by the consumption of products contaminated with the agent that causes BSE.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 189.5; 21 CFR 700.27 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 342; 21 USC 361; 21 USC 371
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Interim Final Rule Effective	07/14/2004	
Interim Final Rule	07/14/2004	69 FR 42256
Interim Final Rule Comment Period End	10/12/2004	
Interim Final Rule (Amendments)	09/07/2005	70 FR 53063
Interim Final Rule (Amendments) Effective	10/07/2005	

Interim Final Rule (Amendments) Comment Period End	11/07/2005	
Interim Final Rule (Amendments)	04/17/2008	73 FR 20785
Interim Final Rule (Amendments) Effective	07/16/2008	
Interim Final Rule (Amendments) Comment Period End	07/16/2008	
Final Action	04/00/2011	

Regulatory Flexibility Analysis Required: Business Government Levels Affected: No
Federalism: No
Energy Affected: No
International Impacts: This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF54

View Related Documents

Title: Use of Materials Derived From Cattle in Medical Products Intended for Use in Humans and Drugs Intended for Use in Ruminants

Abstract: The regulation would prohibit the use of certain cattle material in the manufacture of medical products for humans and drugs for ruminants and would require recordkeeping for products containing or manufactured with cattle materials to enable monitoring and enforcement of the prohibitions. The rule would prohibit the same cattle material that is prohibited in the previous FDA IFR that applies to foods and cosmetics. These include certain high risk tissues (e.g., brain, skull, eyes, spinal cord, trigeminal ganglia, parts of the vertebral column, and dorsal root ganglia) from cattle 30 months and older, tonsils and the distal ileum of cattle of any age, mechanically separated beef, material from nonambulatory disabled cattle, and material from cattle not inspected and passed for human consumption. The prohibitions would apply only to materials derived from animals slaughtered after the effective dates of the rule. The prohibitions would not apply to tallow that met a specified purity standard. The rule would provide criteria for deviations from the requirements based on a showing of safety or appropriate benefit-to-risk ratio.

Priority: Other Significant Agenda Stage of Rulemaking: Final Rule
Major: No Unfunded Mandates: No
CFR Citation: 21 CFR 211.116; 21 CFR 226.60; 21 CFR 300.200; 21 CFR 500.200; 21 CFR 530; 21 CFR 600.16; 21 CFR 895.102; 21 CFR 1271.465; 21 CFR 1271.470 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351 and 352; 21 USC 355; 21 USC 360b; 21 USC 360f; 21 USC 360i; 21 USC 371; 21 USC 374; 21 USC 381; 42 USC 262; 42 USC 264; 42 USC 271
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	01/12/2007	72 FR 1582
NPRM Comment Period End	03/13/2007	
NPRM Comment Period Reopened	03/30/2007	
Final Action	04/00/2011	

Regulatory Flexibility Analysis Required: No Government Levels Affected: No
Small Entities Affected: No Federalism: No
Energy Affected: No
International Impacts: This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.
Related RINs: Merge with 0910-AF55

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF61

View Related Documents

Title: Label Requirement for Food That Has Been Refused Admission Into the United States

Abstract: The final rule will require owners or consignees to label imported food that is refused entry into the United States. The label will read, "UNITED STATES: REFUSED ENTRY." The proposal describes the label's characteristics (such as its size) and processes for verifying that the label has been affixed properly. We are taking this action to prevent the introduction of unsafe food into the United States, to facilitate the examination of imported food, and to implement section 308 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) (Pub. L. 107-188).

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 1.98 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 15 USC 1453 to 1455; 21 USC 321; 21 USC 342 and 343; 21 USC 371; 21 USC 374; 21 USC 381; 42 USC 216; 42 USC 264
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	09/18/2008	73 FR 54106
NPRM Comment Period End	12/02/2008	
Final Action	03/00/2011	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: Undetermined
Federalism: No
Energy Affected: No
International Impacts: This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF81

View Related Documents

Title: Current Good Manufacturing Practice for Combination Products

Abstract: The final rule is intended to clarify and codify the current good manufacturing practice (cGMP) requirements for combination products (combinations of a drug, device, and/or biological product). The final rule is intended to ensure consistency and appropriateness in the regulation of combination products. The final rule will provide a flexible, regulatory framework that recognizes that, in most instances, for combination products, a properly implemented quality system program

under one set of medical product cGMP regulations will meet the requirements of another set (e.g., application of cGMPs for finished pharmaceuticals in 21 CFR parts 210 and 211 will generally meet the requirements of the device quality system regulations in 21 CFR part 820). It would allow manufacturers the flexibility to implement either the drug CGMP or device quality system regulation if both would apply to their manufacture of the combination product, provided that they also incorporate select, key provisions from the other set of these regulations. It would avoid the necessity to fully implement both sets of cGMP regulations when manufacturing combination products.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 4, subchapter A (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 360c to 360f; 21 USC 360h to 360j; 21 USC 360l; 21 USC 360hh to 360ss; 21 USC 360aaa to 360bbb; 21 USC 371a; 21 USC 372 to 374; 21 USC 379e; 21 USC 381; 21 USC 394; 42 USC 216; 42 USC 262; 42 USC 263a; 42 USC 264; 42 USC 271
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	09/23/2009	74 FR 48423
NPRM Extension of Comment Period	11/10/2009	
NPRM Comment Period End	12/22/2009	
Final Action	08/00/2011	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: State
Small Entities Affected: Business
Federalism: Yes
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
RIN: 0910-AF82

View Related Documents

Title: Postmarket Safety Reporting for Combination Products
Abstract: The proposed rule would clarify the postmarket safety reporting requirements for combination products (combinations of a drug, device, and/or biological product). The proposed rule would provide a framework for the reporting of adverse events for combination products. The proposed rule would clarify that a combination product is subject primarily to the reporting requirements associated with the type of marketing application under which the product is approved or cleared. In addition, the proposed rule identifies unique reporting provisions that must be complied with if applicable. The regulation would ensure the consistency and appropriateness of postmarket safety reporting for combination products while avoiding the need for duplicative reporting requirements.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 4, subchapter B (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 360c to 360f; 21 USC 360h to 360j; 21 USC 360l; 21 USC 360hh to 360ss; 21 USC 360aaa to 360bbb; 21 USC 371a; 21 USC 372 to 374; 21 USC 379e; 21 USC 381; 21 USC 394; 42 USC 216; 42 USC 262; 42 USC 263a; 42 USC 264; 42 USC 271
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	10/01/2009	74 FR 50744
NPRM Comment Period End	12/30/2009	

Final Action	08/00/2011	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: State
Small Entities Affected: Business
Federalism: Yes

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF86

View Related Documents

Title: Medical Device Reporting; Electronic Submission Requirements

Abstract: The Food and Drug Administration (FDA) is amending its postmarket medical device reporting (MDR) regulations to require that manufacturers, importers, and user facilities submit mandatory reports of medical device adverse events to the Agency in an electronic format that FDA can process, review, and archive. FDA is taking this action to improve the Agency's systems for collecting and analyzing postmarketing safety reports. The proposed change would help the Agency to more quickly review safety reports and identify emerging public health issues.

Priority: Economically Significant
Agenda Stage of Rulemaking: Final Rule
Major: Yes
Unfunded Mandates: No
CFR Citation: 21 CFR 803 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321, 331, 351, 352, 360c, 360e, 360i to 360j, 371, 374, 381, 393; 42 USC 264, 271
Legal Deadline: None

Regulatory Plan:

Statement of Need: The final rule would require user facilities and medical device manufacturers and importers to submit medical device adverse event reports in electronic format instead of using a paper form. FDA is taking this action to improve its adverse event reporting program by enabling it to more quickly receive and process these reports.

Legal Basis: The Agency has legal authority under section 519 of the Federal Food, Drug, and Cosmetic Act to require adverse event reports. The final rule would require manufacturers, importers, and user facilities to change their procedures to send reports of medical device adverse events to FDA in electronic format instead of using a hard copy form.

Alternatives: There are two alternatives. The first alternative is to allow the voluntary submission of electronic MDRs. If a substantial number of reporters fail to voluntarily submit electronic MDRs, FDA will not obtain the benefits of standardized formats and quicker access to medical device adverse event data. The second alternative is to allow small entities more time to comply. Because so many device companies are small entities, this would significantly postpone the benefits of the rule.

Costs and Benefits: The principal benefit would be to public health because the increased speed in the processing and analysis of 173,000 medical device reports currently submitted annually on paper. In addition, requiring electronic submission would reduce FDA annual operating costs by $1.9 million and generate industry savings of about $9.8 million. The total one-time cost for modifying SOPs and establishing electronic submission capabilities is estimated to range from $81.4 million to $101.0 million. Annually recurring costs totaled $8.8 million and included maintenance of electronic submission capabilities, including renewing the electronic certificate, and for some firms, the incremental cost to maintain high-speed Internet access.

Risks: None

Timetable:

Action	Date	FR Cite
NPRM	08/21/2009	74 FR 42310
NPRM Comment Period End	11/19/2009	
Final Action	06/00/2011	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No

Federalism: No

Energy Affected: No

International Impacts: This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF88

View Related Documents

Title: Electronic Registration and Listing for Devices

Abstract: This rule will convert registration and listing to a paperless process. However, for those companies that do not have access to the Web, FDA will offer an avenue by which they can register, list, and update information with a paper submission. The rule also will amend part 807 to reflect the timeframes for device establishment registration and listing established by sections 222 and 223 of Food and Drug Administration Amendment Act (FDAAA) and to reflect the requirement in section 510(i) of the Act, as amended by section 321 of the Public Health Security and Bioterrorism Preparedness and Response Act (BT Act), that foreign establishments provide FDA with additional pieces of information as part of their registration.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 807 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 110-85; PL 107-188, sec 321; PL 107-250, sec 207; 21 USC 360(a) through 360(j); 21 USC 360(p)
Legal Deadline: None

Regulatory Plan:

Statement of Need: FDA is amending the medical device establishment registration and listing requirements under 21 CFR part 807 to reflect the electronic submission requirements in section 510(p) of the Act, which was added by section 207 of MDUFMA and later amended by section 224 of FDAAA. FDA also is amending 21 CFR part 807 to reflect the requirements in section 321 of the BT Act for foreign establishments to furnish additional information as part of their registration. This rule will improve FDA's device establishment registration and listing system and utilize the latest technology in the collection of this information.

Legal Basis: The statutory basis for our authority includes sections 510(a) through (j), 510(p), 701, 801, and 903 of the Act.

Alternatives: The alternatives to this rulemaking include not updating the registration and listing regulations. Because of the new FDAAA statutory requirements and the advances in data collection and transmission technology, FDA believes this rulemaking is the preferable alternative.

Costs and Benefits: The Agency believes that there may be some one-time costs associated with the rulemaking, which involve resource costs of familiarizing users with the electronic system. Recurring costs related to submission of the information by domestic firms would probably remain the same or decrease because a paper submission and postage is not required. There might be some increase in the financial burden on foreign firms since they will have to supply additional registration information as required by section 321 of the BT Act.

Risks: None

Timetable:

Action	Date	FR Cite
NPRM	03/26/2010	75 FR 14510
NPRM Comment Period End	06/24/2010	
Final Rule	09/00/2011	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No

Small Entities Affected: Business
Federalism: No
Energy Affected: Undetermined
International Impacts: This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF90

View Related Documents

Title: Exceptions or Alternatives To Labeling Requirements for Products Held by the Strategic National Stockpile

Abstract: FDA issued regulations to permit FDA Center Directors to grant an exception or alternative to certain regulatory labeling provisions applicable to human drugs, biological products, or medical devices that are or will be included in the Strategic National Stockpile (SNS). Under this rule, the appropriate FDA Center Director may grant an exception or alternative to such labeling requirements if he or she determines that compliance with such requirements could adversely affect the safety, effectiveness, or availability of specified lots, batches, or other units of human drugs, biological products, or medical devices that are or will be included in the SNS, including not only those that are approved, licensed, or cleared for marketing, but also those that are investigational. A grant of an exception or alternative under these regulations will include any safeguards or conditions deemed appropriate by the FDA Center Director to ensure that the labeling of such products includes information for the safe and effective use of the products given their anticipated circumstances of use. This rule will facilitate the safety, effectiveness, and availability of appropriate medical countermeasures in the event of a public health emergency.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 201; 21 CFR 312; 21 CFR 314; 21 CFR 601; 21 CFR 610; 21 CFR 801; 21 CFR 807; 21 CFR 809; 21 CFR 812; 21 CFR 814 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 15 USC 1451 to 1561; 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355 and 356; 21 USC 358; 21 USC 360; 21 USC 371 to 375; 21 USC 379; 21 USC 381 and 382; 21 USC 393; 42 USC 216; 42 USC 241; 42 USC 262 to 264; 42 USC 271
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Interim Final Rule	12/28/2007	72 FR 73589
Interim Final Rule Comment Period End	03/27/2008	
Final Action	06/00/2011	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: Federal; State
Federalism: Yes
Energy Affected: No
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF96

View Related Documents

Title: Postmarketing Safety Reports for Human Drug and Biological Products: Electronic Submission Requirements

Abstract: The final rule would amend FDA's postmarketing safety reporting regulations for human drug and biological products (21 CFR part 310.305, 314.80, 314.98, 600.80, and 600.81) to require that safety reports submitted to the Agency by persons subject to mandatory reporting requirements be transmitted in an electronic format that FDA can process, review, and archive. FDA is taking this action to improve the Agency's systems for collecting and analyzing postmarketing safety reports. The rule will allow the Agency to review safety reports more quickly, to identify emerging safety problems, and disseminate safety information more rapidly in support of FDA's public health mission. The amendments would be a key element in harmonizing FDA's postmarketing safety reporting regulations with international and ICH standards for the electronic submission of safety information.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 310.305; 21 CFR 314.80; 21 CFR 314.98; 21 CFR 600.80 and 600.81 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355 to 355a; 21 USC 356 to 356c; 21 USC 360; 21 USC 371; 21 USC 374; 21 USC 375; 21 USC 379aa; 21 USC 381; 42 USC 241; 42 USC 262; 42 USC 264; ...
Legal Deadline: None

Timetable:

Action	Date	FR Cite
ANPRM	11/05/1998	63 FR 59746
ANPRM Comment Period End	02/03/1999	
NPRM	08/21/2009	74 FR 42184
NPRM Comment Period End	11/19/2009	
Final Action	09/00/2011	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: No
Federalism: No

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
RIN: 0910-AG15

View Related Documents

Title: Revision of the Requirements for Constituent Materials

Abstract: Constituent materials include ingredients, preservatives, diluents, adjuvants, extraneous protein, and antibiotics that are contained in a biological product. This action will allow flexibility for manufacturing biological products, including innovative lifesaving products, that do not currently comply with the requirements for constituent materials but have been demonstrated to be safe, pure, and potent products. FDA is amending the regulation for constituent materials to allow the Director of the Center for Biologics Evaluation and Research (CBER) and the Director of the Center for Drugs Evaluation and Research (CDER) to approve an exception or alternative to the requirements under section 610.15, when the exception or alternative is sufficient to ensure the safety, purity, and potency of the biological product. This final rule will provide manufacturers of innovative biological products and manufacturers of currently approved products with flexibility, as appropriate, to employ advances in science and technology as they become available, without diminishing public health protection.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 610.15 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351; 21 USC 352; 21 USC 353; 21 USC 355; 21 USC 360; 21 USC 360c; 21 USC 360d; 21 USC 360h; 21 USC 360i; 21 USC 371; 21 USC 372; 21 USC 374; 21 USC 381; 42 USC 216; 42 USC 262; 42 USC 263; 42 USC 263a; 42 USC 264
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	03/30/2010	75 FR 15639
NPRM Comment Period End	06/28/2010	
Final Action	03/00/2011	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
RIN: 0910-AG27

View Related Documents

Title: Direct-to-Consumer Prescription Drug Advertisements: Presentation of the Major Statement in Television and Radio Advertisements in a Clear, Conspicuous, and Neutral Manner
Abstract: The Food and Drug Administration (FDA) is amending its regulations concerning direct-to-consumer (DTC) advertisements of prescription drugs. Advertisements broadcast through media must disclose the product's major risks in what is sometimes called the "major statement." The rule implements provisions of the Food and Drug Administration Amendments Act of 2007 (FDAAA) by requiring that the major statement in DTC television and radio advertisements relating to the side effects and contraindications of an advertised prescription drug be presented in a clear, conspicuous, and neutral manner. FDA is also implementing, as directed by FDAAA, standards that would be considered in determining whether the major statement in these advertisements is presented in the manner required by FDAAA.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 202.1 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321; 21 USC 331; 21 USC 352; 21 USC 355; 21 USC 360b; 21 USC 371; ...
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	03/29/2010	75 FR 15376
NPRM Comment Period End	06/28/2010	
Final Action	10/00/2011	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AG29

View Related Documents

Title: Requirement for Submission of Information on Pediatric Subpopulations That Suffer From a Disease or Condition That a Device Is Intended To Treat, Diagnose, or Cure

Abstract: The regulation would implement section 515A(a) of the Federal Food, Drug, and Cosmetic Act (added by FDAAA) by amending part 814 to require applicants who submit premarket approval applications (PMAs), product development protocols (PDPs), and applications for humanitarian device exemptions (HDEs) to include readily available information regarding the actual and potential pediatric use of their medical device. These applications must include if readily available: A description of any pediatric subpopulations that suffer from the disease or condition that the device is intended to treat, diagnose, or cure; and the number of affected pediatric patients. The proposed rule does not require additional clinical research or other costly efforts, and simply requires the applicant to briefly summarize readily available information that will have been reviewed by the applicant during the course of its development of the device and preparation of its application to FDA. The information submitted will allow FDA to track the number of approved devices for which there is a pediatric subpopulation that suffers from the disease or condition that the device is intended to treat, diagnose, or cure; the number of approved devices labeled for use in pediatric patients; the number of approved pediatric devices that were exempted from a review fee pursuant to section 738(a)(2)(B)(v) of the act; and the review time for each such device.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 814 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321, 331, 351, 352, 360e, 360e-1, 360j, and 371
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Direct Final Rule	04/01/2010	75 FR 16347
NPRM	04/01/2010	75 FR 16365
NPRM Comment Period End	06/15/2010	
Notice of Withdrawal of Direct Final Rule	07/20/2010	75 FR 41986
Final Rule	06/00/2011	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AG32

View Related Documents

Title: Informed Consent Elements

Abstract: The rule is to implement section 801(b)(3)(A) of the Food and Drug Administration Amendments Act of 2007. The provision requires the Food and Drug Administration to update its informed consent regulations to require inclusion in the informed consent documents and process a statement that clinical trial information for such clinical investigation has been or will be submitted for inclusion in the registry data bank pursuant to subsection (j) of section 402 of the Public Health Service Act (PHSA). The regulation will require the insertion of a specific statement in all informed consent documents that, if applicable, the clinical trial information for such clinical investigation has been or will be submitted for inclusion in the registry data bank

pursuant to subsection (j) of section 402 of the PHSA.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 50.25 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 355(i)(4); 21 USC 360j(g)(3)(D); 21 USC 371(a); secs 505(i), 520(g), and 701(a), FD&C Act
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	12/29/2009	74 FR 68750
NPRM Comment Period End	03/01/2010	
Final Action	12/00/2010	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: Federal
Small Entities Affected: Business; Organizations
Federalism: No
Energy Affected: No
International Impacts: This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
RIN: 0910-AA49

View Related Documents

Title: Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs, Including Drugs That Are Regulated Under a Biologics License Application and Animal Drugs

Abstract: The rule will reorganize, consolidate, clarify, and modify current regulations at 21 CFR part 207 concerning who must register establishments and list human drugs, certain biological drugs, and animal drugs. These regulations contain information on when, how, and where to register drug establishments and list drugs, and what information must be submitted for initial registration and listing and for changes to registration and listing. Consistent with amended statutory requirements, the rule will require that this information be submitted electronically. The rule will also make certain changes to the National Drug Code (NDC) system and would require that the appropriate human-readable NDC number appear on labels for drugs subject to the listing requirement.

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 20; 21 CFR 201 and 207; 21 CFR 314 and 330; 21 CFR 514 to 516; 21 CFR 601 and 607; 21 CFR 610; 21 CFR 1271 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321 and 331; 21 USC 351 to 353; 21 USC 355 to 356c; 21 USC 360 and 360b; 21 USC 360c to 360f; 21 USC 360h to 360j; 21 USC 371 and 374; 21 USC 379e and 381; 21 USC 393; 15 USC 1451 to 1561; 42 USC 262 and 264; 42 USC 271
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Final Action	00/00/0000	
NPRM	08/29/2006	71 FR 51276
NPRM Comment Period End	02/26/2007	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: Business
Federalism: No
International Impacts: This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.
Public Comment URL: www.regulations.gov

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AB88

View Related Documents

Title: Current Good Manufacturing Practice in Manufacturing, Packing, Labeling, or Holding Operations for Dietary Supplements

Abstract: The Food and Drug Administration published a final rule in the Federal Register of June 25, 2007 (72 FR 34752), on current good manufacturing practice (CGMP) regulations for dietary supplements. FDA also published an Interim Final Rule in the same Federal Register (72 FR 34959) that provided a procedure for requesting an exemption from the final rule requirement that the manufacturer conduct at least one appropriate test or examination to verify the identity of any component that is a dietary ingredient. This IFR allows for submission to, and review by, FDA of an alternative to the required 100 percent identity testing of components that are dietary ingredients, provided certain conditions are met. This IFR also establishes a requirement for retention of records relating to the FDA's response to an exemption request.

Priority: Economically Significant
Agenda Stage of Rulemaking: Long-term Action
Major: Yes
Unfunded Mandates: Private Sector
CFR Citation: 21 CFR 111 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321; 21 USC 342; 21 USC 343; 21 USC 371; 21 USC 374; 21 USC 381; 21 USC 393; 42 USC 264
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Final Action	00/00/0000	
ANPRM	02/06/1997	62 FR 5700
ANPRM Comment Period End	06/06/1997	
NPRM	03/13/2003	68 FR 12157
NPRM Comment Period End	08/11/2003	
Interim Final Rule	06/25/2007	72 FR 34959
Final Rule	06/25/2007	72 FR 34752
Interim Final Rule Comment Period End	10/24/2007	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: Undetermined
Federalism: No
Energy Affected: No
International Impacts: This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AC50

View Related Documents

Title: Food Labeling: Trans Fatty Acids in Nutrition Labeling: Consumer Research To Consider Nutrient Content and Health Claims and Possible Footnote or Disclosure Statements

Abstract: The Food and Drug Administration issued an Advance Notice of Proposed Rulemaking on July 11, 2003 (68 FR 41507), to solicit information and data that potentially could be used to establish new nutrient content claims about trans fatty acids; to establish qualifying criteria for trans fat in current nutrient content claims for saturated fat and cholesterol, lean and extra lean claims, and health claims that contain a message about cholesterol-raising lipids; and, in addition, to establish disclosure and disqualifying criteria to help consumers make heart-healthy food choices. The Agency also requested comments on whether it should consider statements about trans fat, either alone or in combination with saturated fat and cholesterol, as a footnote in the Nutrition Facts panel or as a disclosure statement in conjunction with claims to enhance consumers' understanding about such cholesterol-raising lipids and how to use the information to make healthy food choices. Information and data obtained from comments and from consumer studies that will be conducted by FDA also may be used to help draft a proposed rule that would establish criteria for certain nutrient content or health claims or require the use of a footnote, or other labeling approach, about one or more cholesterol-raising lipids in the Nutrition Facts panel to assist consumers in maintaining healthy dietary practices.

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 101 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321; 21 USC 343; 21 USC 371
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	00/00/0000	
ANPRM	07/11/2003	68 FR 41507
ANPRM Comment Period End	10/09/2003	
ANPRM Comment Period Reopened for 45 days	03/01/2004	69 FR 9559
ANPRM Comment Period Extended for Additional 60 days	04/19/2004	69 FR 20838
ANPRM Comment Period End	06/18/2004	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: Undetermined
Federalism: Undetermined
Energy Affected: No
International Impacts: This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.
Related RINs: Related to 0910-AB66
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AC54

View Related Documents

Title: Food Standards: General Principles and Food Standards Modernization

Abstract: In 1995, the FDA and FSIS reviewed their regulatory procedures and requirements for food standards to determine

whether any were still needed, and if so, which ones should be modified or streamlined. To request public comment to assist them in their review of the need for food standards, both Agencies published advance notices of proposed rulemaking (ANPRMs) on food standards in December 1995 (60 FR 47453 and 60 FR 67492). These ANPRMs discussed the Agencies' regulations and policy governing food standards, the history of food standards, and the possible need to revise the food standards. Several comments in response to the ANPRMs recommended that the Agencies establish general principles or a fundamental philosophy for reviewing food standards and revising them. The Agencies agreed with these comments and determined that it would be appropriate to develop general principles for reviewing and revising food standards regulations. The Agencies also agreed with the comments that stated that the Agencies should work in concert to develop consistent food standards regulations. FDA and FSIS proposed a set of general principles that define how modern food standards should be structured (70 FR 29214, May 20, 2005). If this proposed rule is adopted, FDA and FSIS will require that a citizen petition for establishing, revising, or eliminating a food standard in 21 CFR parts 130 to 169 and 9 CFR part 319 be submitted in accordance with the general principles. Conversely, the Agencies may find deficient a petition to establish, revise, or eliminate a food standard that does not follow these general principles.

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 130.5 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321; 21 USC 336; 21 USC 341; 21 USC 343; 21 USC 371
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Final Action	00/00/0000	
ANPRM	12/29/1995	60 FR 67492
ANPRM Comment Period End	04/29/1996	
NPRM	05/20/2005	70 FR 29214
NPRM Comment Period End	08/18/2005	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: Undetermined
Small Entities Affected: No
Federalism: No
Energy Affected: No
Related RINs: Related to 0583-AC72
Related Agencies: Joint: FSIS

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
RIN: 0910-AF08

View Related Documents

Title: Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; Revision of Certain Labeling Controls

Abstract: The proposed rule would amend the packaging and labeling control provisions of the current good manufacturing practice regulations for human and veterinary drug products by limiting the application of special control procedures for the use of cut labeling to immediate container labels, individual unit cartons, or multiunit cartons containing immediate containers that are not packaged in individual unit cartons. The proposal would also permit the use of any automated technique, including differentiation by labeling size and shape, that physically prevents incorrect labeling from being processed by labeling and packaging equipment when cut labeling is used.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Long-term Action
Major: Undetermined
Unfunded Mandates: Undetermined
CFR Citation: 21 CFR 211.122 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 351

Legal Deadline: None

Timetable:

Action	Date	FR Cite
Final Action	00/00/0000	
NPRM	07/29/1997	62 FR 40489
NPRM Comment Period End	10/27/1997	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: No

Small Entities Affected: Business

Federalism: Undetermined

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF22

View Related Documents

Title: Food Labeling; Prominence of Calories

Abstract: Section 403(q)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343) requires that certain foods under FDA's jurisdiction bear nutrition information that provides the total number of calories derived from any source and the total number of calories derived from total fat in each serving size or other unit of measure. The ANPRM solicited recommendations on ways to give more prominence to caloric information on the food label.

Priority: Other Significant

Agenda Stage of Rulemaking: Long-term Action

Major: No

Unfunded Mandates: No

CFR Citation: 21 CFR 101.9 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: 21 USC 321; 21 USC 343; 21 USC 371

Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	00/00/0000	
ANPRM	04/04/2005	70 FR 17008
ANPRM Comment Period End	06/20/2005	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

Energy Affected: No

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF23

View Related Documents

Title: Food Labeling; Serving Sizes of Products That Can Reasonably Be Consumed at One Eating Occasion; Updating of Reference Amounts Customarily Consumed; Approaches for Recommending Smaller Portion Sizes

Abstract: Section 403(q)(1)(A)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343 (q)(1)(A)(i)) requires that certain foods under FDA's jurisdiction bear nutrition information that provides the serving size, which is an amount customarily consumed and which is expressed in a common household measure appropriate to the food. As part of FDA's efforts to combat the Nation's obesity problem, the ANPRM solicited recommendations on ways to amend certain provisions of FDA's nutrition labeling regulations concerning serving size and on other approaches to encourage cnsumers to eat smaller portions.

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 101.9; 21 CFR 101.12; 21 CFR 101.60(b) (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321; 21 USC 343; 21 USC 371
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	00/00/0000	
ANPRM	04/04/2005	70 FR 17010
ANPRM Comment Period End	06/20/2005	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: Undetermined
Federalism: Undetermined
Energy Affected: No
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
RIN: 0910-AF25

View Related Documents

Title: Blood Initiative--Requirements for Human Blood and Blood Components Intended for Transfusion or for Further Manufacturing Use

Abstract: The Food and Drug Administration (FDA) is amending the biologics regulations, particularly those related to blood donor eligibility, by removing, revising, or updating specific regulations applicable to blood, blood components, Source Plasma, and Source Leukocytes to be more consistent with current practices and to remove unnecessary or outdated requirements. This action is based on FDA's comprehensive review of the biologics regulations. It is also responsive to reports by the U.S. House of Representatives Committee on Government Reform and Oversight Subcommittee on House Resources and Intergovernmental Relations, the Government Accountability Office (previously, the General Accounting Office), and the Institute of Medicine, and to public comments. These actions are intended to help ensure the continued safety of the Nation's blood supply.

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 606; 21 CFR 610; 21 CFR 630; 21 CFR 640; 21 CFR 660; 21 CFR 820; 21 CFR 1270 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 360c to 360e; 21 USC 360h to 360j; 21 USC 360l; 21 USC 371; 21 USC 372; 21 USC 374; 21 USC 381; 21 USC 383; 42 USC 216; 42 USC 243; 42 USC 262 and 263; 42 USC 263a; 42 USC 264; 42 USC 271
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Final Action	00/00/0000	
NPRM	11/08/2007	72 FR 63416
NPRM Comment Period Extended	01/11/2008	73 FR 1983
NPRM Comment Period End	02/06/2008	
NPRM Comment Period End	08/04/2008	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: Business
Federalism: No
Related RINs: Split From 0910-AB26

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
RIN: 0910-AF34

View Related Documents

Title: Over-the-Counter (OTC) Drug Review--Cough/Cold (Nasal Decongestant) Products

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

Priority: Routine and Frequent
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Final Action (Phenylpropanolamine)	00/00/0000	
NPRM (Amendment) (Sinusitis Claim)	08/02/2004	69 FR 46119
NPRM Comment Period End	11/01/2004	
NPRM (Phenylephrine Bitartrate)	11/02/2004	69 FR 63482
NPRM Comment Period End	01/31/2005	
Final Action (Amendment) (Sinusitis Claim)	10/31/2005	70 FR 58974
NPRM (Phenylpropanolamine)	12/22/2005	70 FR 75988
NPRM Comment Period End	03/22/2006	
Final Action (Phenylephrine Bitartrate)	08/01/2006	71 FR 83358

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: Local; State
Federalism: Yes
Related RINs: Split From 0910-AA01

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF37

View Related Documents

Title: Over-the-Counter (OTC) Drug Review--Labeling of Drug Products for OTC Human Use

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action addresses labeling for convenience (small) size OTC drug packages.

Priority: Routine and Frequent
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 358; 21 USC 360; 21 USC 371; 21 UCS 374; 21 USC 379e
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Final Action	00/00/0000	
NPRM (Convenience Sizes)	12/12/2006	71 FR 74474
NPRM Comment Period End	04/11/2007	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: Local; State
Federalism: Yes
Related RINs: Split From 0910-AA01

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF39

View Related Documents

Title: Over-the-Counter (OTC) Drug Review--Ophthalmic Products

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action finalizes the monograph for emergency first aid eyewash drug products.

Priority: Routine and Frequent
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Final Action (Amendment) (Emergency First Aid Eyewashes)	00/00/0000	
NPRM (Amendment) (Emergency First Aid Eyewashes)	02/19/2003	68 FR 7917

Regulatory Flexibility Analysis Required: Business Government Levels Affected: Local; State
Federalism: Yes
Related RINs: Split From 0910-AA01
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF40

View Related Documents

Title: Over-the-Counter (OTC) Drug Review--Oral Health Care Products
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 NPRM and final action will address oral health care products used to reduce or prevent dental plaque and gingivitis.

Priority: Routine and Frequent Agenda Stage of Rulemaking: Long-term Action
Major: No Unfunded Mandates: No
CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360 to 360a; 21 USC 371 to 371a
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Final Action	00/00/0000	
NPRM (Plaque Gingivitis)	00/00/0000	
ANPRM (Plaque Gingivitis)	05/29/2003	68 FR 32232
ANPRM Comment Period End	08/27/2003	

Regulatory Flexibility Analysis Required: Business Government Levels Affected: Local; State
Federalism: Yes
Related RINs: Split From 0910-AA01
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF44

View Related Documents

Title: Over-the-Counter (OTC) Drug Review--Vaginal Contraceptive Products
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 proposed rule addresses vaginal contraceptive drug products.

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 358; 21 USC 360; 21 USC 371; 21 USC 374; 21 USC 379e
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM (Vaginal Contraceptive Drug Products)	00/00/0000	
Final Action (Warnings)	12/19/2007	72 FR 71769

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: Local; State
Federalism: Yes
Related RINs: Split From 0910-AA01
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
RIN: 0910-AF45

View Related Documents

Title: Over-the-Counter (OTC) Drug Review--Weight Control Products
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 NPRM addresses the use of benzocaine for weight control. The first final action finalizes the 2005 proposed rule for weight control products containing phenylpropanolamine. The second final action will finalize the proposed rule for weight control products containing benzocaine.

Priority: Routine and Frequent
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Final Action (Benzocaine)	00/00/0000	
Final Action (Phenylpropanolamine)	00/00/0000	
NPRM (Benzocaine)	00/00/0000	
NPRM (Phenylpropanolamine)	12/22/2005	70 FR 75988
NPRM Comment Period End	03/22/2006	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: Local; State
Federalism: Yes
Related RINs: Split From 0910-AA01
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF51

View Related Documents

Title: Over-the-Counter (OTC) Drug Review--Overindulgence in Food and Drink Products

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action addresses products containing bismuth subsalicylate for relief of symptoms of upset stomach due to overindulgence resulting from food and drink.

Priority: Routine and Frequent
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Final Action	00/00/0000	
NPRM (Amendment)	01/05/2005	70 FR 741
NPRM Comment Period End	04/05/2005	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: Local; State
Federalism: Yes
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF52

View Related Documents

Title: Over-the-Counter (OTC) Drug Review--Antacid Products

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. One action addresses the labeling of products containing sodium bicarbonate as an active ingredient. The other action addresses the use of antacids to relieve upset stomach associated with overindulgence in food and drink.

Priority: Routine and Frequent
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Final Action (Overindulgence Labeling)	00/00/0000	

Final Action (Sodium Bicarbonate Labeling)	00/00/0000	

Regulatory Flexibility Analysis Required: Business Government Levels Affected: Local; State
Federalism: Yes

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF53

View Related Documents

Title: Over-the-Counter (OTC) Drug Review--Skin Bleaching Products

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action addresses skin bleaching drug products containing hydroquinone.

Priority: Routine and Frequent Agenda Stage of Rulemaking: Long-term Action
Major: No Unfunded Mandates: No
CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Final Action	00/00/0000	
NPRM	08/29/2006	71 FR 51146
NPRM Comment Period End	12/27/2006	

Regulatory Flexibility Analysis Required: Business Government Levels Affected: Local; State
Federalism: Yes

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF56

View Related Documents

Title: Over-the-Counter (OTC) Drug Review--Stimulant Drug Products

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action addresses the use of stimulant active ingredients to relieve symptoms associated with a hangover.

Priority: Routine and Frequent
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM (Amendment) (Hangover)	00/00/0000	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: Local; State
Federalism: Yes

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
RIN: 0910-AF63

View Related Documents

Title: Over-the-Counter (OTC) Drug Review—Antidiarrheal Drug Products

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. These actions address new labeling for antidiarrheal drug products.

Priority: Routine and Frequent
Agenda Stage of Rulemaking: Long-term Action
Major: Undetermined
Unfunded Mandates: No
CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Final Action (New Labeling)	00/00/0000	
NPRM (New Labeling)	00/00/0000	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: Local; State
Federalism: Yes

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
RIN: 0910-AF70

View Related Documents

Title: Over-the-Counter (OTC) Drug Review--Urinary Analgesic Drug Products

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action addresses the products used for urinary pain relief.

Priority: Routine and Frequent
Agenda Stage of Rulemaking: Long-term Action
Major: Undetermined
Unfunded Mandates: No
CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM (Urinary Analgesic)	00/00/0000	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: Local; State
Federalism: Yes

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
RIN: 0910-AF95

View Related Documents

Title: Over-the-Counter (OTC) Drug Review—Certain Category II Active Ingredients

Abstract: The Food and Drug Administration (FDA) is proposing that certain ingredients in over-the-counter (OTC) drug products are not generally recognized as safe and effective or are misbranded. FDA issued this proposed rule because we did not receive any data and information on these ingredients in response to our request on December 31, 2003 (68 FR 75585). This rule will finalize the 2008 proposed rule.

Priority: Routine and Frequent
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Final Action	00/00/0000	
NPRM	06/19/2008	73 FR 34895
NPRM Comment Period End	09/17/2008	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: Local; State
Federalism: Yes

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AG02

View Related Documents

Title: Animal Food Labeling; Declaration of Certifiable Color Additives

Abstract: The Food and Drug Administration (FDA) is proposing to amend its regulations regarding the declaration of certified color additives on the labels of animal food including animal feeds and pet foods. FDA is proposing this amendment in response to the Nutrition Labeling and Education Act of 1990 (PL 101-535), which amended section 403 of the Federal Food, Drug, and Cosmetic Act (21 USC 343) by requiring, among other things, the listing on food labels of the common or usual names of all color additives required to be certified by FDA. An additional purpose of this amendment is to make these regulations consistent with the regulations regarding the declaration of certified color additives on the labels of human food. The proposed rule also suggests appropriate terminology for the declaration of certification-exempt color additives on the labels of animal food.

Priority: Substantive, Nonsignificant Agenda Stage of Rulemaking: Long-term Action
Major: No Unfunded Mandates: No
CFR Citation: 21 CFR 501.22(k) (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 343(i)
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Final Action	00/00/0000	
NPRM	11/23/2009	74 FR 61068
NPRM Comment Period End	02/22/2010	

Regulatory Flexibility Analysis Required: No Government Levels Affected: No
Federalism: Undetermined
International Impacts: This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AG14

View Related Documents

Title: Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements, and Administrative Procedures

Abstract: Pursuant to section 610 of the Regulatory Flexibility Act, FDA is currently undertaking a review of regulations promulgated under the Prescription Drug Marketing Act (PDMA) including those contained in 21 CFR part 203 and 21 CFR sections 205.3 and 205.50 (as amended in 64 FR 67762 and 67763). The purpose of this review is to determine whether the regulations in 21 CFR part 203 and 21 CFR sections 205.3 and 205.50 (as amended in 64 FR 67762 and 67763) should be continued without change, or whether they should be amended or rescinded, consistent with the stated objectives of applicable statues, to minimize adverse impacts on a substantial number of small entities. FDA solicited comments on the following: (1) The continued need for the regulations in 21 CFR part 203 and 21 CFR sections 205.3 and 205.50 (as amended in 64 FR 67762 and 67763); (2) the nature of complaints or comments received from the public concerning the regulations in 21 CFR part

203 and 21 CFR sections 205.3 and 205.50 (as amended in 64 FR 67762 and 67763); (3) the complexity of the regulations in 21 CFR part 203 and 21 CFR sections 205.3 and 205.50 (as amended in 64 FR 67762 and 67763); (4) the extent to which the regulations in 21 CFR part 203 and 21 CFR sections 205.3 and 205.50 (as amended in 64 FR 67762 and 67763) overlap, duplicate, or conflict with other Federal rules, and to the extent feasible, with State and local governmental rules, and (5) the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulations in 21 CFR part 203 and 21 CFR sections 205.3 and 205.50 (as amended in 64 FR 67762 and 67763). FDA received one comment on this review; and FDA notes that portions of the PDMA have been stayed in connection with RxUSA Wholesale, Inc., v. HHS, 467 F. Supp.2d 285 (E.D.N.Y. 2006), aff'd, 2008 U.S. App. LEXIS 14661 (2d Cir. 2008)); and that the litigation itself has been administratively closed (with either party having the right to reopen) through June 30, 2011. FDA is certifying that it is not feasible for the agency to complete its review by December 4, 2010, and therefore is extending the completion date by one year.

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: Undetermined
Unfunded Mandates: No
CFR Citation: 21 CFR 203; 21 CFR 205.3; 21 CFR 205.50 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 331; 21 USC 333; 21 USC 351; 21 USC 352; 21 USC 353; 21 USC 360; 21 USC 371; 21 USC 374; 21 USC 381
Legal Deadline:

Action	Source	Description	Date
Other	Statutory	Planned Section 610 Review	12/03/2009

Timetable:

Action	Date	FR Cite
Begin Review of Current Regulation	11/24/2008	
End Review of Current Regulation	12/00/2011	

Regulatory Flexibility Analysis Required: Business; Governmental Jurisdictions; Organizations
Government Levels Affected: Federal; Local; State
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
RIN: 0910-AG35

View Related Documents

Title: Produce Safety Regulation

Abstract: The Food and Drug Administration (FDA) has determined that enforceable standards (as opposed to voluntary recommendations) for the production and packing of fresh produce are necessary to ensure best practices are commonly adopted. FDA is proposing to promulgate regulations setting enforceable standards for fresh produce safety at the farm and packing house. The purpose of the proposed rule is to reduce the risk of illness associated with contaminated fresh produce. The proposed rule will be based on prevention-oriented public health principles and incorporate what we have learned in the past decade since the agency issued general good agricultural practice guidelines entitled "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables" (GAPs Guide). The proposed rule also will reflect comments received on the agency's 1998 update of its GAPs guide and its July 2009 draft commodity specific guidances for tomatoes, leafy greens, and melons. Although the proposed rule will be based on recommendations that are included in the GAPs guide, FDA does not intend to make the entire guidance mandatory. FDA's proposed rule would, however, set out clear standards for implementation of modern preventive controls. The proposed rule also would emphasize the importance of environmental assessments to identify hazards and possible pathways of contamination and provide examples of risk reduction practices recognizing that operators must tailor their preventive controls to particular hazards and conditions affecting their operations. The requirements of the proposed rule would be scale appropriate and commensurate with the relative risks and complexity of individual operations. FDA intends to issue guidance after the proposed rule is finalized to assist industry in complying with the requirements of the

new regulation.

Priority: Economically Significant
Agenda Stage of Rulemaking: Long-term Action
Major: Yes
Unfunded Mandates: Private Sector
CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 342; 21 USC 371; 42 USC 264
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	00/00/0000	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: No
Federalism: Undetermined
International Impacts: This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
RIN: 0910-AG36

View Related Documents

Title: Modernization of the Current Food Good Manufacturing Practices Regulation
Abstract: The Food and Drug Administration (FDA) is proposing to amend its current good manufacturing practices (CGMP) regulations (21 CFR part 110) for manufacturing, packing, or holding human food. This proposed rule would require food facilities to address issues such as environmental pathogens, food allergens, mandatory employee training, and sanitation of food contact surfaces. The proposed rule also would require food facilities to develop and implement preventive control systems. FDA is taking this action to better address changes that have occurred in the food industry and protect public health.

Priority: Economically Significant
Agenda Stage of Rulemaking: Long-term Action
Major: Yes
Unfunded Mandates: No
CFR Citation: 21 CFR 110 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 342; 21 USC 371; 42 USC 264
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	00/00/0000	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: No
Federalism: Undetermined
International Impacts: This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.
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Department of Health and Human Services (HHS)

Food and Drug Administration (FDA) RIN: 0910-AG42

View Related Documents

Title: Smokeless Tobacco Warning Labels

Abstract: Section 3 of the Comprehensive Smokeless Tobacco Health Education Act of 1986, as amended by section 204 of the Family Smoking Prevention and Tobacco Control Act, requires that packages of smokeless tobacco bear specific warning statements about the health effects of using these products and sets out specific requirements for the location, size, and appearance of such statements. In addition, the Tobacco Control Act requires that warning statements be equally distributed and displayed on packages and rotated quarterly in advertising and requires manufacturers, importers, distributors or retailers to submit warning plans for approval. Section 205 of the Tobacco Control Act authorizes FDA to use rulemaking to adjust the format, type size, and text of any of the label requirements, require color graphics to accompany the text, increase the required label area from 30 percent up to 50 percent of the front and rear panels of the package, or establish the format, type size, and text of any other disclosures required under the Federal Food, Drug, and Cosmetic Act, if FDA finds that such change would promote greater public understanding of the risks associated with the use of smokeless tobacco products. This proposed rule would clarify certain requirements in the statute.

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: Undetermined
Unfunded Mandates: Undetermined
CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 111-31, sec 204, The Family Smoking Prevention and Tobacco Control Act
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	00/00/0000	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: Undetermined
Federalism: Undetermined
International Impacts: This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AG51

View Related Documents

Title: Effective Date of Requirement for Premarket Approval for Four Class III Preamendments Devices

Abstract: The purpose of this proposed rule is to require the submission of a premarket approval application or notice of completion of a product development protocol for four class III preamendments devices. This regulation will provide FDA with more oversight concerning the four class III device types that currently can be marketed via less stringent premarket notification procedures. If finalized, this regulation will require premarket approval for the four class III device types within 90 days of the issuance of a final rule or within 30 months after final classification of the device, whichever is later. The four devices are ventricular bypass (assist) device; pacemaker repair or replacement material; female condom; and transilluminator for breast evaluation. The proposed rule also publicizes advisory panel findings on the four device types and provides an opportunity to request a change in classification of the devices based on new information.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 870; 21 CFR 884; 21 CFR 892 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: 21 USC 360ccc-1 and 360ccc-2; 21 USC 371(a)
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Final Action	00/00/0000	
NPRM	08/25/2010	75 FR 52294
NPRM Comment Period End	11/30/2010	

Regulatory Flexibility Analysis Required: No Government Levels Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF93

View Related Documents

Title: Use of Ozone-Depleting Substances; Removal of Essential Use Designations [Flunisolide, Triamcinolone, Metaproterenol, Pirbuterol, Albuterol and Ipratropium in Combination, Cromolyn, and Nedocromil]

Abstract: Medical products using chlorofluorocarbons (CFCs) and other ozone-depleting substances may only be legally marketed if they are listed in 21 CFR part 2.125 as "essential uses." This final rule would remove the essential use designations after a specified date for metered-dose inhalers (MDIs) containing flunisolide, triamcinolone, metaproterenol, pirbuterol, albuterol and ipratropium in combination, cromolyn, and nedocromil. Under the provisions of this final rule, these MDIs would have to be removed from the market. This final rule is consistent with obligations under the Clean Air Act and the Montreal Protocol on Substances That Deplete the Ozone Layer.

Priority: Economically Significant Agenda Stage of Rulemaking: Completed Action
Major: Yes Unfunded Mandates: Private Sector
CFR Citation: 21 CFR 2.125 (Revision); 40 CFR 82.4; 40 CFR 82.64; 40 CFR 82.66 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321; 21 USC 331; 21 USC 335; 21 USC 342; 21 USC 346a; 21 USC 348; 21 USC 351 and 352; 21 USC 355; 21 USC 360b; 21 USC 361 and 362; 21 USC 371 and 372; 21 USC 374; 42 USC 7671 et seq
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	06/11/2007	72 FR 32030
NPRM Comment Period End	09/10/2007	
Final Action	04/14/2010	75 FR 19213

Regulatory Flexibility Analysis Required: No Government Levels Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AG13

View Related Documents

Title: Premarketing Safety Reporting Requirements for Human Drug and Biological Products

Abstract: The Food and Drug Administration (FDA) has undertaken revisions to 21 CFR 312.32, 312.64, and 320.31 to better protect public health and improve safety reporting by increasing the quality of safety reports, expediting FDA's review of critical safety information, advancing worldwide consistency in the collection and submission of safety information, and strengthening the agency's ability to monitor the safety of certain human drugs and biological products. The final rule amends the premarketing safety reporting requirements for human drugs and biological products to codify the Agency's expectations for timely acquisition, evaluation, and submission of relevant and useful safety information, to improve the overall quality of safety reporting, to implement internationally consistent definitions, to subject bioavailability and bioequivalence studies to safety reporting requirements, and to make other minor revisions. 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. FDA plans to finalize the premarket and postmarket safety reporting requirements in separate final rules.

Priority: Other Significant
Agenda Stage of Rulemaking: Completed Action
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 312; 21 CFR 320 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 216; 42 USC 241; 42 USC 242a; 42 USC 262 and 263; 42 USC 263a to 263n; 42 USC 264; 42 USC 300aa; 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360b to 360j; 21 USC 361a; 21 USC 371; 21 USC 374; 21 USC 375; 21 USC 379e; 21 USC 381
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	03/14/2003	68 FR 12406
NPRM Comment Period Extended	06/18/2003	
NPRM Comment Period End	07/14/2003	
NPRM Comment Period Extended End	10/14/2003	
Final Action	09/29/2010	75 FR 59935

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: Business
Federalism: No
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AG25

View Related Documents

Title: Sterility Requirement for Aqueous-Based Drug Products for Oral Inhalation

Abstract: FDA is undertaking a review of 21 CFR 200.51, under section 610 of the Regulatory Flexibility Act. The purpose of this review is to determine whether this regulation on aqueous-based drug products for oral inhalation should be continued without change, or whether it should be amended or rescinded, consistent with the stated objectives of applicable statues, to minimize adverse impacts on a substantial number of small entities. FDA will consider, and is soliciting comments on the following: (1) The continued need for 21 CFR 200.51; (2) the nature of complaints or comments received concerning 21 CFR 200.51; (3) the complexity of 21 CFR 200.51; (4) the extent to which the regulation overlaps, duplicates, or conflicts with other

Federal, State, or governmental rules; and (5) the degree to which technology, economic conditions, or other factors have changed in the area affected by 21 CFR 200.51. No comments were required. FDA's review of these regulations concluded that they should be continued without change.

Priority: Other Significant
Agenda Stage of Rulemaking: Completed Action
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 200.51 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 358; 21 USC 360e; 21 USC 371; 21 USC 374; 21 USC 375
Legal Deadline:

Action	Source	Description	Date
Other	Statutory	Completion of a section 610 Review	05/26/2010

Timetable:

Action	Date	FR Cite
Begin Review	05/01/2009	
End Review	05/31/2010	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
RIN: 0910-AG33

View Related Documents

Title: Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents

Abstract: This rule establishes regulations restricting the sale and distribution of cigarettes and smokeless tobacco to children and adolescents, implementing section 102 of the Family Smoking Prevention and Tobacco Control Act (FSPTCA). FSPTCA sections 102 and 6(c)(1) require the Secretary to publish, within 270 days of enactment, a final rule regarding cigarettes and smokeless tobacco. This final rule must be identical, except for several changes identified in section 102(a)(2) of FSPTCA, to part 897 of the regulations promulgated by the Secretary of HHS in the August 28, 1996, issue of the Federal Register (61 FR 44396). This final rule prohibits the sale of cigarettes and smokeless tobacco to individuals under the age of 18 and requires manufacturers, distributors, and retailers to comply with certain conditions regarding access to, and promotion of, these products. Among other things, the final rule requires retailers to verify a purchaser's age by photographic identification. It also prohibits, with limited exception, free samples and prohibits the sale of these products through vending machines and self-service displays except in facilities where individuals under the age of 18 are not present or permitted at any time. The rule also limits the advertising and labeling to which children and adolescents are exposed. The rule accomplishes this by generally restricting advertising to which children and adolescents are exposed to a black-and-white, text-only format. The rule also prohibits the sale or distribution of brand-identified promotional, non-tobacco items such as hats and tee shirts. Furthermore, the rule prohibits sponsorship of sporting and other events, teams, and entries in a brand name of a tobacco product, but permits such sponsorship in a corporate name. FDA also published in the same issue of the Federal Register an advance notice of proposed rulemaking requesting comments, data, research, or other information on the regulation of outdoor advertising of cigarettes and smokeless tobacco.

Priority: Economically Significant
Agenda Stage of Rulemaking: Completed Action
Major: Yes
Unfunded Mandates: State, Local, Or Tribal Governments; Private Sector
CFR Citation: 21 CFR 1140 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: 21 USC 301 et seq, The Federal Food, Drug, and Cosmetic Act; PL 111-31, Family Smoking Prevention and Tobacco Control Act

Legal Deadline: Family Smoking Prevention and Tobacco Control Act sections 6(c)(1) and 102(a)(1) require publication of this final rule within 270 days of enactment.

Action	Source	Description	Date
Other	Statutory	Public Law 111-31 sections 6(c)(1) and 102(a)(1)	03/19/2010

Timetable:

Action	Date	FR Cite
ANPRM	03/19/2010	75 FR 13241
Final Rule	03/19/2010	75 FR 13225
ANPRM Comment Period End	05/18/2010	
Final Rule Effective	06/22/2010	

Regulatory Flexibility Analysis Required: Business

Government Levels Affected: Federal; Local; State; Tribal

Federalism: Yes

Related RINs: Related to 0910-AG40

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AG34

View Related Documents

Title: Over-the-Counter Human Drugs; Labeling Requirements

Abstract: Section 201.66 (21 CFR section 201.66) established a standardized format for the labeling of OTC drug products that included: (1) Specific headings and subheadings presented in a standardized order, (2) standardized graphical features such as headings in bold type and the use of “bullet points” to introduce key information, and (3) minimum standards for type size and spacing. FDA issued the final rule to improve labeling after considering comments submitted to the agency following the publication of the proposed regulation in 1997. In 1999, FDA published the final rule and stated that a standardized labeling format would significantly improve readability by familiarizing consumers with the types of information in OTC drug product labeling and the location of that information. In addition, a standardized appearance and standardized content, including various ”user-friendly” visual cues, would help consumers locate and read important health and safety information and allow quick and effective product comparisons, thereby helping consumers to select the most appropriate product. FDA undertook a review of section 201.66 under section 610 of the Regulatory Flexibility Act. The purpose of this review is to determine whether the regulation in section 201.66 should be continued without change, or whether it should be further amended or rescinded, consistent with the stated objectives of applicable statutes, to minimize adverse impacts on a substantial number of small entities. FDA will consider, and is soliciting comments on the following: (1) The continued need for the regulation in section 201.66; (2) the nature of the complaints or comments received concerning the regulation in section 201.66; (3) the complexity of the regulations in section 201.66; (4) the extent to which the regulations in section 201.66 overlap, duplicate, or conflict with other Federal, State, or governmental rules; and (5) the degree to which technology, economic conditions, or other factors have changed for the products still subject to the labeling standard regulations in section 201. No comments were received. FDA's review of these regulations concluded that they should be continued without change.

Priority: Routine and Frequent

Agenda Stage of Rulemaking: Completed Action

Major: No

Unfunded Mandates: No

CFR Citation: 21 CFR 201.66 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: 5 USC 610

Legal Deadline: None

Timetable:

Action	Date	FR Cite

Begin Review of Current Regulation	08/03/2009	
End Review of Current Regulation	05/27/2010	

Regulatory Flexibility Analysis Required: Business Government Levels Affected: Local; State
Federalism: Yes
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Department of Health and Human Services (HHS)
Indian Health Service (IHS) RIN: 0917-AA08

View Related Documents

Title: Standards for the Planning, Design, Construction and Operation of Health Care and Sanitation Facilities
Abstract: Section 311(c)(1) of the Indian Health Care Improvement Act, Public Law No. 94-437 (1976), as amended by the Patient Protection and Affordable Care Act, Pub. L. No. 111-148, section 10221 (2010) requires the Secretary, acting though the Indian Health Service (IHS), to establish, by regulation, standards for the planning, design, construction, and operation of health care and sanitation facilities serving Indians under the Indian Health Care Improvement Act. Additionally, these regulations would stipulate which departmental regulations would be applicable to these activities.

Priority: Other Significant Agenda Stage of Rulemaking: Long-term Action
Major: Undetermined Unfunded Mandates: Undetermined
CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 94-437, sec 311(c)(1); IHCI Act as amended by PL 111-148, sec 10221 PPAC Act
Legal Deadline: None

Timetable:

Action	Date	FR Cite
ANPRM	00/00/0000	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: Undetermined
Federalism: No
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Department of Health and Human Services (HHS)
Indian Health Service (IHS) RIN: 0917-AA09

View Related Documents

Title: Confidentiality of Medical Quality Assurance Records; Qualified Immunity for Participants
Abstract: Section 805(j)) of the Indian Health Care Improvement Act, Public Law No. 94-437 (1976), as amended by the Patient Protection and Affordable Care Act, Pub. L. No. 111-148, section 10221 (2010) requires the Secretary of the Department of Health and Human Services, acting through the Indian Health Service (IHS), to promulgate regulations to implement section 805. Section 805 makes confidential and privileged the medical quality assurance records of Indian health programs and urban Indian organizations, with very limited exceptions. It also prohibits the testimony of individuals that review or create medical quality assurance records, with very limited exceptions. Although section 805 is immediately executable, the

Secretary is required to issue regulations which could substantively affect the implementation of this provision.

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 94-437, sec 805, IHCI ACT; amended by PL 111-148; sec 10221, PPAC Act
Legal Deadline: None

Timetable:

Action	Date	FR Cite
ANPRM	00/00/0000	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: Undetermined
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Indian Health Service (IHS)
RIN: 0917-AA10

View Related Documents

Title: Catastrophis Health Emergency Fund (CHEF)

Abstract: Section 202(d) of the Indian Health Care Improvement Act (IHCIA), Public Law No. 94-437 (1976), as amended by the Patient Protection and Affordable Care Act, Public Law No. 111-148, section 10221 (2010) requires the Secretary of the Department of Health and Human Services, acting through the Indian Health Service (IHS), to promulgate regulations to implement section 202. Section 202 of the IHCIA amends the IHS Catastrophic Health Emergency Fund (CHEF) to revise the threshold cost for reimbursement of the cost of treatment using contract health services funds to an IHS or Tribally managed facility. The law also describes an annual increase in the threshold that is based on the increase in the medical care expenditure category of the consumer price index for all consumers for the 12 month period ending with December of the previous year.

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: Undetermined
Unfunded Mandates: No
CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 94-437, sec 202(d), IHCI Act, as amended by PL 111-148, sec 10221, PPAC Act
Legal Deadline: None

Timetable:

Action	Date	FR Cite
ANPRM	00/00/0000	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: Undetermined
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Indian Health Service (IHS) RIN: 0917-AA11

View Related Documents

Title: American Indians Into Psychology Program

Abstract: Section 217 of the Indian Health Care Improvement Act, Public Law No. 94-437 (1976), as amended by the Patient Protection and Affordable Care Act, Public Law No. 111-148, section 10221 (2010) requires the Secretary to issue regulations for the competitive awarding of grants under the American Indians Into Psychology Program Grant program.

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: Undetermined
CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 94-437, sec 217, IHCI Act, as amended by PL 111-148, sec 10221, PPACare Act
Legal Deadline: None

Timetable:

Action	Date	FR Cite
ANPRM	00/00/0000	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: Undetermined
Federalism: No
Energy Affected: No

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Department of Health and Human Services (HHS)
Centers for Disease Control and Prevention (CDC) RIN: 0920-AA16

View Related Documents

Title: Amendments to Powered Air-Purifying Respirator Requirements for Approval of Respiratory Protection Devices

Abstract: As a component of its ongoing update of respirator certification standards under part 84, NIOSH plans to modify performance testing and other specifications for the certification of powered air-purifying respirators and air-supplied respirators. These respirators are used in a variety of workplace applications, including emergency response activities. Current requirements are outdated. This advance notice of proposed rulemaking (ANPRM) will solicit information from respirator manufacturers and other stakeholders to assist in the development of a notice of proposed rulemaking (NPRM) that will reflect current technological capabilities and needs. NIOSH may also solicit information relevant to the regulatory analyses required for rulemaking.

Priority: Other Significant
Agenda Stage of Rulemaking: PreRule
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 84 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 28 USC 651; 30 USC 3; 30 USC 7; 30 USC 11; 30 USC 842; 30 USC 844
Legal Deadline: None

Timetable:

Action	Date	FR Cite
ANPRM	09/00/2011	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Federalism: No
Energy Affected: No

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Department of Health and Human Services (HHS)
Centers for Disease Control and Prevention (CDC) RIN: 0920-AA14

View Related Documents

Title: Control of Communicable Diseases: Foreign and Possessions; Proposed Revision of HHS/CDC Animal Importation Regulations

Abstract: By statute, the Secretary of Health and Human Services has broad authority to prevent introduction, transmission, and spread of communicable diseases from foreign countries into the United States and from one State or possession into another. The Secretary has designated the authority to prevent the introduction of diseases from foreign countries to the Director, Centers for Disease Control and Prevention (CDC). In this NPRM, HHS/CDC is proposing to broaden its existing regulations pertaining to the importation of dogs and cats to protect the public against communicable diseases, including rabies, and to apply these same requirements to imports of domesticated ferrets. HHS/CDC also proposes to limit the ports of entry where imported live dogs, cats, and ferrets may enter the United States. Furthermore, HHS/CDC proposes to broaden and revise current import restrictions on African rodents that were originally established through an interim final rule in response to an outbreak of Monkeypox to include all members of the order Rodentia. In this NPRM, HHS/CDC is also proposing to codify existing permit requirements on the importation of bats (all animals in the order Chiroptera) into the United States. HHS/CDC is also proposing to codify an appeals provision for permits denied under this subpart. These changes are proposed under CDC's authority to prevent introduction, transmission, and spread of communicable diseases from foreign countries into the United States, which includes the authority to restrict the importation of animals and animal products that pose a risk to human health.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: Yes
Unfunded Mandates: No
CFR Citation: 42 CFR 71 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 264
Legal Deadline: None

Timetable:

Action	Date	FR Cite
ANPRM	07/31/2007	72 FR 41676
ANPRM Comment Period End	10/01/2007	
Notice Extending ANPRM Comment Period	10/01/2007	72 FR 55729
ANPRM Extended Comment Period End	12/01/2007	
NPRM	04/00/2011	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: Undetermined
Federalism: No
Energy Affected: No

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Department of Health and Human Services (HHS)
Centers for Disease Control and Prevention (CDC) RIN: 0920-AA21

View Related Documents

Title: Amendments to Specifications for Medical Examinations of Underground Coal Miners

Abstract: NIOSH plans to modify sections of 42 CFR part 37 to allow for the use of digital radiography in medical screening of coal miners for coal workers' pneumoconiosis. Current provisions of these regulations require the use of film radiography which is being phased out of use at medical facilities in the United States.

Priority: Info./Admin./Other
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 37 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 30 USC 843
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	09/00/2011	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: Federal
Federalism: No

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Department of Health and Human Services (HHS)
Centers for Disease Control and Prevention (CDC) RIN: 0920-AA23

View Related Documents

Title: Control of Communicable Diseases: Foreign and Possessions Regulations; Nonhuman Primate

Abstract: By statute, the Secretary of Health and Human Services has broad authority to prevent introduction, transmission, and spread of communicable diseases from foreign countries into the United States and from one State or possession into another. The Secretary has delegated the authority to prevent the introduction of diseases from foreign countries to the Director, CDC. CDC also enforces entry requirements for certain animals, etiologic agents, and vectors deemed to be of public health significance. CDC is proposing to amend its regulations related to the importation of live nonhuman primates (NHPs) by extending existing requirements for the importation of cynomolgus, African green, and rhesus monkeys to all NHPs. The agency also is proposing to reduce the frequency at which importers of the three species are required to renew their registrations, (from every 180 days to every two years). CDC proposes to incorporate existing guidelines into the regulations and add new provisions to address NHPs imported as part of a circus or trained animal act, NHPs imported by zoological societies, the transfer of NHPs from approved laboratories, and non-live imported NHP products. CDC is also proposing that all NHPs be imported only through ports of entry where a CDC quarantine station is located.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 71.53 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 264
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	01/00/2011	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: Federal; Local
Federalism: No

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Department of Health and Human Services (HHS)
Centers for Disease Control and Prevention (CDC) RIN: 0920-AA28

View Related Documents

Title: Medical Examination of Aliens

Abstract: The Secretary of Health and Human Services has the authority to promulgate regulations that establish requirements for the medical examination of aliens. Under this authority, CDC/HHS is amending its regulations that govern medical examinations that aliens must undergo before they may be admitted to the United States. In this NPRM, HHS/CDC is proposing to update and modernize its existing regulations by revising the list of diseases identified as a ''communicable disease of public health significance'' and by revising the definitions for drug abuse and drug addiction. This NPRM is also proposing the addition of the vaccination requirements as provided in Section 212 of the Immigration and Nationality Act. HHS/CDC is revising these regulations to reflect current medical knowledge and practices. These revisions will give CDC the maximum flexibility it needs to identify and respond to newly emerging and re-emerging diseases among U.S.-bound immigrants and refugees.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: Undetermined
CFR Citation: 42 CFR 34 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 8 USC 1182; 8 USC 1222; 42 USC 252
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	04/00/2011	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Centers for Disease Control and Prevention (CDC) RIN: 0920-AA30

View Related Documents

Title: Possession, Use, and Transfer of Select Agents and Toxins: 1918 Influenza

Abstract: The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 authorizes the HHS Secretary to regulate the possession, use, and transfer of select agents and toxins that have the potential to pose a severe threat to public health and safety. These regulations are set forth at 42 CFR 73. Based on public comments we received, we are proposing to revise the entry for the 1918 pandemic influenza virus from "reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments" to "Chimeric influenza viruses containing gene segments from the 1918 pandemic influenza strain."

Priority: Economically Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: Undetermined
Unfunded Mandates: No
CFR Citation: 42 CFR 73.3 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 107-188
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	11/00/2011	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Federalism: No
Energy Affected: No
Related RINs: Related to 0920-AA09
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Department of Health and Human Services (HHS)
Centers for Disease Control and Prevention (CDC) RIN: 0920-AA34

View Related Documents

Title: Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Biennial Review and Republication of the Select Agent and Toxin List

Abstract: By statute, the Secretary of Health and Human Services has broad authority to prevent introduction, transmission, and spread of communicable diseases from foreign countries into the United States and from one State or possession into another. Communicable disease regulations are divided into two parts: Part 71 pertaining to foreign arrivals and part 70 pertaining to interstate matters. This rule (42 CFR Part 71) will update and improve CDC's response to both global and domestic disease threats by creating a multi-tiered illness detection and response process thus substantially enhancing the public health system's ability to slow the introduction, transmission, and spread of communicable disease. The final rule focuses primarily on requirements relating to the reporting of deaths and illnesses onboard aircrafts and ships, and the collection of specific traveler contact information for the purpose of CDC contacting travelers in the event of an exposure to a communicable disease.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: None (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: Not Yet Determined
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	10/00/2011	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Centers for Disease Control and Prevention (CDC) RIN: 0920-AA35

View Related Documents

Title: Amendments to Closed-Circuit Self-Contained Breathing Apparatus Performance Requirements for Approval of Respiratory Protective Devices

Abstract: NIOSH certifies respirators used in a variety of industrial settings; regulations governing certification are codified in

42 CFR part 84. The fees charged to respirator manufacturers for certification of their products have not changed since 1972; the current certification fees cover less than 10 percent of the costs of generating certificates. Updating these fees will allow NIOSH's certification program to recover the costs associated with the certification process. This project will revise those fees and align them with the current requirements of 42 CFR part 84 so that fees are charged for the creation, modification and maintenance of approvals granted by NIOSH's National Personal Protective Technology Laboratory.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: Undetermined
Unfunded Mandates: No
CFR Citation: 42 CFR 84 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 29 USC 651 et seq; 30 USC 3 and 5; 30 USC 7; 30 USC 842(h) and 844; 30 USC 957; ...
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	10/00/2011	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: Undetermined
Federalism: Undetermined
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Department of Health and Human Services (HHS)
Centers for Disease Control and Prevention (CDC)
RIN: 0920-AA36

View Related Documents

Title: Amendments To Establish Wildland Firefighting Protection Performance Requirements for Approval of Respiratory Protective Devices

Abstract: NIOSH certifies respirators used in a variety of industrial settings; regulations governing certification are codified in 42 CFR part 84. Currently, although wildland firefighters are exposed to dangerous smoke and fire gases of varying concentrations in an outdoor environment, NIOSH regulations do not provide for the certification of respirators for these workers. The National Fire Protection Association Technical Committee on Respiratory Protection Equipment has requested that NIOSH develop a new standard for wildland firefighter respiratory protection. NIOSH is currently drafting a Proposed Rule to codify this new standard for respirators for wildland firefighters under 42 CFR part 84.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 84 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 29 USC 651 et seq; 30 USC 3 and 5; 30 USC 7; 30 USC 811 and 842(h); 30 USC 844; 30 USC 957; ...
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	05/00/2011	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Centers for Disease Control and Prevention (CDC) RIN: 0920-AA37

View Related Documents

Title: Control of Communicable Diseases: Foreign and Possessions; Proposed Revision of CDC Etiological Agents Importation Regulations

Abstract: By statute, the Secretary of Health and Human Services has broad authority to prevent introduction, transmission, and spread of communicable diseases from foreign countries into the United States and from one State or possession into another. The Secretary has designated the authority to prevent the introduction of diseases from foreign countries to the Director, Centers for Disease Control and Prevention (CDC). CDC also enforces entry requirements for certain animals, etiologic agents, and vectors deemed to be of public health significance. CDC is proposing to amend its regulations found at 42 CFR 71.54 restricting the importation and transportation of etiologic agents. Currently, potential importers of etiologic agents are required to complete a permit application under the Etiologic Agent Import Permit Program (EAIPP), but there is not an on-site inspection of importer facilities. CDC is proposing to develop procedures that will improve safety and limit potential breakage, leakage, and exposure to etiologic agents.

Priority: Economically Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: Undetermined
Unfunded Mandates: No
CFR Citation: 42 CFR 71.54 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PHA as amended (42 USC 216, 264-272)
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	04/00/2011	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No

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Department of Health and Human Services (HHS)
Centers for Disease Control and Prevention (CDC) RIN: 0920-AA38

View Related Documents

Title: Open-Circuit Self-Contained Breathing Apparatus End-of-Service-Time Indicator Performance Requirements

Abstract: As a component of its ongoing update of respirator certification standards under part 84 and in response to a petition to amend 42 CFR 84.83(f), NIOSH proposes a revision to the current requirement for service-life indicators, which are devices built into a respirator to alert the user that the oxygen provided by the respirator is close to depletion. The Agency intends to revise the current standard to allow the indicators to be set to better match the different worker protection needs of different work operations.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 84.83(f) (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 29 USC 651 et seq; 30 USC 3 and 5; 30 USC 7; 30 USC 842(h) and 30 USC 844; 30 USC 957
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	05/00/2011	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Centers for Disease Control and Prevention (CDC) RIN: 0920-AA39

View Related Documents

Title: Guidelines for Determining the Probability of Causation Under the Energy Employees Occupational Illness Compensation Program Act of 2000; Revision of Guidelines for Non-Radiogenic Cancers

Abstract: The Department of Health and Human Services (HHS) is proposing to treat chronic lymphocytic leukemia (CLL) as a radiogenic cancer under the Energy Employees Occupational Illness Compensation Program Act of 2000 (EEOICPA). Under current guidelines (42 CFR 81), CLL is not considered to be caused by radiation and hence is currently not potentially compensable under EEOICPA. HHS proposes to reverse its decision to exclude CLL from such treatment.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 81.30 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 7384n; EO 13179
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	10/00/2011	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: Federal
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Centers for Disease Control and Prevention (CDC) RIN: 0920-AA42

View Related Documents

Title: Amendments to Respirator Certification Fees

Abstract: NIOSH certifies respirators used in a variety of industrial settings; regulations governing certification are codified in 42 CFR part 84. The fees charged to respirator manufacturers for certification of their products have not changed since 1972; the current certification fees cover less than 10 percent of the costs of generating certificates. Updating these fees will allow NIOSH's certification program to recover the costs associated with the certification process. This project will revise those fees and align them with the current requirements of 42 CFR part 84 so that fees are charged for the creation, modification and

maintenance of approvals granted by NIOSH's National Personal Protective Technology Laboratory.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 84.20 to 84.22 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 29 USC 651 et seq; 30 USC 3 and 5; 30 USC 7; 30 USC 842(h) and 844; 30 USC 957
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	06/00/2011	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: Business
Federalism: No
Energy Affected: Undetermined
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Department of Health and Human Services (HHS)
Centers for Disease Control and Prevention (CDC)
RIN: 0920-AA12

View Related Documents

Title: Control of Communicable Diseases: Foreign and Possessions

Abstract: By statute, the Secretary of Health and Human Services has broad authority to prevent introduction, transmission, and spread of communicable diseases from foreign countries into the United States and from one State or possession into another. Communicable disease regulations are divided into two parts: Part 71 pertaining to foreign arrivals and part 70 pertaining to interstate matters. This rule (42 CFR Part 71) will update and improve CDC's response to both global and domestic disease threats by creating a multi-tiered illness detection and response process thus substantially enhancing the public health system's ability to slow the introduction, transmission, and spread of communicable disease. The final rule focuses primarily on requirements relating to the reporting of deaths and illnesses onboard aircrafts and ships, and the collection of specific traveler contact information for the purpose of CDC contacting travelers in the event of an exposure to a communicable disease.

Priority: Economically Significant
Agenda Stage of Rulemaking: Final Rule
Major: Yes
Unfunded Mandates: Private Sector
CFR Citation: 42 CFR 71 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 243; 42 USC 264 and 265; 42 USC 267 and 268; 42 USC 270 and 271
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	11/30/2005	70 FR 71892
NPRM Comment Period End	01/20/2006	
Final Action	12/00/2010	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Centers for Disease Control and Prevention (CDC) RIN: 0920-AA22

View Related Documents

Title: Control of Communicable Diseases: Interstate

Abstract: By statute, the Secretary of Health and Human Services has broad authority to prevent introduction, transmission, and spread of communicable diseases from foreign countries into the United States and from one State or possession into another. Communicable disease regulations are divided into two parts: Part 71 dealing with foreign arrivals and part 70 dealing with interstate matters. This rule (42 CFR Part 70) will update and improve CDC's response to both global and domestic disease threats by creating a multi-tiered illness detection and response process thus substantially enhancing the public health system's ability to slow the introduction, transmission, and spread of communicable disease. The final rule focuses primarily on requirements relating to the reporting of deaths and illnesses onboard aircrafts, and the collection of specific traveler contact information for the purpose of CDC contacting travelers in the event of an exposure to a communicable disease.

Priority: Economically Significant
Agenda Stage of Rulemaking: Final Rule
Major: Yes
Unfunded Mandates: Private Sector
CFR Citation: 42 CFR 70 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 28 USC 198; 28 USC 231; 25 USC 1661; 42 USC 243; 42 USC 248 and 249; 42 USC 264; 42 USC 266 to 268; 42 USC 270 to 272; 42 USC 2001
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	11/30/2005	70 FR 71892
NPRM Comment Period End	01/30/2006	
Final Action	12/00/2010	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: Business
Federalism: No
Energy Affected: Undetermined
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Department of Health and Human Services (HHS)
Centers for Disease Control and Prevention (CDC) RIN: 0920-AA31

View Related Documents

Title: Possession, Use, and Transfer of Select Agents and Toxins (Sars-CoV)

Abstract: The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 authorizes the HHS Secretary to regulate the possession, use, and transfer of select agents and toxins that have the potential to pose a severe threat to public health and safety. These regulations are set forth at 42 CFR 73. Criteria used to determine whether a select agent or toxin should be included under the provisions of these regulations are based on: (1) The effect on human health as a result of exposure to the agent or toxin, (2) the degree of contagiousness of the agent or toxin, (3) the methods by which the agent or toxin is transferred to humans, (4) the availability and effectiveness of pharmacotherapies and immunizations to treat and prevent any illness resulting from infection by the agent or toxin, and (5) any other criteria, including the needs of children and other vulnerable populations that the HHS Secretary considers appropriate. We are proposing this action because SARS-CoV (1) causes significant mortality, especially in the elderly; (2) has the capability to easily transmit from human to human; (3) there is currently no method to treat or prevent infections caused by the SARS-CoV virus; and (4) it has been documented that the virus persists in the environment.

Priority: Economically Significant
Agenda Stage of Rulemaking: Final Rule
Major: Undetermined
Unfunded Mandates: No
CFR Citation: 42 CFR 73.3 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 107-188

Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	07/13/2009	74 FR 33401
NPRM Comment Period End	09/11/2009	
Final Action	11/00/2011	

Regulatory Flexibility Analysis Required: No Government Levels Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Centers for Disease Control and Prevention (CDC) RIN: 0920-AA32

View Related Documents

Title: Possession, Use, and Transfer of Select Agents and Toxins: Chapare Virus

Abstract: The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 authorizes the HHS Secretary to regulate the possession, use, and transfer of select agents and toxins that have the potential to pose a severe threat to public health and safety. These regulations are set forth at 42 CFR 73. Criteria used to determine whether a select agent or toxin should be included under the provisions of these regulations are based on: (1) The effect on human health as a result of exposure to the agent or toxin, (2) the degree of contagiousness of the agent or toxin, (3) the methods by which the agent or toxin is transferred to humans, (4) the availability and effectiveness of pharmacotherapies and immunizations to treat and prevent and illness resulting from infection by the agent or toxin, and (5) any other criteria, including the needs of children and other vulnerable populations that the HHS Secretary considers appropriate. Based on these criteria, we are proposing to amend the list of HHS select agents and toxins by adding Chapare virus to the list. After consulting with subject matter experts from CDC, the National Institutes of Health (NIH), the Food Drug Administration (FDA), the United States Department of Agriculture (USDA) /Animal and Plant Health Inspection Service (APHIS), USDA/Agricultural Research Service (ARS), USDA/CVB (Center for Veterinary Biologics), and the Department of Defense (DOD)/United States Army Medical Research Institute for Infectious Diseases (USAMRIID) and review of relevant published studies, we believe the Chapare virus should be added to the list of HHS select agents and toxins based on our conclusion that the Chapare virus has been phylogenetically identified as a Clade B arenavirus and is closely related to other South American arenaviruses that cause haemorrhagic fever, particularly Sabia virus.

Priority: Economically Significant Agenda Stage of Rulemaking: Final Rule
Major: Undetermined Unfunded Mandates: No
CFR Citation: 42 CFR 73.3 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 107-188
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	08/19/2009	74 FR 159
NPRM Comment Period End	10/19/2009	
Final Action	11/00/2011	

Regulatory Flexibility Analysis Required: No Government Levels Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Centers for Disease Control and Prevention (CDC) RIN: 0920-AA33

View Related Documents

Title: Total Inward Leakage Requirements for Respirators

Abstract: As a component of its ongoing update of respirator certification standards under Part 84, NIOSH plans to improve certification requirements for half-mask air-purifying particulate respirators. The proposed requirements would specify minimum performance requirements and testing to be conducted by NIOSH and respirator manufacturers to demonstrate that these respirators, when selected and used correctly, provide effective respiratory protection to intended users against toxic dusts, mists, fumes, fibers, and biological and infectious aerosols. The Agency intends to improve the functionality of these respirators.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 84 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 29 USC 651 et seq; 29 USC 657(g); 30 USC 3; 30 USC 7; 30 USC 811; 30 USC 842(h) and 844
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	10/30/2009	74 FR 66935
NPRM Comment Period End	12/29/2009	
NPRM Comment Period Reopened	04/20/2010	75 FR 20546
NPRM Public Meeting	07/29/2010	75 FR 29699
NPRM Comment Period End	09/30/2010	
Final Rule	10/00/2011	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: No
Small Entities Affected: Governmental Jurisdictions
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Centers for Disease Control and Prevention (CDC) RIN: 0920-AA04

View Related Documents

Title: Quality Assurance Requirements for Respirators

Abstract: NIOSH plans to modify the Administrative/Quality Assurance sections of 42 CFR part 84, Approval of Respiratory Protective Devices. Areas for potential modification in this module are: (1) Upgrade of quality assurance requirements; (2) ability to use private sector quality auditors and private sector testing laboratories in the approval program; and (3) revised approval label requirements.

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 84 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 29 USC 651 et seq; 30 USC 3; 30 USC 5; 30 USC 7; 30 USC 811; 30 USC 842(h); 30 USC 844
Legal Deadline: None

Timetable:

Action	Date	FR Cite

Final Action	00/00/0000	
NPRM	12/10/2008	73 FR 75045
NPRM Comment Period End	02/09/2009	
NPRM Comment Period Reopened	03/04/2009	74 FR 9381
NPRM Comment Period Reopened End	04/10/2009	
NPRM Comment Period Reopening Extended	05/21/2009	74 FR 23815
NPRM Comment Period End	10/09/2009	

Regulatory Flexibility Analysis Required: Governmental Jurisdictions

Government Levels Affected: No

Federalism: No

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Department of Health and Human Services (HHS)
Centers for Disease Control and Prevention (CDC) RIN: 0920-AA10

View Related Documents

Title: Approval Tests and Standards for Closed-Circuit Escape Respirators

Abstract: NIOSH plans to modify sections of 42 CFR part 84 concerning performance testing and other specifications for the certification of closed-circuit, self-contained breathing apparatus. These respiratory protective devices are used in emergencies for the protection of miners and workers in other industries.

Priority: Other Significant

Agenda Stage of Rulemaking: Long-term Action

Major: No

Unfunded Mandates: No

CFR Citation: 42 CFR 84 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: 29 USC 651 et seq; 30 USC 3; 30 USC 5; 30 USC 7; 30 USC 811; 30 USC 842; 30 USC 844

Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	12/10/2008	73 FR 75027
NPRM Comment Period End	02/09/2009	
NPRM Comment Period Reopened	03/04/2009	74 FR 9380
NPRM Comment Period End	04/10/2009	
NPRM Comment Period Reopened	05/21/2009	74 FR 23814
NPRM Comment Period End	06/19/2009	
Final Action	12/00/2011	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: No

Small Entities Affected: Business

Federalism: No

Energy Affected: No

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Department of Health and Human Services (HHS)
Centers for Disease Control and Prevention (CDC) RIN: 0920-AA17

View Related Documents

Title: Amendments to Performance Requirements for Chemical, Biological, Radiological, and Nuclear (CBRN) Approval of Respiratory Protective Devices

Abstract: NIOSH plans to modify sections of 42 CFR part 84 concerning performance testing and other specifications for the certification of closed-circuit, self-contained breathing apparatus; supplied air respirators; and combination (supplied air and air purifying capable) respirators against CBRN respiratory hazards. These respirators are used in emergency response situations.

Priority: Other Significant
Agenda Stage of Rulemaking: Completed Action
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 84 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 29 USC 651; 30 USC 3; 30 USC 5; 30 USC 7; 30 USC 11; 30 USC 842l; 30 USC 844
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Withdrawn	07/29/2010	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: Business
Federalism: No
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Department of Health and Human Services (HHS)
National Institutes of Health (NIH)
RIN: 0925-AA43

View Related Documents

Title: National Institutes of Health Loan Repayment Programs

Abstract: NIH proposes to issue a single set of regulations to govern all of its loan repayment (LRP) authorities. This action will include rescinding the current regulations at 42 CFR part 68a and at 42 CFR part 68c replaced by the new consolidated set of LRP regulations. Establishing a single set of regulations to govern all eight of the current NIH loan repayment programs rather than issuing a separate set of regulations for each program will serve to streamline regulatory requirements for the programs and enhance program participants' understanding of and compliance with program requirements.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 68 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 216; 42 USC 288-5a; 42 USC 287c-33; 42 USC 288-1; 42 USC 288-3; 42 USC 288-5 and 288-6
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	03/00/2011	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
National Institutes of Health (NIH) RIN: 0925-AA47

View Related Documents

Title: Endowment Program

Abstract: The Director of the National Institute for Minority Health and Health Disparities Research is authorized under section 485E(h)(1) of the Public Health Service Act to carry out a program to facilitate minority health disparities research and other health disparities research by providing for research endowments at 15 centers of excellence under section 736 (Public Health Service Act). NIH plans to issue implementing regulations to govern these research endowments.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 52i (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 216; 42 USC 287c-31
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	04/00/2011	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
National Institutes of Health (NIH) RIN: 0925-AA48

View Related Documents

Title: Undergraduate Scholarship Program Regarding Professions Needed by the National Institutes of Health

Abstract: Section 487D of the Public Health Service Act, as added by NIH Revitalization Act of 1993, creates a program offering scholarships to individuals from disadvantaged backgrounds who are enrolled as full-time students at accredited institutions pursuing academic programs appropriate for careers in professions needed by NIH. For each year of scholarship support, the recipient agrees to provide service (employment) after graduation, at NIH, for 1 year. Additionally, the individual agrees to provide at least 10 consecutive weeks of service (employment) at NIH during which the individual is attending the educational institution and receiving the NIH scholarship. The proposed new regulations will govern this program.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 68b (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 216; 42 USC 288-4
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	04/00/2011	

Regulatory Flexibility Analysis Required: No
Small Entities Affected: No
Energy Affected: No
Government Levels Affected: No
Federalism: No

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Department of Health and Human Services (HHS)
National Institutes of Health (NIH) RIN: 0925-AA49

View Related Documents

Title: NIH Training Grants

Abstract: NIH plans to amend the Agency's existing training grants regulations to: (1) Reflect their applicability to the training authorities set forth in sections 464W and 485F of the Public Health Service Act; (2) reflect their applicability to training programs of the National Institute on Minority Health and Health Disparities (NCMHD) and Fogarty International Center (FIC) awards; and (3) reflect their applicability for grants that the National Institute of Nursing Research (NINR) makes to nonprofit institutions to provide training and instruction in the study and investigation of the prevention of disease, health promotion, and the nursing care of individuals with, and the families of individuals with acute and chronic illnesses.

Priority: Substantive, Nonsignificant
Major: No
Agenda Stage of Rulemaking: Proposed Rule
Unfunded Mandates: No

CFR Citation: 42 CFR 63a (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 216; 42 USC 2421; 42 USC 285q-1; 42 USC 287c-31 and 287c-32
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	04/00/2011	

Regulatory Flexibility Analysis Required: No
Small Entities Affected: No
Energy Affected: No
Government Levels Affected: No
Federalism: No

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Department of Health and Human Services (HHS)
National Institutes of Health (NIH) RIN: 0925-AA55

View Related Documents

Title: Expanded Registration and Results Reporting at ClinicalTrials.gov

Abstract: The National Institutes of Health (NIH) proposes to issue new regulations that will prescribe procedures for registering and reporting the results, including adverse events, of clinical trials at ClinicalTrials.gov, in accordance with section 801 of the Food and Drug Administration Amendments Act of 2007, (FDAAA, Pub. L. 110-85). As previously announced, the agency intends to proceed with a single rulemaking to implement the expanded registry, results reporting, and adverse event information reporting requirements of the statute. The rulemaking will also consider topics that the statute requires to be addressed in regulations intended to provide more complete results information and to enhance patient access to and understanding of the results of clinical trials [as codified in 42 U.S.C. 282(j)(3)(D), including whether results information should be required to be submitted for applicable clinical trials of drugs, biological products, or devices that have not been approved, licensed, or cleared by the Food and Drug Administration, and whether narrative summaries of clinical trials and their results can be included in the data bank without being misleading or promotional. These topics were the subject of discussion at the Public Meeting organized by NIH agency in April 2009, and of written public comments. The regulations will identify the trials that are subject to the registration and results reporting requirements (including adverse event reporting); the specific information and format of the information that must be submitted to ClinicalTrials.gov; deadlines for registering and reporting results; procedures for extending the deadlines or wavering the submission requirements; and procedures for agency review and public posting of submitted information.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 3 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 216, 282(j)
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		09/27/2010

Timetable:

Action	Date	FR Cite
NPRM	02/00/2011	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: Business
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
National Institutes of Health (NIH)
RIN: 0925-AA57

View Related Documents

Title: National Institutes of Health Construction Grants

Abstract: The National Institutes of Health (NIH) proposes to review and/or amend the existing regulations at 42 CFR 52b governing grants awarded by the agency and its components for construction of new buildings and the alteration, renovation, remodeling, improvement, expansion, and repair of existing buildings, including the provision of equipment necessary to make the building (or applicable part of the building) suitable for which it was constructed. The NIH proposes to revise and/or amend the regulations to promote consistency with the Department of Health and Human Services (HHS) regulations at 45 CFR 74 applicable to recovery and insurance coverage. Specifically, NIH proposes to replace language in section 52b.9(a)(1) with the language in 45 CFR 74.32(c)(2), and replace the language in section 52b.10(n) with the language in 45 CFR 74.31. The narrative in section 52b.12(b) that refers to the National Cancer Institute having copies of certain resource documents would be updated. Citations in section 52b.12(c) design and construction standards would be updated. Section 52b.14(c) would be amended to reference Executive Order 12372, Intergovernmental Review of Federal Programs. Reference numbers (1), (3), (4), (5), (6), and (7) in section 53b.14(d) Policies would be updated.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Proposed Rule
Major: Undetermined
Unfunded Mandates: No

CFR Citation: 42 CFR 52b (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 216; 42 USC 285a-2 and 285a-3; 42 USC 285b-3 and 285b-4; 42 USC 285d-6 and 285i; 42 USC 285m-3 and 285o-4; 42 USC 287a-2 and 287a-3; 42 USC 300cc-41
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	04/00/2011	

Regulatory Flexibility Analysis Required: No
Small Entities Affected: No
Energy Affected: No
Government Levels Affected: No
Federalism: No

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Department of Health and Human Services (HHS)
National Institutes of Health (NIH) RIN: 0925-AA53

View Related Documents

Title: Amendment of Regulation of the Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding Is Sought and Responsible Prospective Contractors

Abstract: The Department of Health and Human Services (HHS) and the Public Health Service (PHS) proposes to amend the regulations on the Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought and Responsible Prospective Contractors. Since the promulgation of the current regulations in 1995, biomedical and behavioral research and the resulting interactions among government research institutions and the private sector have become increasingly complex. This complexity, as well as a need to strengthen accountability, have led to the proposal of amendments that would expand and add transparency to investigator disclosure of significant financial of interests, enhance regulatory compliance and effective institutional oversight and management of investigators' financial conflicts of interests, as well as the agency's ability to ensure compliance.

Priority: Other Significant
Major: No
Agenda Stage of Rulemaking: Final Rule
Unfunded Mandates: No
CFR Citation: 45 CFR 94 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 216; 42 USC 289b-1; 42 USC 299c-4; Sec. 219, Tit.II, Div D, Pub 111-117, 123 Stat. 3034
Legal Deadline: None

Timetable:

Action	Date	FR Cite
ANPRM	05/08/2009	74 FR 21610
ANPRM Comment Period End	07/07/2009	
NPRM	05/21/2010	75 FR 28688
NPRM Comment Period End	08/19/2010	75 FR 42362
Final Action	04/00/2011	

Regulatory Flexibility Analysis Required: No
Small Entities Affected: Business
Energy Affected: No
Government Levels Affected: No
Federalism: No

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Department of Health and Human Services (HHS)
Substance Abuse and Mental Health Services Administration (SAMHSA) RIN: 0930-AA16

View Related Documents

Title: Community Mental Health Services and Substance Abuse Prevention and Treatment Block Grants

Abstract: Sections 1911 through 1956 of the Public Health Service Act authorize the Community Mental Health Services (CMHS) Block Grant and the Substance Abuse Prevention and Treatment (SAPT) Block Grant. Regulations establishing the criteria that the Secretary would use in approving applications for the CMHS Block Grant have never been issued. Regulations establishing the criteria for the SAPT Block Grant, except for implementation of section 1926 related to tobacco, were issued on March 31, 1993, in compliance with section 1932(d). The regulations with regard to section 1926 were issued on January 19, 1996. The rule will establish criteria for approving applications for the CMHS Block Grant for the first time, and update the regulations for the SAPT to reflect changes in statute and our experience over the past seventeen years. The regulations will emphasize consistent and effective planning, reporting and expenditure of obligations, helping States prepare for the implementation of health care reform, and emphasizing the agency's role in assisting states to build and maintain more effective behavioral health systems for prevention and treatment, services and recovery supports.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: Yes
Unfunded Mandates: No
CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: Sections 1911 through 1956 of the PHS Act Authorize the Community Mental Health Services (CMHS) Block Grant and the Substance Abuse Prevention and Treatment (SAPT) Block Grant
Legal Deadline:

Action	Source	Description	Date
NPRM	Statutory		11/30/2010

Timetable:

Action	Date	FR Cite
NPRM	12/00/2010	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: State
Federalism: Yes
Energy Affected: No
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Department of Health and Human Services (HHS)
Substance Abuse and Mental Health Services Administration (SAMHSA) RIN: 0930-AA10

View Related Documents

Title: Requirements Governing the Use of Seclusion and Restraint in Certain Nonmedical Community-Based Facilities for Children and Youth

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 requires 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.

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: Undetermined
Unfunded Mandates: No
CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 106-310, 42 USC 290jj to 290jj-2
Legal Deadline:

Action	Source	Description	Date
NPRM	Statutory		04/00/2001

Timetable:

Action	Date	FR Cite
NPRM	00/00/0000	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: State
Federalism: Yes
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Department of Health and Human Services (HHS)
Substance Abuse and Mental Health Services Administration (SAMHSA)
RIN: 0930-AA14

View Related Documents

Title: Opioid Drugs in Maintenance or Detoxification Treatment of Opiate Addiction
Abstract: This rule will amend the Federal opioid treatment program regulations. It will modify the dispensing requirements for buprenorphine and buprenorphine combination products that are approved by the Food and Drug Administration (FDA) for opioid dependence and used in federally certified and registered opioid treatment programs.

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 8 to 12 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 823 (9); 42 USC 257a; 42 USC 290aa(d); 42 USC 290dd-2; 42 USC 300xx-23; 42 USC 300x-27(a); 42 USC 300y-11
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Final Action	00/00/0000	
NPRM	06/19/2009	74 FR 29153
NPRM Comment Period End	08/18/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Substance Abuse and Mental Health Services Administration (SAMHSA)
RIN: 0930-AA15

View Related Documents

Title: Protection and Advocacy for Individuals With Mental Illness

Abstract: A final rule implementing the requirements of the Protection and Advocacy with Mental Illness Act was published on October 15, 1997, Federal Register Vol. 62, No. 193, page 53548. This proposed rule clarifies some of the requirements from that rule and implements changes made to the statute in the Children's Health Act of 2000 (Pub. L. 106-310 section 3206). Most notably Public Law 106-310 extended the authority of the protection and advocacy (P&A) systems authorized in the legislation to provide representation to individuals living in a community setting including their own home if the total allotment under the program for any fiscal year was $30 million or more. Prior to the passage of Public Law 106-310, the P&A systems could only represent individuals living in inpatient or residential institutions. The allotment for the P&A program has been above $30 million since fiscal year 2000.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Long-term Action
Major: Undetermined
Unfunded Mandates: No
CFR Citation: 42 CFR 51 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: Protection and Advocacy with Mental Illness Act; 42 USC 10801
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	00/00/0000	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: Undetermined
Energy Affected: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS)
RIN: 0938-AQ51

View Related Documents

Title: Emergency Medical Treatment and Labor Act: Applicability to Hospital Inpatients (CMS-1350-ANPRM)

Abstract: This advanced notice of proposed rulemaking is requesting comments on 2 issues: 1) The applicability of EMTALA to hospital inpatients, and 2) the EMTALA obligation of a hospital with specialized capabilities once an individual has been admitted. Comments received on this rule will determine the need to revisit the policies published in the September 9, 2003 and August 19, 2008 Federal Registers.

Priority: Info./Admin./Other
Agenda Stage of Rulemaking: PreRule
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 489 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 1395cc; 42 USC 1395dd
Legal Deadline: None

Timetable:

Action	Date	FR Cite
ANPRM	12/00/2010	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Related RINs: Related to 0938-AM34; Related to 0938-AP15

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AG81

View Related Documents

Title: Home Health Agency (HHA) Conditions of Participation (CoPs) (CMS-3819-P)

Abstract: This proposed rule would revise the existing Conditions of Participation (CoPs) that Home Health Agencies (HHAs) must meet to participate in the Medicare program. The CoPs were last revised in 1989. The new requirements will focus on the actual care delivered to patients by HHAs, reflect an interdisciplinary view of patient care, allow HHAs greater flexibility in meeting quality standards, and eliminate unnecessary procedural requirements. These changes are an integral part of our efforts to achieve broad-based improvements and measurements of the quality of care furnished through federal programs while at the same time reducing procedural burdens on providers.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 409, 42 CFR 418, 42 CFR 484 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: 42 USC 1302; 42 USC 1395x; 42 USC 1395cc(a); 42 USC 1395hh; 42 USC 1395bb
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	03/10/1997	62 FR 11005
NPRM Comment Period End	06/09/1997	
Second NPRM	07/00/2011	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: No
Small Entities Affected: Business; Organizations
Federalism: No
Energy Affected: No
Related RINs: Related to 0938-AJ11

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AO10

View Related Documents

Title: Medical Improvement Eligibility Group and Definition of Work (CMS-2143-P)

Abstract: This proposed rule would codify in regulations certain statutory provisions established under the Balanced Budget Act of 1997 and the Ticket to Work and Work Incentives Improvement Act of 1999 (TWWIIA). These statutory provisions allow States to provide Medicaid coverage to employed individuals with disabilities who, due to improvement in medical conditions, lose eligibility for disability benefits that confer Medicaid eligibility. This proposed rule would also provide a definition for "severe

medically determinable impairment" under the TWWIIA.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 435 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 105-33, sec 4733 Balanced Budget Act of 1997; PL 106-170, sec 201 Ticket to Work and Work Incentives Improvement Act of 1999
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	04/00/2011	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: State
Small Entities Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS)
RIN: 0938-AO53

View Related Documents

Title: Home and Community-Based Services (HCBS) State Plan Services Program (CMS-2249-P2)
Abstract: In 2008, CMS issued a proposed rule that would define and describe State plan home and community-based services (HCBS) plan services implementing new section 1915(i) of the Social Security Act as added by section 6086 of the Deficit Reduction Act of 2005. This section allows States, at their option, to provide home and community-based services (HCBS) under their regular State Medicaid plans. This rule revises that proposed rule to implement provisions of the Affordable Care Act of 2010 that require oversight and assessment of the administration of home and community based services. In addition, this rule would respond to public comments received on the pervious proposed rule pertaining to the HCBS benefit under the Medicaid State plan.

Priority: Economically Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: Yes
Unfunded Mandates: No
CFR Citation: 42 CFR 431; 42 CFR 440 and 441 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: Deficit Reduction Act of 2005; PL 109-171, sec 6086;; PL 111-148, sec 2402
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		01/01/2007

Timetable:

Action	Date	FR Cite
NPRM	04/04/2008	73 FR 18676
NPRM Comment Period End	06/03/2008	
Second NPRM	07/00/2011	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: State
Small Entities Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AO91

View Related Documents

Title: Emergency Preparedness Requirements for Medicare Participating Providers and Suppliers (CMS-3178-P)

Abstract: This rule would establish national emergency preparedness requirements for Medicare and Medicaid participating providers and suppliers to ensure that they adequately plan for both natural and man-made disasters and coordinate with federal, state, tribal, regional and local emergency preparedness systems.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: Undetermined
Unfunded Mandates: No
CFR Citation: 42 CFR 403; 42 CFR 416 and 418; 42 CFR 460; 42 CFR 483 to 486; 42 CFR 491; ... (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 1821; 42 USC 1861 (ff) (3)(B)(i)(ii); 42 USC 1913 (c)(1) et al
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	01/00/2011	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: Business
Federalism: No
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP01

View Related Documents

Title: Establishing Additional Medicare Provider and Supplier Enrollment Safeguards (CMS-6045-P)

Abstract: This proposed rule would expand existing provider and supplier enrollment requirements to obtain or maintain Medicare billing privileges.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: Undetermined
CFR Citation: 42 CFR 424.40; 42 CFR 424.44; 42 CFR 424.525 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: sec. 4312(a) of BBA of 1997
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	09/00/2011	

Regulatory Flexibility Analysis
Government Levels Affected: Undetermined

Required: Undetermined
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP32

View Related Documents

Title: Requirements for Long-Term Care Facilities: Hospice Services (CMS-3140-F)
Abstract: This rule establishes that in order to participate in the Medicare and Medicaid programs, long-term care facilities must have an agreement with hospice agencies when hospice care is provided in a long-term care facility. The rule also contains quality of care requirements.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 483 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 1302; 42 USC 1395hh
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	10/22/2010	75 FR 65282
NPRM Comment Period End	12/21/2010	
Final Action	10/00/2013	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: Undetermined
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP51

View Related Documents

Title: Conditions of Participation (CoPs) for Community Mental Health Centers (CMHCs)(CMS-3202-P)
Abstract: The proposed rule would establish Conditions of Participation for community mental health centers (CMHCs) to ensure that CMHCs furnish services meeting essential health and safety standards. The rule focuses on patient-centered and outcome-oriented care and is based on four core requirements: 1) Patient's rights; 2) admission, assessment, and discharge; 3) treatment and coordination of services; and 4) governance.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Proposed Rule
Major: Undetermined
Unfunded Mandates: No
CFR Citation: 42 CFR 485 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: sec 1102 42 USC 1302; sec 1861 42 USC 1395 hh
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	02/00/2011	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP61

View Related Documents

Title: Home and Community Based Services: Waiver Requirements (CMS-2296-P)

Abstract: This proposed rule would clarify that a State may design a waiver program that is cross-disability in nature and would include requirements for State-defined and CMS-approved criteria for characteristics of any home and community-based setting. These changes would remove Federal barriers to the States' ability to design needs-based, person-centered HCBS Programs, rather than programs based solely upon an individual's diagnosis.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 300 to 310 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 1396n(c)
Legal Deadline: None

Timetable:

Action	Date	FR Cite
ANPRM	06/22/2009	74 FR 29453
ANPRM Comment Period End	08/21/2009	
NPRM	04/00/2011	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: Undetermined
Federalism: No
Energy Affected: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP68

View Related Documents

Title: Implementing Regulations for Reauthorization of the Children's Health Insurance Program (CHIP) (CMS-2301-P)

Abstract: This proposed rule would reauthorize the Children's Health Insurance Program (CHIP) and introduce several new features as a result of the passage of the Children's Health Insurance Program Reauthorization Act. For example, the rule would define and provide more guidance on the parameters of the new Express Lane Eligibility option for States including what it means to be an Express Lane agency. It would also define the parameters for the new state option to cover pregnant women in CHIP and provide further guidance regarding the newly required dental benefit package. In addition, it would codify the definition of individuals who are lawfully residing in the US but who are not citizens who can be enrolled in Medicaid and CHIP.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: Undetermined
Unfunded Mandates: Undetermined
CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: CHIPRA of 2009 (PL 111-3)
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	08/00/2011	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: State
Federalism: Undetermined
Energy Affected: Undetermined
Related RINs: Related to 0938-AP54

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS)
RIN: 0938-AP70

View Related Documents

Title: Extension of Transitional Medical Assistance Under the American Recovery and Reinvestment Act of 2009 (CMS-2475-P)

Abstract: This proposed rule would extend the Transitional Medical Assistance (TMA) program through December 31, 2010, as a result of the American Recovery and Reinvestment Act of 2009.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: Undetermined
Unfunded Mandates: Undetermined
CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: American Recovery and Reinvestment Act of 2009 (PL 111-5)
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	11/00/2011	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: State; Tribal
Federalism: Undetermined

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP71

View Related Documents

Title: Children's Health Insurance Program (CHIP) Child Enrollment Contingency Fund Payments (CMS-2488-P)

Abstract: This proposed rule would establish the "CHIP contingency fund" to eliminate State shortfalls in funding beginning in FY 2009. A State may qualify for the contingency funds if it projects a funding shortfall for the fiscal year (not counting any redistributed amounts they may receive) and its average monthly child enrollment exceeds its target average number of enrollees for the fiscal year. Contingency payments equal a State's projected per capita Federal spending multiplied by the excess amount. This proposed rule implements provisions of the Children's Health Insurance Program Reauthorization Act of 2009.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: Undetermined
Unfunded Mandates: Undetermined
CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: Children's Health Insurance Program Reauthorization Act of 2009 (PL 111-3)
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	08/00/2011	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: State
Federalism: Undetermined
Energy Affected: No
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP92

View Related Documents

Title: Influenza Vaccination Standard for Certain Medicare Participating Providers and Suppliers(CMS-3213-P)

Abstract: This proposed rule would require certain Medicare providers and suppliers to offer all patients an annual influenza vaccination, unless medically inadvisable or if the patient declines vaccination. This proposed rule is intended to increase the number of patients receiving annual vaccination against seasonal influenza and to decrease the morbidity and mortality rate from influenza.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: Undetermined
Unfunded Mandates: No
CFR Citation: 42 CFR 405 and 412; 42 CFR 418; 42 CFR 484 and 485 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: Social Security Act sec 1881, 1861, 1920, 1102, 1871, 1965
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	01/00/2011	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: No
Federalism: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP94

View Related Documents

Title: Medicare Beneficiary Notification of the Right To Access a Quality Improvement Organizations (QIOs) for Certain Health Care Facilities (CMS-3225-P)

Abstract: This proposed rule would amend the patients' rights requirements of certain providers and suppliers to inform patients that they can communicate with the local QIO regarding quality of care issues. This revision would ensure beneficiaries are fully informed of their right to utilize the services of the QIO program.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: Undetermined
Unfunded Mandates: No

CFR Citation: 42 CFR 403; 42 CFR 416 and 418; 42 CFR 460; 42 CFR 483 to 486; 42 CFR 491 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: 42 USC 1395 hh

Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	01/00/2011	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: Business
Federalism: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP96

View Related Documents

Title: Survey and Enforcement Requirements for Home Health Agencies (CMS-2297-P)

Abstract: This proposed rule would establish requirements for unannounced, standard and extended surveys for home health agencies (HHAs), and provides a number of sanctions that may be imposed when HHAs are out of compliance with Federal requirements. This rule is necessary to implement changes in OBRA '87 in section 1891 of the Social Security Act. The rule would emphasizes quality of care, health, and safety for patients receiving home health services. The goal is to move systems away from a simple test of compliance to one geared toward quality services provided to patients.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: Undetermined
Unfunded Mandates: Undetermined
CFR Citation: 42 CFR 488 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: Omnibus Budget Reconciliation Act of 1987 (OBRA' 87)
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	07/00/2011	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS)
RIN: 0938-AP97

View Related Documents

Title: Hospital Conditions of Participation: Requirements for Hospital Inpatient Psychiatric and Rehabilitation Units Excluded From the Prospective Payment System and LTCH Requirements (CMS-3177-P)

Abstract: This proposed rule would transfer the existing process requirements for hospital inpatient psychiatric and rehabilitation units that are excluded from prospective payment systems to the hospital conditions of participation (CoPs) part of the Act. This would allow accrediting organizations to deem these units as part of their hospital accreditation process providing a timely and cost effective survey and certification process under the CoPs. In addition, this rule would propose long term care hospital requirements mandated by the Medicare, Medicaid and SCHIP Extension Act of 2007.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: Undetermined
Unfunded Mandates: No
CFR Citation: 42 CFR 482; 42 CFR 412 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 1385 X; 42 USC 1396 d; 42 USC 1395 hh
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	05/00/2011	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: Undetermined
Federalism: Undetermined
Energy Affected: No
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS)
RIN: 0938-AP99

View Related Documents

Title: Medicaid Health Care-Related Tax Definition (CMS-2314-P)

Abstract: This proposed rule would clarify existing regulatory text pertaining to the definition of a health care related tax in order to ensure compliance with the statutory requirements governing what is considered a health care related tax.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 433 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 1302
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	01/00/2011	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: State
Small Entities Affected: No
Federalism: No
Energy Affected: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS)
RIN: 0938-AQ00

View Related Documents

Title: Medicare Program; Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs (CMS-4144-F)

Abstract: This rule will set forth programmatic and operational changes to the Medicare Advantage (MA) program and prescription drug benefit program.

Priority: Economically Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: Yes
Unfunded Mandates: No
CFR Citation: 42 CFR 422 and 423 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: MMA 2003, MIPPA (title XVIII of the Social Security Act),; PL 111-148
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	11/22/2010	75 FR 71189
NPRM Comment Period End	01/21/2011	
Final Action	11/00/2013	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: Federal
Small Entities Affected: Organizations
Federalism: No
Energy Affected: Undetermined

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AQ09

View Related Documents

Title: Requirements for Long-Term Care Facilities: Notification of Facility Closure (CMS-3230-IFC)

Abstract: This rule would ensure that, in the case of a facility closure, any individual who is the administrator of the facility provides written notification of closure and the plan for the relocation of residents at least 60 days prior to the impending closure, or if the facility's participation in Medicare or Medicaid is terminated, not later than the date the HHS Secretary determines appropriate.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 483; 42 CFR 488; 42 CFR 489 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: PL 111-148, sec 6113
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		03/23/2011

Regulatory Plan:

Statement of Need: Section 6113 of the Affordable Care Act of 2010 (ACA) amends the Act by setting forth certain requirements for LTC facility closures to ensure that, among other things, in the case of a facility closure, any individual who is the administrator of the facility provides written notification of the closure and a plan for the relocation of residents at least 60 days prior to the impending closure or, if the Secretary terminates the facility's participation in Medicare or Medicaid, not later than the date the Secretary determines appropriate.

Legal Basis: Sections 1819(b)(1)(A) of the Social Security Act (the Act) for NFs and 1919 (b)(1)(A) for SNFs state that a skilled nursing facility must care for its residents in such a manner and in such an environment as will promote maintenance or enhancement of the quality of life of each resident. Sections 1819(c)(2)(A) and 1919 (c)(2)(A) of the Act state that, in general, with certain specified exceptions, a nursing facility must permit each resident to remain in the facility and must not transfer or discharge the resident from the facility. Section 6113 of ACA amends section 1128I of the Act by setting forth certain requirements for LTC facility closures.

Alternatives: None. This implements a statutory requirement.

Costs and Benefits: The costs associated with the implementation of this rule are related to the efforts made by each facility to develop a plan for closure. The benefits would include the protection of residents' health and safety and a smooth transition for residents who need to be relocated, as well as their family members and facility staff.

Risks: LTC facility closures have implications related to access, the quality of care, availability of services, and the overall health of residents. Without an organized process for facilities to follow in the event of a nursing home closure, there is a risk to the health and safety of residents.

Timetable:

Action	Date	FR Cite
NPRM	02/00/2011	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: Business
Federalism: No
Energy Affected: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AQ10

View Related Documents

Title: Long-Term Care Facility Quality Assessment and Performance Improvement (CMS-3231-P)

Abstract: This rule would implement provisions of the Affordable Care Act of 2010 that require long-term care facilities to establish and implement a quality assurance and performance improvement program.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 483 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 111-148, sec 6102; 42 USC 1320a-7j
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	01/00/2012	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: Business
Federalism: No
Energy Affected: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AQ17

View Related Documents

Title: Request for Information on Availability of Medicare Data for Performance Measurement (CMS-0031-P)

Abstract: Under the Affordable Care Act of 2010, this rule would authorize the release and use of standardized extracts of Medicare claims data to measure the performance of providers and suppliers in ways that protect patient privacy and in accordance with other requirements.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: Undetermined
Unfunded Mandates: Undetermined
CFR Citation: None (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 111-148, sec 10882
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		01/01/2012

Timetable:

Action	Date	FR Cite
NPRM	05/00/2011	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: Undetermined
Federalism: Undetermined
Energy Affected: Undetermined

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AQ19

View Related Documents

Title: Use of Recovery Audit Contractors (CMS-6034-P)

Abstract: This proposed rule would provide guidance to States related to Federal/State funding of State start-up, operation and maintenance costs of Medicaid Recovery Audit Contractors (Medicaid RACs), and the payment methodology for State payments to Medicaid RACs in accordance with section 6411 of the Affordable Care Act. In addition, this rule proposes requirements for States to assure that adequate appeals processes are in place for providers to dispute adverse determinations made by Medicaid RACs. Finally, the rule proposes that States and Medicaid RACs coordinate efforts with existing contractors and entities auditing Medicaid providers and with State and Federal law enforcement agencies.

Priority: Economically Significant

Agenda Stage of Rulemaking: Proposed Rule

Major: Yes

Unfunded Mandates: State, Local, Or Tribal Governments; Private Sector

CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: PL 111-148, sec 6411; PL 111-152

Legal Deadline:

Action	Source	Description	Date
Other	Statutory		12/31/2010

Timetable:

Action	Date	FR Cite
NPRM	12/00/2010	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: State

Small Entities Affected: Business; Governmental Jurisdictions

Federalism: Yes

Energy Affected: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AQ21

View Related Documents

Title: Omnibus Physician and Supplier Enrollment (CMS-6033-P)

Abstract: This rule would implement additional provider and supplier enrollment requirements under the Affordable Care Act of 2010. This rule would reduce fraud, waste, and abuse in the Medicare program.

Priority: Other Significant

Agenda Stage of Rulemaking: Proposed Rule

Major: Undetermined

Unfunded Mandates: Undetermined

CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: PL 111-148
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		01/01/2010

Timetable:

Action	Date	FR Cite
NPRM	05/00/2011	

Regulatory Flexibility Analysis Required: Undetermined
Small Entities Affected: Business
Energy Affected: No
Government Levels Affected: No
Federalism: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AQ22

View Related Documents

Title: Medicare Shared Savings Program: Accountable Care Organizations (CMS-1345-P)

Abstract: This rule would propose a shared savings program for provider groups to establish Accountable Care Organizations, agree to meet quality measures, and share in savings generated for Medicare by meeting certain benchmarks. Consistent with section 3022 of the Affordable Care Act of 2010, the shared savings program must be established by January 1, 2012.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 111-148, sec 3022
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		01/01/2012

Regulatory Plan:

Statement of Need: This rule would propose a shared savings program for provider groups to establish Accountable Care Organizations (ACOs), agree to meet quality measures, and share in savings generated for Medicare by meeting certain cost and quality benchmarks beginning January 1, 2012. This rule is aimed at improving quality and Medicare expenditures for Medicare beneficiaries and the Medicare program.

Legal Basis: Section 3022 of the Affordable Care Act of 2010 requires the Secretary to establish a shared savings program by January 1, 2012.

Alternatives: None. This is a statutory requirement.

Costs and Benefits: Medicare expenditures will be adjusted beginning January 1, 2012.

Risks: If this regulation is not published, the shared savings program will not be established by January 1, 2012, as required by ACA, thereby violating the statute.

Timetable:

Action	Date	FR Cite
NPRM	01/00/2011	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AQ23

View Related Documents

Title: Inpatient Psychiatric Facilities Prospective Payment System--Update for Rate Year and Fiscal Year Beginning July 1, 2011 (CMS-1346-P)
Abstract: This rule is necessary to update the prospective payment rates for inpatient psychiatric facilities with discharges beginning July 1, 2011.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: Undetermined
Unfunded Mandates: Undetermined
CFR Citation: 42 CFR 412.400, subpart N (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 106-113, sec 124 BBRA
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		07/01/2011

Timetable:

Action	Date	FR Cite
NPRM	01/00/2011	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: Local
Small Entities Affected: Business
Federalism: No
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AQ24

View Related Documents

Title: Proposed Changes to the Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and FY 2012 Rates and to the Long-Term Care Hospital PPS and RY 2012 Rates (CMS-1518-P)
Abstract: This annual major proposed rule would revise the Medicare hospital inpatient and long-term care prospective payment systems (IPPS) for operating and capital-related costs. This proposed rule would implement changes arising from our continuing experience with these systems.

Priority: Economically Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: Yes
Unfunded Mandates: Undetermined
CFR Citation: 42 CFR 412 (To search for a specific CFR, visit the Code of Federal Regulations)

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

Legal Deadline:

Action	Source	Description	Date
NPRM	Statutory		04/01/2011
Other	Statutory		08/01/2011

Regulatory Plan:

Statement of Need: CMS annually revises the Medicare hospital inpatient prospective payment systems (IPPS) for operating and capital-related costs to implement changes arising from our continuing experience with these systems. In addition, we describe the proposed changes to the amounts and factors used to determine the rates for Medicare hospital inpatient services for operating costs and capital-related costs. Also, CMS annually updates the payment rates for the Medicare prospective payment system (PPS) for inpatient hospital services provided by long-term care hospitals (LTCHs). The proposed rule solicits comments on the proposed IPPS and LTCH payment rates and new policies. CMS will issue a final rule containing the payment rates for the FY 2012 IPPS and LTCHs at least 60 days before October 1, 2011.

Legal Basis: The Social Security Act (the Act) sets forth a system of payment for the operating costs of acute care hospital inpatient stays under Medicare Part A (Hospital Insurance) based on prospectively set rates. The Act requires the Secretary to pay for the capital-related costs of hospital inpatient and Long-Term Care stays under a PPS. Under these PPSs, Medicare payment for hospital inpatient and Long-Term Care operating and capital-related costs is made at predetermined, specific rates for each hospital discharge. These changes would be applicable to services furnished on or after October 1, 2011.

Alternatives: None. This implements a statutory requirement.

Costs and Benefits: Total expenditures will be adjusted for FY 2012.

Risks: If this regulation is not published timely, inpatient hospital and LTCH services will not be paid appropriately beginning October 1, 2011.

Timetable:

Action	Date	FR Cite
NPRM	04/00/2011	

Regulatory Flexibility Analysis Required: Business Government Levels Affected: No

Federalism: No

Energy Affected: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AQ25

View Related Documents

Title: Revisions to Payment Policies Under the Physician Fee Schedule and Part B for CY 2012 (CMS-1524-P)

Abstract: This proposed rule would revise payment polices under the physician fee schedule, as well as other policy changes to payment under Part B. These changes would be applicable to services furnished on or after January 1, annually.

Priority: Economically Significant Agenda Stage of Rulemaking: Proposed Rule

Major: Yes Unfunded Mandates: Undetermined

CFR Citation: 42 CFR 405; 42 CFR 410 to 411; 42 CFR 413 to 414; 42 CFR 426 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: Social security Act, sec 1102; Social Security Act, sec 1871

Legal Deadline: The statute requires that the final rule be issued by November.

Action	Source	Description	Date
Other	Statutory		11/01/2011

Regulatory Plan:

Statement of Need: The statute requires that we establish each year, by regulation, payment amounts for all physicians' services furnished in all fee schedule areas. This major proposed rule would make changes affecting Medicare Part B payment to physicians and other Part B suppliers. The final rule has a statutory publication date of November 1, 2011, and an implementation date of January 1, 2012.

Legal Basis: Section 1848 of the Social Security Act (the Act) establishes the payment for physician services provided under Medicare. Section 1848 of the Act imposes a deadline of no later than November 1 for publication of the final physician fee schedule rule.

Alternatives: None. This implements a statutory requirement.

Costs and Benefits: Total expenditures will be adjusted for CY 2012.

Risks: If this regulation is not published timely, physician services will not be paid appropriately.

Timetable:

Action	Date	FR Cite
NPRM	06/00/2011	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

Energy Affected: Undetermined

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AQ26

View Related Documents

Title: Changes to the Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System for CY 2012 (CMS-1525-P)

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

Priority: Economically Significant

Agenda Stage of Rulemaking: Proposed Rule

Major: Yes

Unfunded Mandates: Undetermined

CFR Citation: 42 CFR 410; 42 CFR 416; 42 CFR 419 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: sec 1833 of the Social Security Act

Legal Deadline:

Action	Source	Description	Date
Other	Statutory		11/01/2011

Regulatory Plan:

Statement of Need: Medicare pays over 4,000 hospitals for outpatient department services under the hospital outpatient prospective payment system (OPPS). The OPPS is based on groups of clinically similar services called ambulatory payment classification groups (APCs). CMS annually revises the APC payment amounts based on the most recent claims data, proposes new payment policies, and updates the payments for inflation using the hospital operating market basket. The proposed rule solicits comments on the proposed OPPS payment rates and new policies. Medicare pays roughly 5,000 Ambulatory Surgical Centers (ASCs) under the ASC payment system. CMS annually revises the payment under the ASC payment system, proposes

new policies, and updates payments for inflation using the Consumer Price Index for All Urban Consumers (CPI-U). CMS will issue a final rule containing the payment rates for the 2012 OPPS and ASC payment system at least 60 days before January 1, 2012.

Legal Basis: Section 1833 of the Social Security Act establishes Medicare payment for hospital outpatient services and ASC services. The final rule revises the Medicare hospital OPPS and ASC payment system to implement applicable statutory requirements. In addition, the proposed and final rules describe changes to the outpatient APC system, relative payment weights, outlier adjustments, and other amounts and factors used to determine the payment rates for Medicare hospital outpatient services paid under the prospective payment system as well as changes to the rates and services paid under the ASC payment system. These changes would be applicable to services furnished on or after January 1, 2012.

Alternatives: None. This is a statutory requirement.

Costs and Benefits: Total expenditures will be adjusted for CY 2012.

Risks: If this regulation is not published timely, outpatient hospital and ASC services will not be paid appropriately beginning January 1, 2012.

Timetable:

Action	Date	FR Cite
NPRM	06/00/2011	

Regulatory Flexibility Analysis Required: Business Government Levels Affected: Federal
Federalism: Undetermined
Energy Affected: No
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AQ27

View Related Documents

Title: Changes to the ESRD Prospective Payment System for CY 2012 (CMS-1577-P)

Abstract: This proposed rule would update the bundled payment system for End Stage Renal Disease (ESRD) facilities as required by the Medicare Improvments for Patients and Providers Act (MIPPA). These changes would be applicable to services furnished on or after January 1 annually.

Priority: Economically Significant Agenda Stage of Rulemaking: Proposed Rule
Major: Yes Unfunded Mandates: Undetermined
CFR Citation: 42 CFR 410; 42 CFR 413 and 414 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: Sec 1881 of the Social Security Act
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		11/01/2011

Timetable:

Action	Date	FR Cite
NPRM	06/00/2011	

Regulatory Flexibility Analysis Required: Business Government Levels Affected: Federal
Federalism: Undetermined
Energy Affected: No
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AQ28

View Related Documents

Title: Prospective Payment System for Inpatient Rehabilitation Facilities for FY 2012 (CMS-1349-P)
Abstract: This proposed rule would update rates for the prospective payment system for inpatient rehabilitation facilities.

Priority: Economically Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: Yes
Unfunded Mandates: Undetermined
CFR Citation: 42 CFR 412 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: Social Security Act, sec 1886(j); PL 106-554; PL 106-113
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		08/01/2011

Timetable:

Action	Date	FR Cite
NPRM	05/00/2011	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: Undetermined
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AQ29

View Related Documents

Title: Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities—Update for FY 2012 (CMS-1351-P)
Abstract: This proposed rule would update the payment rates used under the prospective payment system for skilled nursing facilities effective October 1st.

Priority: Economically Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: Yes
Unfunded Mandates: Undetermined
CFR Citation: 42 CFR 482 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: Social Security Act, sec 1888(e)
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		07/31/2011

Timetable:

Action	Date	FR Cite
NPRM	05/00/2011	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: No

Energy Affected: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AQ30

View Related Documents

Title: Home Health Prospective Payment System Refinements and Rate Update for CY 2012 (CMS-1353-P)

Abstract: This proposed rule would update the 60-day national episode rate (based on the applicable Home Health Market Basket Update and case-mix adjustment) and would also update the national per-visit rates (used to calculate low utilization payment adjustments (LUPAs) and outlier payments) amounts under the Medicare Prospective Payment System for home health agencies. These changes would be applicable to services furnished on or after January 1st.

Priority: Economically Significant

Agenda Stage of Rulemaking: Proposed Rule

Major: Yes

Unfunded Mandates: Undetermined

CFR Citation: 42 CFR 484 (To search for a specific CFR, visit the Code of Federal Regulations)

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

Legal Deadline:

Action	Source	Description	Date
Other	Statutory		11/01/2011

Timetable:

Action	Date	FR Cite
NPRM	07/00/2011	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

Energy Affected: Undetermined

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AQ31

View Related Documents

Title: Hospice Wage Index for FY 2012 (CMS-1355-P)

Abstract: This proposed rule would announce the annual update to the hospice wage index to reflect local differences in wage levels. The update would take effect beginning October 1.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: Undetermined
Unfunded Mandates: Undetermined
CFR Citation: 42 CFR 418 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 1814(i) (1) of the Act, 1814(i) (2)
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		08/00/2010

Timetable:

Action	Date	FR Cite
NPRM	05/00/2011	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: Undetermined
Small Entities Affected: Business
Federalism: Undetermined
Energy Affected: Undetermined
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS)
RIN: 0938-AQ32

View Related Documents

Title: Medicaid Reconsideration of Disallowance (CMS-2292-P)

Abstract: This proposed rule would provide policy guidance to States requesting a reconsideration of a disallowance of Medicaid claims under the Medicare Improvements for Patients and Providers Act (MIPPA). Also, this rule would address provisions of the Affordable Care Act concerning the reconsideration process, the change from 60 days to 1-year for overpayments, and changes to the disallowance repayment schedule.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: Undetermined
Unfunded Mandates: Undetermined
CFR Citation: 42 CFR 430; 45 CFR 16 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 1316; PL 111-148
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		03/23/2010

Timetable:

Action	Date	FR Cite
NPRM	07/00/2011	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: State
Federalism: Undetermined
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AQ33

View Related Documents

Title: Revisions to Deeming Authority Survey, Certification, and Enforcement Procedures (CMS-2322-P)

Abstract: This proposed rule would revise the survey, certification, and enforcement procedures related to organizations with CMS deeming authority. These revisions are necessary to comply with the Medicare Improvement for Patients and Providers Act (MIPPA) provisions and for the agency to provide effective oversight of the accreditation organizations that apply for and are granted deeming authority.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 488 and 489 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: Sections 1864 and 1865 of the Social Security Act
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	07/00/2011	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: No
Federalism: No
Energy Affected: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AQ34

View Related Documents

Title: Payment Adjustment for Health Care-Acquired Conditions (CMS-2400-P)

Abstract: This rule, under the Affordable Care Act of 2010, would adjust Medicaid payment for services related to health care acquired conditions.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: Undetermined
Unfunded Mandates: Undetermined
CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 111-148, sec 2702
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		07/01/2011

Timetable:

Action	Date	FR Cite
NPRM	12/00/2010	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: State

Federalism: Undetermined

Energy Affected: No

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

RIN: 0938-AQ35

View Related Documents

Title: Community First Choice (CMS-2337-P)

Abstract: This rule, under the Affordable Care Act of 2010, establishes an optional Medicaid benefit through which States could offer community-based attendant services and supports to Medicaid beneficiaries with disabilities who would otherwise require the level of care offered in a hospital, nursing facility, or intermediate care facility for the mentally retarded.

Priority: Other Significant

Agenda Stage of Rulemaking: Proposed Rule

Major: Undetermined

Unfunded Mandates: Undetermined

CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: PL 111-148, sec 2401

Legal Deadline:

Action	Source	Description	Date
Other	Statutory		10/01/2011

Timetable:

Action	Date	FR Cite
NPRM	02/00/2011	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: State

Federalism: Undetermined

Energy Affected: No

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

RIN: 0938-AQ36

View Related Documents

Title: Home Health Physician Encounter (CMS-2348-P)

Abstract: This proposed rule would implement a provision under the Affordable Care Act of 2010 that would require a physician to have a face-to-face encounter with an individual prior to issuing a certification for home health services.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: Undetermined
Unfunded Mandates: Undetermined
CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 111-148, sec 6407
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		01/01/2010

Timetable:

Action	Date	FR Cite
NPRM	05/00/2011	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: State
Federalism: Undetermined
Energy Affected: No
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AQ37

View Related Documents

Title: Medicaid Disproportionate Share Hospital Payments (CMS-2315-P)
Abstract: This proposed rule would define individuals who have no health insurance (or other source of third party coverage) for purposes of calculating limits on the amount of payments to disproportionate share hospitals. Recently, CMS has become aware of the potential for unintended financial impact on States and hospitals resulting from guidance associated with the 2009 promulgation of CMS-2198-F, Medicaid Disproportionate Share Hospital Payments. This proposed rule will ensure consistency with longstanding CMS policy and avoid any such unintended financial impact.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 447 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 1923(g) of the Social Security Act
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	03/00/2011	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: State
Small Entities Affected: Business; Governmental Jurisdictions
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AQ38

View Related Documents

Title: Medicare, Medicaid, and CLIA Programs; Patient's Access to Laboratory Test Report (CMS-2319-P)

Abstract: This proposed rule would revise portions of the Clinical Laboratory Improvement Amendments of 1988 (CLIA) to clarify existing policy, promote patient access to laboratory test reports and establish electronic health records.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: Undetermined
Unfunded Mandates: No
CFR Citation: 42 CFR 493 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 263a
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	02/00/2011	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: Undetermined
Small Entities Affected: Business; Governmental Jurisdictions
Federalism: No
Energy Affected: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AQ41

View Related Documents

Title: Covered Outpatient Drugs (CMS-2345-P)

Abstract: This proposed rule would implement provisions of the Affordable Care Act of 2010 that revise the rebate for single source and innovator multiple source outpatient prescription drugs. The rule would also revise the definition of average manufacturer price.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: Undetermined
Unfunded Mandates: Undetermined
CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 111- 48, secs 2501 and 2503
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		01/01/2010

Timetable:

Action	Date	FR Cite
NPRM	04/00/2011	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: State

Federalism: Undetermined

Energy Affected: No

Related RINs: Related to 0938-AP26; Related to 0938-AP67

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AQ43

View Related Documents

Title: Medicaid Automated Data System Requirements and Data Elements Necessary for Program Integrity, Program Oversight, and Administration (CMS-2317-P)

Abstract: This proposed rule would implement several provisions of the Affordable Care Act of 2010. It would implement the provision that requires States, for data submitted on or after January 1, 2010, to include data elements from the automated data system that CMS determines to be necessary for program integrity, program oversight, and administration, at such frequency as CMS shall determine. It also would implement the provision that requires for managed care patients that the managed care plans provide data to States at a frequency and level of detail as specified by CMS. In addition, the rule would implement the provision that provides for withholding of Federal Matching Payments to States that fail to report enrollee encounter data in the Medicaid Statistical Information System.

Priority: Other Significant

Agenda Stage of Rulemaking: Proposed Rule

Major: Undetermined

Unfunded Mandates: No

CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: PL 111-148, sec 6402(c); PL 111-148, sec 6504(a); PL 111-148, sec 6504(b)

Legal Deadline:

Action	Source	Description	Date
Other	Statutory		01/01/2010

Timetable:

Action	Date	FR Cite
NPRM	06/00/2011	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Tribal

Federalism: No

Energy Affected: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AQ49

View Related Documents

Title: 5-Year Period Approvals and Renewals for Waivers and Demonstration Projects (CMS-2323-P)

Abstract: This rule, in response to provsions of the Affordable Care Act of 2010, clarifies that Medicaid waivers for coordinating care for dual eligible beneficiaries could be authorized for as long as five years. Any waiver that provides medical assistance for dual eligible individuals (including any such waivers under which non dual eligible individuals may be enrolled) may be conducted for a period of 5 years and, upon request of the State, may be extended for additional 5-year periods.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 111-152, sec 2601
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	07/00/2011	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: State
Federalism: No
Energy Affected: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS)
RIN: 0938-AQ53

View Related Documents

Title: Federal Funding for Medicaid Eligibility Determination and Enrollment Activities (CMS-2346-P)

Abstract: The Affordable Care Act requires States' residents to apply, enroll, receive determinations, and participate in the State health subsidy programs known as "the Exchange". The ACA requires many changes to State eligibility and enrollment systems and each State is responsible for developing a secure, electronic interface allowing the exchange of data. Existing legacy eligibility systems are not able to implement the numerous requirements. This proposed rule is key to informing States about the higher rates that CMS will provide to help them update or build legacy eligibility systems that meet the ACA requirements.

Priority: Economically Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: Yes
Unfunded Mandates: No
CFR Citation: 42 CFR 433 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 111-148, sec 1413
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	11/08/2010	75 FR 68583
NPRM Comment Period End	01/07/2011	

Regulatory Flexibility Analysis Required: Governmental Jurisdictions
Government Levels Affected: State
Federalism: Yes
Energy Affected: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AQ54

View Related Documents

Title: Standards for Demonstrating Access to Covered Medicaid Services (CMS-2328-P)

Abstract: The Medicaid statute requires that state plans provide sufficient procedures and methods to ensure that payment rates for Medicaid services are sufficient to enlist qualified providers to ensure that care and services are available to Medicaid beneficiaries at least to the extent that care and services are available to the general public in the same geographic area. This proposed rule seeks to clarify the definition of access to care and services and provide standard data elements and measures that states must submit to CMS to demonstrate that payment rates are sufficient to provide access to covered Medicaid services.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 447 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 1396 to 1396v; 1902(a)(30)(A) of the Social Security Act
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	04/00/2011	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: State
Small Entities Affected: No
Federalism: Yes
Energy Affected: No
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AJ17

View Related Documents

Title: Medicare Changes in Conditions of Participation Requirements and Payment Provisions for Rural Health Clinics and Federally Qualified Health Centers (CMS-1910-F2)

Abstract: This rule finalizes the provisions of the proposed rule published on June 27, 2008, which reissued provisions of the final rule that was published on December 24, 2003, but was subsequently suspended. This final rule amends the Medicare certification requirements for rural health clinics (RHCs), as required by section 4205 of the Balanced Budget Act of 1997. It updates the regulations pertaining to RHC staffing requirements, allows RHCs to contract with RHC nonphysician providers, and revises the RHC and Federally Qualified Health Center (FQHC) payment methodology.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 405; 42 CFR 491 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 1302; 42 USC 1395hh; Deficit Reduction Act of 2005 (PL 109-171), sec 6083
Legal Deadline:

Action	Source	Description	Date

Other	Statutory	MMA Section 902	06/27/2011

Timetable:

Action	Date	FR Cite
NPRM	02/28/2000	65 FR 10450
NPRM Comment Period End	04/28/2000	
Final Rule	12/24/2003	68 FR 74791
Interim Final Rule	09/22/2006	71 FR 55341
Interim Final Rule Comment Period End	11/21/2006	
Second NPRM	06/27/2008	73 FR 36463
NPRM Comment Period End	08/26/2008	
Final Action	06/00/2011	

Regulatory Flexibility Analysis Required: No
Small Entities Affected: Business
Energy Affected: No
Government Levels Affected: Federal
Federalism: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AO50

View Related Documents

Title: Optional State Plan Case Management Services (CMS-2237-F)

Abstract: This final rule revises current Medicaid regulations to incorporate changes made by the Deficit Reduction Act of 2005. The rule finalizes portions of the interim final rule published on December 4, 2007, that were not rescinded under the Congressional moratoria. The rule clarifies what is reimbursable under the Medicaid case management and targeted case management benefit and is intended to offer guidance to States on implementing the DRA provisions.

Priority: Economically Significant
Major: Yes
Agenda Stage of Rulemaking: Final Rule
Unfunded Mandates: No

CFR Citation: 42 CFR 431, 42 CFR 440 to 441 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: Deficit Reduction Act of 2005; PL 109-171, sec 6052

Legal Deadline: Public Law 110-28 established a 1-year moratorium on rule until May 25, 2008. Public Law 110-252 extended the moratorium to March 31, 2009. Public Law 111-5 extended moratorium to June 30, 2009.

Action	Source	Description	Date
Other	Statutory		01/01/2006

Timetable:

Action	Date	FR Cite
Interim Final Rule	12/04/2007	72 FR 68077
Interim Final Rule Comment Period End	02/04/2008	
Interim Final Rule Effective	03/03/2008	
Final Action	07/00/2011	

Regulatory Flexibility Analysis Required: Undetermined
Small Entities Affected: Governmental Jurisdictions
Energy Affected: No
Government Levels Affected: No
Federalism: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP53

View Related Documents

Title: Children's Health Insurance Program (CHIP); Allotment Methodology and States' Fiscal Year 2009 CHIP Allotments (CMS-2291-F)

Abstract: This final rule describes the implementation of certain funding provisions under the Social Security Act (the Act), the Children's Health Insurance Program (CHIP), as amended by the Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA), by the Medicare, Medicaid, and SCHIP Extension Act of 2007 (MMSEA), and by other related CHIP legislation. Specifically, this rule addresses methodologies and procedures for determining States' FY 2009 through FY 2015 allotments and payments in accordance with sections 2104 and 2105 of the Act, as amended by CHIPRA and the Affordable Care Act.

Priority: Economically Significant
Agenda Stage of Rulemaking: Final Rule
Major: Yes
Unfunded Mandates: No
CFR Citation: 42 CFR 457.600 to 457.630 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 1397dd(g); 42 USC 1397ee(g); secs 2104(e) and 2104(f) of the Social Security Act; CHIPRA of 2009 (PL 111-3)
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		09/30/2009

Timetable:

Action	Date	FR Cite
NPRM	09/16/2009	74 FR 47517
NPRM Comment Period End	11/16/2009	
Final Action	01/00/2011	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: State
Small Entities Affected: Governmental Jurisdictions
Federalism: No
Related RINs: Related to 0938-AP54

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP79

View Related Documents

Title: Revisions to Payment Policies Under the Physician Fee Schedule and Part B for CY 2011 (CMS-1503-C)

Abstract: This annual final rule revises payment polices under the physician fee schedule, as well as other policy changes to payment under Part B for CY 2011.

Priority: Economically Significant
Agenda Stage of Rulemaking: Final Rule
Major: Yes
Unfunded Mandates: No
CFR Citation: 42 CFR 405; 42 CFR 410 to 411; 42 CFR 413 to 414; 42 CFR 426 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: Social Security Act, sec 1102; Social Security Act, sec 1871
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		11/01/2010

Timetable:

Action	Date	FR Cite
NPRM	07/13/2010	75 FR 40040
NPRM Comment Period End	09/24/2010	
Final Action	12/00/2010	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP81

View Related Documents

Title: Part B Monthly Actuarial Rates, Monthly Premium Rates, and Annual Deductible Beginning January 1, 2011 (CMS-8042-N)
Abstract: This notice announces the monthly actuarial rates for aged (age 65 and over) and disabled (under age 65) enrollees in Part B of Medicare for CY 2011. It also announces the monthly Part B premiums and the Part B deductible during CY 2011.

Priority: Economically Significant
Agenda Stage of Rulemaking: Final Rule
Major: Yes
Unfunded Mandates: No
CFR Citation: None (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 1395r; Social Secrity Act, sec 1839; MMA, sec 629; MMA, sec 811; DRA, sec 5111
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		09/30/2010

Timetable:

Action	Date	FR Cite
Final Action	12/00/2010	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP82

View Related Documents

Title: Changes to the Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System for CY 2011 (CMS-1504-C)

Abstract: This final rule revises the Medicare hospital outpatient prospective payment system to implement applicable statutory requirements and changes arising from our continuing experience with this system. The rule also describes changes to the amounts and factors used to determine payment rates for services. In addition, the rule changes the Ambulatory Surgical Center Payment System list of services and rates.

Priority: Economically Significant
Agenda Stage of Rulemaking: Final Rule
Major: Yes
Unfunded Mandates: No
CFR Citation: 42 CFR 410 to 413; 42 CFR 416; 42 CFR 419,; 482,485, and 489 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: sec 1833 of the Social Security Act; BBA, BA, BIPA, MMA, PPACA
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		11/01/2010

Timetable:

Action	Date	FR Cite
NPRM	08/03/2010	75 FR 46169
NPRM Comment Period End	08/31/2010	
Final Action	12/00/2010	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: Federal
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP85

View Related Documents

Title: Part A Premiums for CY 2011 for the Uninsured Aged and for Certain Disabled Individuals Who Have Exhausted Other Entitlement (CMS-8041-N)

Abstract: This notice announces the Hospital Insurance premium for calendar year 2011 under Medicare's Hospital Insurance program (Medicare Part A) for the uninsured aged and for certain disabled individuals who have exhausted other entitlement.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: None (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 1395i-2(d)(2); 42 USC 1395i-2a(d)(2); Social Security Act, sec 1818(d)(2); Social Security Act, sec 1818A(d)(2)
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		09/30/2010

Timetable:

Action	Date	FR Cite

Final Action	12/00/2010	

Regulatory Flexibility Analysis Required: No
Small Entities Affected: No
Energy Affected: No
Government Levels Affected: No
Federalism: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP86

View Related Documents

Title: Inpatient Hospital Deductible and Hospital and Extended Care Services Coinsurance Amounts for CY 2011 (CMS-8040-N)

Abstract: This notice announces the inpatient hospital deductible and the hospital and extended care services coinsurance amounts for services furnished in calendar year 2011 under Medicare's Hospital Insurance program (Medicare Part A). The Medicare statute specifies the formula used to determine these amounts.

Priority: Economically Significant
Major: Yes
Agenda Stage of Rulemaking: Final Rule
Unfunded Mandates: No

CFR Citation: None (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 1395e-2(b)(2); Social Security Act, sec 1813 (b)(2)
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		09/15/2010

Timetable:

Action	Date	FR Cite
Final Action	12/00/2010	

Regulatory Flexibility Analysis Required: No
Small Entities Affected: No
Energy Affected: No
Government Levels Affected: No
Federalism: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP98

View Related Documents

Title: Administrative Fees for the Vaccines for Children Program (CMS-2310-IFC)

Abstract: This rule updates the interim regional maximum charges that providers may impose for the administration of pediatric vaccines to Federally vaccine-eligible children under the Pediatric Immunization Distribution Program, more commonly known as the Vaccines for Children (VFC) program. These charges have not been updated since the VFC program became

effective October 1, 1994. The publication of these updated administration charges is essential to the continued implementation of the VFC program.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: Undetermined
Unfunded Mandates: Undetermined
CFR Citation: 42 CFR 447 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: Ominibus Budget Reconciliation Act of 1993 (PL 103-66)
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Interim Final Rule	07/00/2011	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: State
Federalism: Undetermined
Energy Affected: Undetermined
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AQ02

View Related Documents

Title: Civil Money Penalties for Nursing Homes (CMS-2435-F)
Abstract: This rule revises and expands current Medicare and Medicaid regulations regarding the imposition of civil money penalties by CMS when nursing homes are not in compliance with Federal participation requirements.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 488 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 1302 and 1395 (hh)
Legal Deadline:

Action	Source	Description	Date
Other	Statutory	1 year after enactment of PPACA	03/23/2011

Regulatory Plan:

Statement of Need: The intent of this final rule is to improve the efficiency and effectiveness of the nursing home enforcement process, particularly as it relates to civil money penalties imposed by CMS. The new provisions will reduce the delay between the identification of problems with noncompliance and the effect of certain penalties that are intended to motivate a nursing home to maintain continuous compliance with basic expectations regarding the provision of quality care. The new provisions also eliminate a facility's ability to significantly defer the direct financial effect of an applicable civil monetary penalty until after an often long litigation process. Specifically, this rule would allow for civil money penalty reductions when facilities self-report and promptly correct their noncompliance; offer, in cases where civil money penalties are imposed, an independent informal dispute resolution process where interests of both facilities and residents are represented and balanced; provide for the establishment of an escrow account where civil money penalties may be placed until any applicable administrative appeal processes have been completed; and improve the extent to which civil money penalties collected from Medicare facilities can benefit nursing home residents. Through the proposed revisions, we intend to directly promote and improve the health, safety, and overall well-being of residents.

Legal Basis: Section 6111 of the Affordable Care Act of 2010 amended the Act to incorporate specific provisions pertaining to the imposition and collection of civil money penalties when facilities do not meet Medicare and Medicaid participation requirements.

Alternatives: None. This rule implements a statutory requirement. The proposed rule was published on July 12, 2010.

Alternatives proposed by commenters will be considered in the preparation of the final rule.

Costs and Benefits: The regulatory impact statement provides that these regulatory proposals would have no consequential effect on State, local, or tribal governments or on the private sector. The anticipated benefits of this regulation include stronger protections for nursing home residents, improved due process for nursing homes, incentives for prompt self-correction of deficiencies, and increased quality improvement.

Risks: CMS does not expect any additional risks to providers and/or States as a result of the implementation of this rule.

Timetable:

Action	Date	FR Cite
NPRM	07/12/2010	75 FR 39641
NPRM Comment Period End	08/11/2010	
Final Action	03/00/2011	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: State
Federalism: No
Energy Affected: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AQ12

View Related Documents

Title: Administrative Simplification: Adoption of Authoring Organizations for Operating Rules and Adoption of Operating Rules for Eligibility and Claims Status (CMS-0032-IFC)

Abstract: This rule implements provisions of the Affordable Care Act of 2010 under Administrative Simplification that require the adoption or authoring organizations for operating rules and the adoption of operating rules for eligibility and claims status, and to consider those operating rules developed by a qualified nonprofit entity that meets specific criteria.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: Undetermined
Unfunded Mandates: Undetermined
CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 111-148, sec 1104

Legal Deadline:

Action	Source	Description	Date
Other	Statutory		07/01/2011

Timetable:

Action	Date	FR Cite
Interim Final Rule	06/00/2011	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: Undetermined
Small Entities Affected: Organizations
Federalism: No
Energy Affected: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AQ13

View Related Documents

Title: Administrative Simplification: Standard Unique Identifier for Health Plans (CMS-0040-IFC)

Abstract: This rule implements provisions of the Affordable Care Act of 2010 under Administrative Simplification that establish a unique health plan identifier. This health plan identifier will be used to identify health plans in HIPAA standard transactions.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: Undetermined
Unfunded Mandates: Undetermined
CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 111-148, sec 1104
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		10/01/2012

Timetable:

Action	Date	FR Cite
Interim Final Rule	07/00/2011	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: Undetermined
Small Entities Affected: Business
Federalism: Undetermined
Energy Affected: No
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AQ14

View Related Documents

Title: Inpatient Hospital Deductible and Hospital and Extended Care Services Coinsurance Amounts for CY 2012 (CMS-8043-N)

Abstract: This notice announces the inpatient hospital deductible and the hospital and extended care services coinsurance amounts for services furnished in calendar year 2012 under Medicare's Hospital Insurance program (Medicare Part A). The Medicare statute specifies the formula used to determine these amounts.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: Yes
Unfunded Mandates: No
CFR Citation: None (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 1395e-2(b)(2); Social Security Act, sec 1813 (b)(2)
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		09/15/2011

Timetable:

Action	Date	FR Cite
Final Action	09/00/2011	

Regulatory Flexibility Analysis Required: No
Small Entities Affected: No
Energy Affected: No
Government Levels Affected: No
Federalism: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AQ15

View Related Documents

Title: Part A Premiums for CY 2012 for the Uninsured Aged and for Certain Disabled Individuals Who Have Exhausted Other Entitlement (CMS-8044-N)

Abstract: This notice announces the Hospital Insurance premium for calendar year 2012 under Medicare's Hospital Insurance program (Medicare Part A) for the uninsured aged and for certain disabled individuals who have exhausted other entitlement.

Priority: Other Significant
Major: Undetermined
Agenda Stage of Rulemaking: Final Rule
Unfunded Mandates: No

CFR Citation: None (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: 42 USC 1395i-2(d)(2); 42 USC 1395i-2a(d)(2); Social Security Act, sec 1818(d0(2); Social Security Act, sec 1818A(d0(2)

Legal Deadline:

Action	Source	Description	Date
Other	Statutory		09/30/2011

Timetable:

Action	Date	FR Cite
Final Action	09/00/2011	

Regulatory Flexibility Analysis Required: No
Small Entities Affected: No
Energy Affected: No
Government Levels Affected: No
Federalism: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AQ16

View Related Documents

Title: Part B Monthly Actuarial Rates, Monthly Premium Rates, and Annual Deductible Beginning January 1, 2012 (CMS-8045-N)

Abstract: This major notice announces the monthly actuarial rates for aged (age 65 and over) and disabled (under age 65) enrollees in Part B of Medicare for CY 2012. It also announces the monthly Part B premiums and the Part B deductible during CY 2012.

Priority: Other Significant
Major: Undetermined
Agenda Stage of Rulemaking: Final Rule
Unfunded Mandates: No

CFR Citation: None (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 1395r; Social Security Act, sec 1839; MMA, sec 629; mma, sec 811; DRA, sec 5111
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		09/30/2011

Timetable:

Action	Date	FR Cite
Final Action	09/00/2011	

Regulatory Flexibility Analysis Required: No
Small Entities Affected: No
Energy Affected: No
Government Levels Affected: No
Federalism: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AQ20

View Related Documents

Title: Additional Screening, Application Fees, and Temporary Moratoria for Providers and Suppliers (CMS-6028-F)
Abstract: This rule implements additional provider and supplier enrollment requirements under the Affordable Care Act of 2010. This rule reduces fraud, waste, and abuse in the Medicare program and significantly improve the screening mechanism to prevent questionable providers and suppliers from entering the program.

Priority: Economically Significant
Major: Yes
Agenda Stage of Rulemaking: Final Rule
Unfunded Mandates: No
CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 111-148
Legal Deadline: Rule includes several ACA provisions effective beginning 180 days after enactment.

Action	Source	Description	Date
Other	Statutory		01/01/2011

Timetable:

Action	Date	FR Cite
NPRM	09/23/2010	75 FR 58203
NPRM Comment Period End	11/16/2010	
Final Action	01/00/2011	

Regulatory Flexibility Analysis Required: Undetermined
Small Entities Affected: Business
Energy Affected: No
Government Levels Affected: No
Federalism: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AQ39

View Related Documents

Title: Adult Health Quality Services (CMS-2420-NC)

Abstract: This notice announces a recommended core set of adult health quality measures for Medicaid-eligible adults under the Affordable Care Act of 2010.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 111-148, sec 2701
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		01/01/2012

Timetable:

Action	Date	FR Cite
Final Action	12/00/2010	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AQ40

View Related Documents

Title: Cost Limit for Providers Operated by Units of Government and Provisions to Ensure the Integrity of Federal-State Financial Partnership (CMS-2361-F)

Abstract: This final rule amends Medicaid regulations to conform with the United States District Court for the District of Columbia ruling in Alameda County Medical Center, et al. v. Michael O. Leavitt, Secretary, U.S. Department of Health and Human Services, et al. (No. 1:08-cv-00422). This court order vacated all provisions in the final rule with comment period published on May 29, 2007. That final rule eliminated, modified, or implemented regulatory requirements pertaining to the financial relationship between Federal and State governments.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 433; 42 CFR 447 and 457 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: Alameda County Medical Center, et al. v. Michael O. Leavitt, Secretary, U.S. Department of Health and Human Services, et al. (No 1:08-cv-00422).
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Interim Final Rule	12/00/2010	

Regulatory Flexibility Analysis Required: No
Small Entities Affected: No
Energy Affected: No
Related RINs: Related to 0938-AO57
Government Levels Affected: No
Federalism: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AQ42

View Related Documents

Title: State Allotments for Payment of Medicare Part B Premiums for Qualifying Individuals: Federal Fiscal Year 2011 (CMS-2318-N)

Abstract: This notice sets forth final allotments available to States to pay the Medicare Part B premiums for Qualifying Individuals (QIs) for the Federal fiscal year (FY) 2010 and the preliminary QI allotments for FY 2011.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: Social Security Act, sec 1902
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Final Action	12/00/2010	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: State
Federalism: No
Energy Affected: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AQ44

View Related Documents

Title: Final FY 2009 and 2010 and Preliminary FY 2011 Disproportionate Share Hospital (DSH) Payment Allotments and Institutions for Mental Disease DSH Limits (CMS-2321-N)

Abstract: This notice sets forth the States' final and preliminary fiscal year disproportionate share hospital (DSH) payment allotments and States' institutions for mental disease (IMD) DSH limits under the Medicaid program.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: Social Security Act, sec 1923(f)(3)
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Final Action	12/00/2010	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: State
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS)
RIN: 0938-AQ46

View Related Documents

Title: Proposed Changes to the Demonstration Review and Approval Process (CMS-2325-F)

Abstract: This rule implements provisions of the Affordable Care Act of 2010 and address concerns about transparency in the demonstration review and approval process. This rule establishes requirements for submitting new proposals and the requirements to amend or extend an approved demonstration project. This rule also provides guidance regarding public notice, monitoring, compliance, the evaluation of demonstration projects and the submission of reports to the Secretary for approved demonstrations.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 431 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 111-148, sec 10201
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		09/19/2010

Timetable:

Action	Date	FR Cite
NPRM	09/17/2010	75 FR 56946
NPRM Comment Period End	11/16/2010	
Final Action	06/00/2011	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: State
Small Entities Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS)
RIN: 0938-AQ52

View Related Documents

Title: HIPAA Mental Health Parity and Addiction Equity Act of 2008 Amendments (CMS-4140-F)

Abstract: This final rule would further clarify statutory changes to the Public Health Services Act (PHSA) affecting the group health insurance markets and non-federal governmental plans, made by the Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA).

Priority: Economically Significant
Agenda Stage of Rulemaking: Final Rule
Major: Undetermined
Unfunded Mandates: No
CFR Citation: 45 CFR 136 and 146 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 110-343
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Request for Information	04/28/2009	74 FR 19155
Request for Information Comment Period Ended	05/28/2009	
Interim Final Rule	02/02/2010	75 FR 5410
Interim Final Rule Comment Period End	05/03/2010	
Final Action	09/00/2011	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Related RINs: Related to 0938-AP65
Related Agencies: Joint: EBSA; Joint: IRS

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS)
RIN: 0938-AJ96

View Related Documents

Title: Use of Restraints and Seclusion in Residential Treatment Facilities Providing Inpatient Psychiatric Services to Individuals Under Age 21 (CMS-2065-F)

Abstract: This final rule addresses standards of practice that residential treatment facilities providing inpatient psychiatric services for individuals under age 21 must meet with regard to the use of restraints (including psychoactive drugs) and seclusion.

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 441 and 442; 42 CFR 483 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 1302; 42 USC 1396d
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Final Rule	00/00/0000	
Interim Final Rule	01/22/2001	66 FR 7148
Interim Final Rule Effective	03/23/2001	
Interim Final Rule Comment Period End	03/23/2001	
60-Day Delay of Effective Date to 05/22/2001	03/21/2001	66 FR 15800
Interim Final Rule Amendment With Clarification	05/22/2001	66 FR 28110
Interim Final Rule Comment Period End	07/23/2001	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: Business
Federalism: No

Energy Affected: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AO34

View Related Documents

Title: Cytology Proficiency Testing (CMS-2252-F)

Abstract: This rule revises certain Clinical Laboratory Improvement Amendments (CLIA) of 1988, including proficiency testing requirements for clinical laboratories offering cytology services and for individuals examining gynecological cytology specimens (pap smears). Revisions are also made to CMS approval requirements for programs offering proficiency testing for gynecologic cytology. Evaluating the competency of each individual who examines gynecologic cytology specimens is required by Federal law and regulations.

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 493 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 263a, Clinical Laboratory Improvement Amendments of 1988; 42 USC 1395x, secs 1861s(15) to 1861s(17); of the Social Security Act
Legal Deadline:

Action	Source	Description	Date
Other	Statutory	MMA Section 902	01/16/2012

Timetable:

Action	Date	FR Cite
Final Action	00/00/0000	
NPRM	01/16/2009	74 FR 3264
NPRM Comment Period End	03/17/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP49

View Related Documents

Title: Identification of Backward Compatible Version of Adopted Standard for the E-Prescribing and Medicare Prescription Drug Program (Version 10.6)(CMS-0023-F)

Abstract: This rule finalizes the voluntary use of Version 10.6 of the National Council for Prescription Drug Programs (NCPDP) SCRIPT standard for certain e-prescribing transactions, which would enable use of e-prescribing in long-term care settings. Although this is a discretionary rule, it stems from the recommendation of the National Committee on Vital and Health

Statistics (NCHVS), based on input from industry stakeholders. Because use of the standard would be voluntary, the rule imposes no adverse impact; however, it would allow the long-term care industry to realize the potential workflow and patient care benefits of e-prescribing.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 1395
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Interim Final Rule	07/01/2010	75 FR 38026
Interim Final Rule Comment Period End	08/30/2010	
Final Action	07/00/2013	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS)
RIN: 0938-AP59

View Related Documents

Title: Limited Changes to the Competitive Acquisition of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)(CMS-1561-F)

Abstract: This final rule, as mandated by section 154 of the Medicare Improvements for Patients and Providers Act (MIPPA), requires the temporary delay of Round 1 of the DMEPOS Competitive Bidding Program. As such, a new competition excluding certain services will be necessary. Section 154 also requires the program to provide a process for giving suppliers feedback on missing financial documents and mandates the disclosure of subcontractors under a competitive bidding program.

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 414 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 1302; 42 USC 1395hh; 42 USC 1395rr(b)(1)
Legal Deadline:

Action	Source	Description	Date
Other	Statutory	MMA section 902	01/16/2012

Timetable:

Action	Date	FR Cite
Interim Final Rule	01/16/2009	74 FR 2873
Interim Final Rule Comment Period End	03/17/2009	
Final Action	01/00/2012	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: No
Federalism: No
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP64

View Related Documents

Title: Medicare Advantage and Prescription Drug Benefit Programs; Payments to Sponsors of Retiree Prescription Drug Plans (CMS-4131-F2)

Abstract: This rule will specify whether Retiree Drug Subsidy plan sponsors can continue to choose to report either the "pass-through price" or the "lock-in price" when reporting part D drug cost data.

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 422 and 423 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 1302; 42 USC 1395w-101 to 1395w-152; 42 USC 1395hh
Legal Deadline:

Action	Source	Description	Date
Other	Statutory	MMA section 902	01/12/2012

Timetable:

Action	Date	FR Cite
NPRM	01/12/2009	74 FR 1550
NPRM Comment Period End	03/13/2009	
Final Action	01/00/2012	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: Business
Federalism: No
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP91

View Related Documents

Title: Quality Incentives in the End-Stage Renal Disease (ESRD) Program (CMS-3206-F)

Abstract: This rule establishes the methodology for assessing the total performance of each provider of services and renal dialysis facility based on performance standards for the measures called for under the Social Security Act. The rule establishes performance standards, performance periods, and a methodology for assessing the total performance of each provider/facility. If a provider/facility fails to meet or exceed the total performance score with respect to the performance standards established for the selected measures, payments to the provider/facility will be reduced by up to two percent as determined appropriate by the Secretary.

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 413 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: section 1881 (h) of the Social Security Act
Legal Deadline: Payment consequence occurs with respect to renal dialysis services furnished on or after January 1, 2012.

Action	Source	Description	Date
Other	Statutory		01/01/2012

Timetable:

Action	Date	FR Cite
NPRM	08/12/2010	75 FR 49215
NPRM Comment Period End	09/24/2010	
Final Action	01/00/2012	

Regulatory Flexibility Analysis Required: No
Small Entities Affected: Business
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Government Levels Affected: No
Federalism: No

Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP93

View Related Documents

Title: Ambulatory Surgical Centers Conditions for Coverage: Same-Day Services (CMS-3217-F)
Abstract: This rule amends and clarifies several requirements from the November 18, 2008, Outpatient Prospective Payment System final rule. Medicare beneficiaries may be medically disadvantaged by certain requirements in the patient rights condition. Specifically, the patient rights condition requires that Ambulatory Surgical Centers (ASCs) furnish certain information to patients in advance of the date of the procedure. Those ASCs who routinely perform same-day procedures will be unable to provide this information prior to the date of surgery and will be out of compliance with the regulation. Therefore, patients will be denied same-day procedures in an ASC because of current regulatory requirements.

Priority: Other Significant
Major: No
Agenda Stage of Rulemaking: Long-term Action
Unfunded Mandates: No
CFR Citation: 42 CFR 416 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: Social Security Act sec 1832(a)(2)(F)(i)
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	04/23/2010	75 FR 21207
NPRM Comment Period End	06/22/2010	
Final Action	04/00/2013	

Regulatory Flexibility Analysis Required: No
Small Entities Affected: Business
Energy Affected: No
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Government Levels Affected: No
Federalism: No

Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AQ01

View Related Documents

Title: Changes in Provider and Supplier Enrollment, Ordering and Referring, and Documentation Requirements; and Changes in Provider Agreements (CMS-6010-F)

Abstract: This final rule implements several provisions set forth in the Affordable Care Act. Specifically, the rule requires providers and suppliers under title XVIII and XIX programs that qualify for a national provider identifier (NPI) to include their NPI on all applications to enroll in such programs and all claims for payment submitted under such programs. The rule also requires, in accordance with section 6405 of the Affordable Care Act, that physician and nonphysician practitioner (NPP) who are eligible to order and refer services for Medicare beneficiaries be enrolled in Medicare and adds requirements for physicians to provide documentation on referrals to programs at high risk of waste and abuse.

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 424 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 1302 and 1395hh
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		03/23/2010

Timetable:

Action	Date	FR Cite
Interim Final Rule	05/05/2010	75 FR 24437
Interim Final Rule Comment Period End	07/06/2010	
Final Action	05/00/2013	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Federalism: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AQ05

View Related Documents

Title: Changes Affecting Hospital and Critical Access Hospital (CAH) Conditions of Participation (CoPs): Credentialing and Privileging of Telemedicine Physicians and Practitioners (CMS-3227-F)

Abstract: This rule revises the conditions of participation (CoPs) for both hospitals and critical access hospitals (CAHs). These revisions allow for a new credentialing and privileging process for physicians and practitioners providing telemedicine services.

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 482; 42 CFR 485 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 1302; 42 USC 1395hh and 1395rr
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	05/26/2010	75 FR 29479
NPRM Comment Period End	07/26/2010	

Final Action	05/00/2013	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: Business
Federalism: No
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS)
RIN: 0938-AQ11

View Related Documents

Title: Administrative Simplification: Adoption of Standard and Operating Rule for Electronic Funds Transfer (EFT) and Operating Rule for Remittance Advice (CMS-0024-IFC)

Abstract: This rule implements provisions of the Affordable Care Act of 2010 under Administrative Simplification that require the adoption of standards and operating rules for Electronic Funds Transfers (EFT) and operating rules for remittance advice, and to consider those operating rules developed by a qualified nonprofit entity that meets specific criteria.

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: Undetermined
CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 111-148, sec 1104
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		01/01/2012

Timetable:

Action	Date	FR Cite
Interim Final Rule	12/00/2011	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: Undetermined
Small Entities Affected: Business
Federalism: Undetermined
Energy Affected: No
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS)
RIN: 0938-AQ48

View Related Documents

Title: State Option To Provide Health Homes for Enrollees With Chronic Conditions (CMS-2331-P)

Abstract: This rule would provide guidance on section 2703 of the Affordable Care Act of 2010, which authorizes a new Medicaid State Plan option to provide health homes for enrollees with chronic conditions.

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 111-152, sec 2703

Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	02/00/2014	

Regulatory Flexibility Analysis Required: No
Small Entities Affected: No
Energy Affected: No
Government Levels Affected: State
Federalism: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AO82

View Related Documents

Title: Waiver of Disapproval of Nurse Aide Training Program in Certain Cases (CMS-2266-F)

Abstract: This rule permits a waiver of a nurse aide training disapproval as it applies to skilled nursing facilities, in the Medicare program, and nursing facilities, in the Medicaid program, that are assessed a civil money penalty of at least $5,000 for noncompliance that is not related to quality of care. This is a statutory provision enacted by section 932 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

Priority: Other Significant
Major: No
Agenda Stage of Rulemaking: Completed Action
Unfunded Mandates: No

CFR Citation: 42 CFR 483 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: sec 932(c)(2) MMA; secs 1819(g)(1)(D) and 1919(g)(1)(D) of the Social Security Act

Legal Deadline:

Action	Source	Description	Date
Other	Statutory	MMA Section 902	11/23/2010

Timetable:

Action	Date	FR Cite
NPRM	11/23/2007	72 FR 65692
NPRM Comment Period End	12/24/2007	
Final Action	04/23/2010	75 FR 21175

Regulatory Flexibility Analysis Required: No
Federalism: No
Energy Affected: No
Government Levels Affected: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AO90

View Related Documents

Title: Establishing Additional Provider and Supplier Requirements for Enrollment Standards and Related Issues (CMS-6036-F)

Abstract: This rule clarifies, expands, and adds to the existing enrollment requirements that Durable Medical Equipment and Prosthetics, Orthotics, and Supplies (DMEPOS) suppliers must meet to establish and maintain billing privileges in the Medicare program.

Priority: Other Significant
Agenda Stage of Rulemaking: Completed Action
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 424 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: Sections 1102 and 1871 of the Act
Legal Deadline:

Action	Source	Description	Date
Other	Statutory	MMA Section 902	01/25/2011

Timetable:

Action	Date	FR Cite
NPRM	01/25/2008	73 FR 4503
NPRM Comment Period End	03/25/2008	
Final Action	08/27/2010	75 FR 52629
Final Action Effective	09/27/2010	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: Federal
Small Entities Affected: Business
Federalism: No
Energy Affected: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS)
RIN: 0938-AP57

View Related Documents

Title: End Stage Renal Disease Bundled Payment System (CMS-1418-F)

Abstract: This rule implements a bundled payment system for ESRD facilities beginning January 1, 2011, as required by the Medicare Improvements for Patients and Providers Act.

Priority: Economically Significant
Agenda Stage of Rulemaking: Completed Action
Major: Yes
Unfunded Mandates: No
CFR Citation: 42 CFR 410; 42 CFR 413 and 414 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: sec 153 of MIPPA; sec 1881(b) of the Social Security Act
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		01/01/2011

Timetable:

Action	Date	FR Cite
NPRM	09/29/2009	74 FR 49922
NPRM Comment Period End	12/16/2009	
Final Action	08/12/2010	75 FR 49029

Regulatory Flexibility Analysis Required: No
Government Levels Affected: Federal
Federalism: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP66

View Related Documents

Title: Final and Preliminary Fiscal Year Disproportionate Share Hospital Payment Allotments and Institutions for Mental Disease Limits (CMS-2300-N)

Abstract: This notice sets forth the States' final and preliminary fiscal year disproportionate share hospital (DSH) payment allotments and States' institutions for mental disease (IMD) DSH limits in the Medicaid program. It also announces provisions of the American Recovery and Reinvestment Act that revise DSH allotments.

Priority: Other Significant
Agenda Stage of Rulemaking: Completed Action
Major: No
Unfunded Mandates: No
CFR Citation: None (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: Title XIX of the Social Security Act, sec 1923(f) and (h); American Recovery and Reinvestment Act of 2009 (PL 111-5)
Legal Deadline:

Action	Source	Description	Date
Other	Statutory	Detemination of Fiscal year DSH allotment and IMD DSH Limits.	09/30/2009

Timetable:

Action	Date	FR Cite
Final Action	04/23/2010	75 FR 21314

Regulatory Flexibility Analysis Required: No
Government Levels Affected: State
Small Entities Affected: No
Federalism: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP67

View Related Documents

Title: Medicaid Program; Withdrawal of Determination of Average Manufacturer Price, Multiple Source Drug Definition, and Upper Limits for Multiple Source Drugs (CMS-2238-F2)

Abstract: In this rule, we withdraw two provisions that we published in a final rule, titled Medicaid Program; Prescription Drugs (referred to hereafter as AMP final rule) on July 17, 2007 in the Federal Register: the determination of Average Manufacturer Price (AMP), and the Federal upper limits (FULs) for multiple source drugs. We also withdraw the definition of multiple source drug as it was revised in the Medicaid Program; Multiple Source Drug Definition final rule published on October 7, 2008. The provisions of the AMP final rule and the definition of multiple source drug that we are proposing to withdraw were challenged in a lawsuit that was filed in November 2007. As a result of this action, the Court issued a preliminary injunction

which prohibits the Center for Medicare and Medicaid Services (CMS) from undertaking any and all action to implement the AMP final rule to the extent such action affects Medicaid reimbursement rates for retail pharmacies under the Medicaid program and, subject to certain exceptions, prohibits CMS from posting any AMP data on a public website or otherwise disclosing any AMP data to any individual or entities. With the issuance of the preliminary injunction, CMS has been unable to implement certain provisions of the Deficit Reduction Act of 2005 (as regulated in the July 17, 2007 AMP final rule.) In the meantime, the challenged regulations have been superseded in significant part by the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, and the Education, Jobs and Medicaid Assistance Act. This document withdraws the regulatory provisions challenged in the aforementioned litigation.

Priority: Other Significant
Agenda Stage of Rulemaking: Completed Action
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 447 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 1302
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	09/03/2010	75 FR 54073
NPRM Comment Period End	10/04/2010	
Final Action	11/15/2010	75 FR 69591
Final Action Effective	12/15/2010	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: State
Small Entities Affected: No
Federalism: No
Energy Affected: No
Related RINs: Related to 0938-AP26

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS)
RIN: 0938-AP69

View Related Documents

Title: Medicaid Program and Children's Health Insurance Program (CHIP); Revisions to the Medicaid Eligibility Quality Control and Payment Error Rate Measurement Programs (CMS-6150-F)

Abstract: This final rule implements provisions from the Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA) with regard to the Medicaid Eligibility Quality Control (MEQC) and Payment Error Rate Measurement (PERM) programs. This final rule also codifies several procedural aspects of the process for estimating improper payments in Medicaid and the Children's Health Insurance Program (CHIP). The final rule will provide structure to the improper payments measurement changes required by CHIPRA beginning with FY 2009 and subsequent fiscal years in order to reduce cost and burden or otherwise improve the Medicaid and CHIP programs.

Priority: Other Significant
Agenda Stage of Rulemaking: Completed Action
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 431, 447, 457 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: CHIPRA of 2009 PL No. 111-3
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	07/15/2009	74 FR 34468
NPRM Comment Period End	08/14/2009	
Final Action	08/11/2010	75 FR 48816

Regulatory Flexibility Analysis Required: No
Small Entities Affected: Business; Governmental Jurisdictions
Energy Affected: No
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Government Levels Affected: State
Federalism: No

Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP72

View Related Documents

Title: State Flexibility for Medicaid Benefit Packages (CMS-2232-F4)

Abstract: This final rule amends the final rule published on April 30, 2010, entitled "State Flexibility for Medicaid Benefit Packages," which implemented the provisions of section 1937 of the Social Security Act (the Act) related to the coverage of medical assistance under approved State plans. It also incorporates provisions of the Affordable Care Act (ACA), which further amended section 1937(b) of the Act and explicitly requires States that choose to provide medical assistance through benchmark or benchmark-equivalent coverage to provide certain specified services.

Priority: Other Significant
Major: No
Agenda Stage of Rulemaking: Completed Action
Unfunded Mandates: No
CFR Citation: 42 CFR 440 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 109-171, sec 6044
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		04/30/2010

Timetable:

Action	Date	FR Cite
NPRM	10/30/2009	74 FR 56151
NPRM Comment Period End	11/19/2009	
Final Rule	11/30/2009	74 FR 62501
Second Final Rule	04/30/2010	75 FR 23068

Regulatory Flexibility Analysis Required: No
Government Levels Affected: State
Federalism: No
Energy Affected: No
Related RINs: Related to 0938-AO48
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP73

View Related Documents

Title: Premiums and Cost Sharing (CMS-2244-FC)

Abstract: This final rule revises the November 25, 2008, final rule entitled, "Medicaid Programs; Premiums and Cost Sharing

(73 FR 71828)," that implemented and interpreted provisions of the Deficit Reduction Act of 2005 (DRA) and the Tax Relief and Health Care Act of 2006 (TRHCA). In addition, this final rule responds to public comments on the November 25, 2008 final rule which were received after a notice was published on January 27, 2009 to reopen the comment period and temporarily delay for 60 days the effective date of the final rule and after a notice was published on March 27, 2009, to reopen the comment period and delay the final rule's effective date until December 31, 2009. This final rule also solicits public comments on revisions proposed to the final rule in response to the American Recovery and Reinvestment Act of 2009 (the Recovery Act), which was enacted during the temporary delay of the November 25, 2008, final rule.

Priority: Other Significant
Agenda Stage of Rulemaking: Completed Action
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 447; 42 CFR 457 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 109-171, sec 6041 and 6042; PL 109-432, sec 6043; PL 111-5; sec 5008 (a) of the Recovery Act
Legal Deadline: Rule must by 6/1/10 to be effective by 7/1/10.

Action	Source	Description	Date
Other	Statutory		06/01/2010

Timetable:

Action	Date	FR Cite
NPRM	10/30/2009	74 FR 56151
NPRM Comment Period End	11/19/2009	
Final Rule	11/30/2009	74 FR 62501
Final Action	05/28/2010	75 FR 30244

Regulatory Flexibility Analysis Required: No
Government Levels Affected: State; Tribal
Small Entities Affected: No
Federalism: No
Energy Affected: Yes
Related RINs: Related to 0938-AO47
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS)
RIN: 0938-AP77

View Related Documents

Title: Revisions to the Medicare Advantage and Medicare Prescription Drug Benefit Programs for Contract Year 2011 (CMS-4085-F)
Abstract: This final rule makes revisions to the regulations governing the Medicare Advantage (MA) program (Part C) and prescription drug benefit program (Part D) based on our continued experience in the administration of the Part C and D programs. The revisions strengthen various program participation and exit requirements; strengthen beneficiary protections; ensure that plan offerings to beneficiaries include meaningful differences; improve plan payment rules and processes; improve data collection for oversight and quality assessment; implement new policy such as a Part D formulary policy; and clarify program policy.

Priority: Economically Significant
Agenda Stage of Rulemaking: Completed Action
Major: Yes
Unfunded Mandates: Private Sector
CFR Citation: 42 CFR 417; 42 CFR 422 and 423; 42 CFR 480 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: MMA 2003; MIPPA (title XVIII of the Social Security Act)
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	10/22/2009	74 FR 54634
NPRM Comment Period End	12/07/2009	
Final Action	04/15/2010	75 FR 19678

Regulatory Flexibility Analysis Required: Organizations

Government Levels Affected: State

Federalism: No

Energy Affected: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP78

View Related Documents

Title: Electronic Health Record (EHR) Incentive Program (CMS-0033-F)

Abstract: This rule would implement provisions of the American Recovery Act of 2009 (Recovery Act) that authorize incentive payments to eligible professionals (EPS) and eligible hospitals participating in the Medicare and Medicaid programs for adopting and becoming meaningful users of certified electronic health records (HER) technology. In accordance with the Recovery Act, the rule will establish maximum annual incentive amounts and include Medicare penalties for failing to meaningfully use EHRs beginning in 2015.

Priority: Economically Significant

Agenda Stage of Rulemaking: Completed Action

Major: Yes

Unfunded Mandates: No

CFR Citation: 42 CFR 412 and 413; 42 CFR 422 and 495 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: PL 111-5 (The American Recovery and Reinvestment Act of 2009, Title IV of Division B, Medicare and Medicaid Health Information Technology)

Legal Deadline: Establishes policies and procedures required before the incentive program can begin. Additionally, supplemental payments are available in 2011 and 2012. If eligible professionals and hospitals are not meaningful Electronic Health Record users by 2015, there will be a Medicare payment adjustment imposed.

Action	Source	Description	Date
Other	Statutory	Date can start incentive payments to hospitals (Medicare).	10/01/2010
Other	Statutory	Date can start incentive payments to eligible professionals (Medicare).	01/01/2011

Timetable:

Action	Date	FR Cite
NPRM	01/13/2010	75 FR 1843
NPRM Comment Period End	03/15/2010	
Final Action	07/28/2010	75 FR 44413

Regulatory Flexibility Analysis Required: Organizations

Government Levels Affected: State

Federalism: No

Related RINs: Related to 0991-AB58

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP80

View Related Documents

Title: Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System

Abstract: This rule updates the fiscal year (FY) 2011 hospital inpatient prospective payment systems (IPPS) and long-term care prospective payment system (LTCH PPS). This rule payments to hospitals for inpatient services that are contained in the Patient Protection and Affordable Care Act (the Affordable Care Act) as amended by the Health Care and Education Reconciliation Act of 2010 (HCERA) (collectively known as the Affordable Care Act). It would also specify statutorily required changes to the amounts and factors used to determine the rates for Medicare acute care hospital inpatient services for operating costs and capital-related costs, and for long-term care hospital costs.

Priority: Economically Significant
Agenda Stage of Rulemaking: Completed Action
Major: Yes
Unfunded Mandates: No
CFR Citation: 42 CFR 412 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: Sec 1886(d) of the Social Security Act
Legal Deadline:

Action	Source	Description	Date
NPRM	Statutory		04/01/2010
Other	Statutory		08/01/2010

Timetable:

Action	Date	FR Cite
NPRM	05/04/2010	75 FR 23851
Second NPRM	06/02/2010	75 FR 30917
NPRM Comment Period End	06/18/2010	
Second NPRM Comment Period End	07/02/2010	
Final Action	08/16/2010	75 FR 50041

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: Federal
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP83

View Related Documents

Title: Inpatient Psychiatric Facility Prospective Payment System--Update for Rate Year Beginning July 1, 2010 (RY 2011) (CMS-1424-N)

Abstract: This annual notice will update the rates for inpatient psychiatric facilities with discharges occurring during July 1, 2010 through June 30, 2011.

Priority: Economically Significant
Agenda Stage of Rulemaking: Completed Action
Major: Yes
Unfunded Mandates: No
CFR Citation: 42 CFR 412.400, subpart N (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 106-113, sec 124 BBRA
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		05/01/2010

Timetable:

Action	Date	FR Cite
Final Action	04/30/2010	75 FR 23106

Regulatory Flexibility Analysis Required: No
Small Entities Affected: Business
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Government Levels Affected: Local
Federalism: No

Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP84

View Related Documents

Title: Hospice Wage Index for FY 2011 (CMS-1523-NC)
Abstract: This notice announces the annual update to the hospice wage index (beginning October 1st) that reflects local differences in wage levels.

Priority: Economically Significant
Major: Yes
CFR Citation: 42 CFR 418 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 1814(i)(1) of the Act; 1814(i) (2)
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		08/00/2010

Agenda Stage of Rulemaking: Completed Action
Unfunded Mandates: No

Timetable:

Action	Date	FR Cite
Notice	07/22/2010	75 FR 42943

Regulatory Flexibility Analysis Required: No
Small Entities Affected: Business
Energy Affected: No
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Government Levels Affected: No
Federalism: No

Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP87

View Related Documents

Title: Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities—Update for FY 2011 (CMS-1338-N)
Abstract: This notice updates the payment rates used under the SNF PPS. These changes are applicable to services furnished on or after October 1st.

Priority: Economically Significant

Agenda Stage of Rulemaking: Completed Action

Major: Yes Unfunded Mandates: No

CFR Citation: 42 CFR 483 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: Social Security Act, sec 1888(e)

Legal Deadline:

Action	Source	Description	Date
Other	Statutory		07/31/2010

Timetable:

Action	Date	FR Cite
Notice	07/22/2010	75 FR 42886

Regulatory Flexibility Analysis Required: No Government Levels Affected: No

Small Entities Affected: Business Federalism: No

Energy Affected: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP88

View Related Documents

Title: Home Health Prospective Payment System Refinements and Rate Update for CY 2011 (CMS-1510-F)

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

Priority: Economically Significant Agenda Stage of Rulemaking: Completed Action

Major: Yes Unfunded Mandates: No

CFR Citation: 42 CFR 484 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: Social Security Act, secs 1102 and 1871; 42 USC 1302 and 42 USC 1395(hh); Social Security Act, sec 1895

Legal Deadline:

Action	Source	Description	Date
Other	Statutory		11/01/2010

Timetable:

Action	Date	FR Cite
NPRM	07/23/2010	75 FR 43236
NPRM Comment Period End	09/14/2010	
Final Action	11/17/2010	75 FR 70371
Final Action Effective	01/01/2011	

Regulatory Flexibility Analysis Required: No Government Levels Affected: No

Federalism: No

Energy Affected: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP89

View Related Documents

Title: Prospective Payment System for Inpatient Rehabilitation Facilities for FY 2011 (CMS-1344-N)

Abstract: This notice updates rates for the prospective payment system for inpatient rehabilitation facilities. These changes are applicable to services furnished on or after October 1st.

Priority: Economically Significant
Agenda Stage of Rulemaking: Completed Action
Major: Yes
Unfunded Mandates: No
CFR Citation: 42 CFR 412 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: Social Security Act, sec 1886(j); PL 106-554; PL 106-113
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		08/01/2010

Timetable:

Action	Date	FR Cite
Notice	07/22/2010	75 FR 42836

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: Business
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP90

View Related Documents

Title: Qualifying Individual (QI) Allotments (CMS-2309-N)

Abstract: This notice provides the States' final allotments available to pay the Medicare Part B premiums for Qualifying Individuals (QIs) for the Federal fiscal year (FY) 2009 and the preliminary QI allotments for FY 2010. The amounts of these QI allotments were determined in accordance with the methodology set forth in existing regulations and reflect funding for the QI program made available under recent legislation.

Priority: Other Significant
Agenda Stage of Rulemaking: Completed Action
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 433 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 110-275; PL 110-379; PL 111-5
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Final Action	04/23/2010	75 FR 21329

Regulatory Flexibility Analysis Required: No
Government Levels Affected: State

Federalism: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AQ03

View Related Documents

Title: Hospital IPPS for Acute Care Hospitals and Fiscal Year 2010 Rates and to the Long-Term Care Hospital PPS and Rate Year 2010 Rates (CMS-1406-N)

Abstract: This notice contains the final wage indices, hospital reclassifications, payment rates, impacts, and other related tables effective for the fiscal year (FY) 2010 hospital inpatient prospective payment systems (IPPS) and rate year 2010 long-term care hospital (LTCH) prospective payment system (PPS) . The rates, tables, and impacts included in this notice reflect changes required or resulting from the implementation of several provisions of the Patient Protection and Affordable Care Act as amended by the Health Care and Education Reconciliation Act of 2010. These provisions require the extension of the expiration date for certain geographic reclassifications and special exception wage indices through September 30, 2010, and certain market basket updates for the IPPS and LTCH PPS effective April 1, 2010.

Priority: Economically Significant Agenda Stage of Rulemaking: Completed Action
Major: Yes Unfunded Mandates: No
CFR Citation: 42 CFR 412 and 413; 42 CFR 415; 42 CFR 485 and 489 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 111 148; PL 111-152
Legal Deadline: The Patient Protection and Affordable Care Act as amended by the Health Care and Education Reconciliation Act of 2010 makes these provisions effective by April 1, 2010.

Action	Source	Description	Date
Other	Statutory		04/01/2010

Timetable:

Action	Date	FR Cite
Final Action	06/02/2010	75 FR 31118

Regulatory Flexibility Analysis Required: Business Government Levels Affected: Federal
Federalism: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AQ04

View Related Documents

Title: Medicare Coverage Gap Discount Program Model Manufacturer Agreement (CMS-4151-NC)

Abstract: This notice with comment period provides a model agreement for use by the Secretary and manufacturers under the Medicare Coverage Gap Discount Program (Discount Program) established by the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act. Under the agreement, manufacturers must provide applicable discounts to applicable Medicare beneficiaries for applicable covered Part D drugs while in the coverage gap beginning in 2011.

Priority: Other Significant Agenda Stage of Rulemaking: Completed Action

Major: No Unfunded Mandates: No
CFR Citation: 42 CFR 423 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 111-148; PL 111-152
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		01/01/2011

Timetable:

Action	Date	FR Cite
Final Action	05/26/2010	75 FR 29555

Regulatory Flexibility Analysis Required: No Government Levels Affected: No
Federalism: No
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AQ06

View Related Documents

Title: Proposed Changes to the Hospital and Critical Access Hospital Conditions of Participation to Ensure Visitation Rights for All Patients (CMS-3228-F)
Abstract: This rule revises the Medicare conditions of participation for hospitals and critical access hospitals to ensure the protection of visitation rights for all patients.

Priority: Other Significant Agenda Stage of Rulemaking: Completed Action
Major: No Unfunded Mandates: No
CFR Citation: 42 CFR 482 and 485 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 1302 and 1395(hh)
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	06/28/2010	75 FR 36610
NPRM Comment Period End	08/27/2010	
Final Rule	11/19/2010	75 FR 70831
Final Rule Effective	01/18/2011	

Regulatory Flexibility Analysis Required: No Government Levels Affected: No
Small Entities Affected: Business Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AQ07

View Related Documents

Title: Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act

Abstract: This document contains interim final regulations implementing the rules for group health plans and health insurance coverage in the group and individual markets under provisions of the Patient Protection and Affordable Care Act regarding preventive health services.

Priority: Economically Significant
Agenda Stage of Rulemaking: Completed Action
Major: Yes
Unfunded Mandates: No
CFR Citation: 45 CFR 147 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 111-148
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Interim Final Rule	07/19/2010	75 FR 41726

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Related Agencies: Common : DHS

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS)
RIN: 0938-AQ08

View Related Documents

Title: Medicare Program; Changes to the Hospital Outpatient Prospective Payment System for CY 2010, Changes to the Ambulatory Surgical Center Payment System for CY 2010, and Extension of Payment Under Part B

Abstract: This Notice contains the final wage indices, hospital reclassifications, payment rates, impacts and addenda for payments made under the Medicare hospital outpatient payment system (OPPS) for CY 2010. This Notice also contains the payment rates and addenda for payments made under the Medicare Ambulatory Surgical Center (ASC) payment system for CY 2010.

Priority: Economically Significant
Agenda Stage of Rulemaking: Completed Action
Major: Yes
Unfunded Mandates: No
CFR Citation: None (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 111-148
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Final Action	06/02/2010	75 FR 31118

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AQ18

View Related Documents

Title: Establishment of Special Payment Rules, Provisions and Standards for Providers and Suppliers of Prosthetics and Certain Custom Fabricated Orthotics (CMS-6012-P)

Abstract: This proposed rule would specify the qualification standards and the type of prosthetic and orthotic devices billable to the Medicare program. It also proposes the accreditation deadline for the entities billing orthotics and prosthetics and identifies the DMEPOS product categories exempt from accreditation requirements.

Priority: Other Significant
Agenda Stage of Rulemaking: Completed Action
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 424 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 1302 and 1395 hh
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Merged With RIN 0938-AP01	11/23/2010	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: Undetermined
Small Entities Affected: Business
Federalism: No
Energy Affected: No

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Department of Health and Human Services (HHS)
Office of Public Health and Science (OPHS) RIN: 0940-AA01

View Related Documents

Title: Public Health Service Standards for the Protection of Research Misconduct Whistleblowers

Abstract: To implement section 493(e) of the Public Health Service Act (added by sec. 163 of the National Institutes of Health Revitalization Act of 1993, Pub. L. 103-43), the Department is proposing to add a new part 94 to title 42 of the Code of Federal Regulations. Under this proposed regulation, covered institutions must follow certain requirements for preventing and responding to occurrences of retaliation against whistleblowers. The purpose of this part is to protect: 1) Persons who make a good faith allegation that a covered institution or member thereof engaged in, or failed to respond adequately, to an allegation of research misconduct; and 2) persons who cooperate in good faith with an investigation of research misconduct.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 94 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 216 and 289b; 42 USC 241
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Final Action	00/00/0000	
NPRM	11/28/2000	65 FR 70830
NPRM Comment Period End	01/29/2001	

Regulatory Flexibility Analysis Required: No
Small Entities Affected: No
Related RINs: Related to 0940-AA04
Government Levels Affected: No
Federalism: No

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Department of Health and Human Services (HHS)
Office of Consumer Information and Insurance Oversight (OCIIO) RIN: 0950-AA02

View Related Documents

Title: Requirements To Implement American Health Benefit Exchanges and Other Provisions of the Affordable Care Act

Abstract: The Affordable Care Act requires the establishment of health insurance exchanges –new, competitive, consumer-centered health insurance marketplaces – that will put greater control and greater choice in the hands of individuals and small businesses. The exchanges will make purchasing health insurance easier by providing eligible consumers and businesses with “one-stop-shopping” where they can compare and purchase health insurance coverage. The Affordable Care Act authorized grants to the states to help them design and establish exchanges in time for millions of Americans to choose their coverage for 2014. This proposed rule would establish the requirements for exchanges.

Priority: Economically Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: Yes
Unfunded Mandates: Undetermined
CFR Citation: 45 CFR 155 to 157 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: Affordable Care Act; secs 1301 to 1343; secs 1401 to 1413
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	03/00/2011	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: Undetermined
Federalism: Undetermined
Energy Affected: No

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Department of Health and Human Services (HHS)
Office of Consumer Information and Insurance Oversight (OCIIO) RIN: 0950-AA04

View Related Documents

Title: Public Use Files of Health Plan Data

Abstract: The Affordable Care Act requires generating public use files on data that HHS collects from health plans, and includes specific data and their application (or not) to the Trade Secrets Act. This rule would clarify statutory requirements under the Affordable Care Act.

Priority: Economically Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: Undetermined
Unfunded Mandates: Undetermined
CFR Citation: 45 CFR 159 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: PL 111-148
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	09/00/2011	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: Undetermined
Federalism: Undetermined
Energy Affected: No

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Department of Health and Human Services (HHS)
Office of Consumer Information and Insurance Oversight (OCIIO) RIN: 0950-AA07

View Related Documents

Title: Transparency Reporting

Abstract: The Affordable Care Act requires group health plans and health insurance issuers to submit specific information to the Secretary, the State insurance commissioner, and to make the information available to the public. This includes information on claims payment policies, the number of claims denied, data on rating practices and other information as determined by the Secretary. The provision also requires plans and issuers to provide to individuals upon request the amount of cost sharing that the individual would be responsible for paying for a specific item or service provided by a participating provider. This interim final rule would implement information disclosure provisions in section 2715A of the Public Health Service Act, as added by the Affordable Care Act.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: Undetermined
Unfunded Mandates: Undetermined
CFR Citation: 45 CFR 153, Insurance Rules (sec 2715A) (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 111-148, title I, subtitle A, sec 1001 PHS Act, sec 2715A
Legal Deadline: None

Regulatory Plan:

Statement of Need: The Department of Health and Human Services, along with the Department of Labor and the Treasury Department, will issue interim final rules to implement the information disclosure provisions in section 2715A of the Public Health Service Act, as added by the Affordable Care Act. This regulation will improve the transparency of information about how health coverage works so consumers will have better information to use and assess the coverage they have now, and/or make choices among different coverage options.

Legal Basis: Title I, subtitle A, section 1001 of the Affordable Care Act adds section 2715A to the Public Health Service Act that will require group health plans and health insurance issuers to make certain disclosures to the Secretary, the State insurance commissioner, the public, and in some cases, individuals.

Alternatives: None--statutory requirement.

Costs and Benefits: HHS estimates the benefits of this regulation to come from improved information for consumers and regulators, which will in tern result in a more efficient insurance market. Improved information for consumers will allow them to make better health insurance choices -- to choose higher quality insurers and ones that more closely match their preferences with respect to plan design. This could result in increased satisfaction and decreased morbidity. In addition, consumers may be more likely to choose insurers with more efficient processes, which could result in a reduction in administrative costs. Improved information for regulators will allow for monitoring of the markets to track current industry practices, which will allow for better enforcement of current market regulations through more targeted audits that are based upon insurer responses. Additionally, reporting requirements and the threat of targeted audit will likely influence issuer behavior to motivate compliance. I is not possible to quantify the benefits at this time. The direct costs imposed by the regulation are reporting requirements. These

requirements are still being developed, and will be quantified in the regulation.

Risks:

Timetable:

Action	Date	FR Cite
NPRM	03/00/2011	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

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Department of Health and Human Services (HHS)
Office of Consumer Information and Insurance Oversight (OCIIO) RIN: 0950-AA10

View Related Documents

Title: Affordable Care Act Waiver for State Innovation; Review and Approval Process

Abstract: The Affordable Care Act requires that the Secretary issue regulations regarding the Waiver for State Innovation. This regulation provides a process for public notice and comment at the State level, including public hearings, sufficient to ensure a meaningful level of public input; a process for the submission of an application that ensures the disclosure of the provisions of law that the state involved seeks to waive and the specific plans of the State to ensure that the waiver will be in compliance with subsection (b) of section 1332 of the Affordable Care Act; a process for providing public notice and comment after the application is received by the Secretary, that is sufficient to ensure a meaningful level of public input and that does not impose requirements that are in addition to, or duplicative of, requirements imposed under the Administrative Procedures Act, or requirements that are unreasonable or unnecessarily burdensome with respect to state compliance; a process for the submission to the Secretary of periodic reports by the state concerning the implementation of the program under the waiver; and a process for the periodic evaluation by the Secretary of the program under the waiver.

Priority: Other Significant

Agenda Stage of Rulemaking: Proposed Rule

Major: Yes

Unfunded Mandates: No

CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: PL 111-148

Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	12/00/2010	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: State

Federalism: No

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Department of Health and Human Services (HHS)
Office of Consumer Information and Insurance Oversight (OCIIO) RIN: 0950-AA03

View Related Documents

Title: Rate Review

Abstract: The Affordable Care Act requires the Secretary to work with states to establish an annual review of unreasonable rate increases, to monitor premium increases and to award grants to states to carry out their rate review process. This interim final rule would implement the rate review process.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: Yes
Unfunded Mandates: Undetermined
CFR Citation: 45 CFR 154 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 111-148
Legal Deadline: None

Regulatory Plan:

Statement of Need: The Affordable Care Act requires standards to be set for the review of rate increases. The proposed rule will detail standards for when and how health insurance issuers will be required to report rate increases, as well as detail the relevant data and documentation that must be submitted in support of the rate increases. The proposed rule will detail criteria for how determinations of unreasonableness will be made by HHS, and also sets forth the conditions under which HHS will adopt unreasonableness determinations made by States. This regulation is part of the health insurance market reform and will increase affordability of health insurance for all Americans.

Legal Basis: The Affordable Care Act.

Alternatives: There are no alternatives, as this rulemaking is a matter of law based on the Affordable Care Act.

Costs and Benefits: HHS expects that costs associated with this rulemaking will be minimal as insurers routinely report to States on rate increases. Insurers may experience slight additional costs in connection with completion of policy rate data collection forms and any necessary submission of justification forms for rates that trigger unreasonable designations. The benefits of these requirements include increased consumer protections around unsubstantiated premium rate increases, reduced health insurance rate increases, increased transparency and consumer confidence in the products they buy, and ensuring financially solvent companies that can pay promised benefits.

Risks:

Timetable:

Action	Date	FR Cite
Interim Final Rule	07/03/2010	75 FR 45014
Interim Final Rule Comment Period End	09/28/2010	
Final Action	12/00/2010	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: Undetermined
Federalism: Undetermined
Energy Affected: No

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Department of Health and Human Services (HHS)
Office of Consumer Information and Insurance Oversight (OCIIO) RIN: 0950-AA06

View Related Documents

Title: Medical Loss Ratios

Abstract: The Affordable Care Act requires health insurance issuers offering individual or group coverage to submit annual reports to the Secretary on the percentages of premiums that the coverage spends on reimbursement for clinical services and activities that improve health care quality, and to provide rebates to enrollees if this spending does not meet minimum standards for a given plan year. This interim final rule would implement the definition and methodology associated with the calculation of the Medical Loss Ratio (MLR) provisions of the Affordable Care Act and the calculation of the rebate to consumers for plans that

do not satisfy the MLR.

Priority: Economically Significant
Agenda Stage of Rulemaking: Final Rule
Major: Yes
Unfunded Mandates: No
CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 111-148
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		12/00/2011

Timetable:

Action	Date	FR Cite
Interim Final Rule	12/01/2010	75 FR 74864
Interim Final Rule Comment Period End	01/31/2011	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: State
Federalism: Yes
Energy Affected: No
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Department of Health and Human Services (HHS)
Office of Consumer Information and Insurance Oversight (OCIIO) RIN: 0950-AA08

View Related Documents

Title: Uniform Explanation of Benefits, Coverage Facts, and Standardized Definitions

Abstract: The Affordable Care Act requires the Secretary to develop standards for use by group health plans and health insurance issuers in compiling and providing a summary of benefits and coverage explanation that accurately describes benefits and coverage. The Secretary must also set standards for the definitions of terms used in health insurance coverage, including specific terms set out in the statute. Plans and issuers must provide information according to these standards no later than 24 months after enactment. This interim final rule would implement the information disclosure provisions in section 2715 of PHSA , as added by the Affordable Care Act.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: Undetermined
Unfunded Mandates: Undetermined
CFR Citation: 45 CFR 153, Insurance Rules (sec 2715) (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 111-148, title I, subtitle A, sec 1001 (Public Health Service Act, sec 2715)
Legal Deadline: None

Regulatory Plan:

Statement of Need: The Department of Health and Human Services, along with the Departments of Labor and the Treasury, will issue interim final rules to implement the information disclosure provisions in section 2715 of PHSA, as added by the Affordable Care Act. This regulation will provide consumers with a simplified and uniform overview of their benefits, specific "Coverage Facts" or scenarios for the costs of coverage for specific episodes of care, and standardized consumer-friendly health coverage definitions. This will allow consumers to better understand the coverage that they have and allow consumers choosing coverage to better compare coverage options.

Legal Basis: Title I, subtitle A, section 1001, of the Affordable Care Act adds section 2715 to the Public Health Service Act that will require group health plans and health insurance issuers to provide a summary of benefits and coverage explanations and standardized definitions to applicants, enrollees, and policyholders.

Alternatives: None--statutory requirement.

Costs and Benefits: HHS estimates the benefits of this regulation to come from improved information for consumers and regulators, which will in turn result in a more efficient insurance market. Improved information for consumers will allow them to make better health insurance choices--to chose higher quality insurers and ones that more closely match their preference with respect to plan design. This could result in increased satisfaction and decreased morbidity. It is not possible to quantify the benefits at this time. The direct costs imposed by the regulation are the creation and provision of summary documents to consumers at the time of application, prior to enrollment and at re-enrollment. There will also be costs imposed by the creation of the coverage facts label section of the summary documents. These requirements are still being developed and will be quantified in the regulation.

Risks:

Timetable:

Action	Date	FR Cite
Interim Final Rule	03/00/2011	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

Energy Affected: Undetermined

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Department of Health and Human Services (HHS)
Office of Consumer Information and Insurance Oversight (OCIIO) RIN: 0950-AA11

View Related Documents

Title: Health Care Reform Insurance Web Portal Requirements

Abstract: The Affordable Care Act requires the establishment of an Internet website through which individuals can obtain information about the insurance coverage options that may be available to them in their State. This final rule would further clarify statutory requirements.

Priority: Other Significant

Agenda Stage of Rulemaking: Final Rule

Major: Undetermined

Unfunded Mandates: Undetermined

CFR Citation: 45 CFR 151 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: PL 111-148

Legal Deadline: None

Timetable:

Action	Date	FR Cite
Interim Final Rule	05/05/2010	75 FR 24470
Interim Final Rule Effective	05/10/2010	
Final Action	12/00/2010	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

Energy Affected: Undetermined

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Department of Health and Human Services (HHS)
Office of Consumer Information and Insurance Oversight (OCIIO) RIN: 0950-AA00

View Related Documents

Title: Preexisting Condition Exclusions, Lifetime and Annual Limits, Prohibition on Discrimination and Patient Protections

Abstract: The Affordable Care Act implements a new Patient's Bill of Rights, which will help children (and eventually all Americans) with pre-existing conditions gain coverage and keep it; protect all Americans' choice of doctors; and end lifetime limits on the care consumers may receive. This rule would finalize the requirements and respond to any comments resulting from the interim final rule.

Priority: Economically Significant
Agenda Stage of Rulemaking: Long-term Action
Major: Yes
Unfunded Mandates: No
CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 111-148
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Final Action	00/00/0000	
Interim Final Rule	06/28/2010	75 FR 37188
Interim Final Rule Comment Period End	08/27/2010	
Interim Final Rule Effective	08/27/2010	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: Undetermined
Federalism: Undetermined
Energy Affected: Undetermined
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Department of Health and Human Services (HHS)
Office of Consumer Information and Insurance Oversight (OCIIO) RIN: 0950-AA01

View Related Documents

Title: Internal Claims, Appeals, and External Review Processes Under the Affordable Care Act

Abstract: The Affordable Care Act provides consumers with the right to appeal decisions made by their health carrier to an outside, independent decisionmaker, regardless of the State of residence or type of health insurance. Under interim final regulations issued earlier this year, non-grandfathered plans and issuers must comply with a State external review process or the Federal external review process. This rule would finalize the regulations and provide an opportunity to respond to public comments.

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: Undetermined
Unfunded Mandates: No
CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 111-148
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Final Action	00/00/0000	
Interim Final Rule	07/23/2010	75 FR 43330
Interim Final Rule Effective	09/21/2010	
Interim Final Rule Comment Period End	09/21/2010	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: Undetermined
Federalism: Undetermined
Energy Affected: Undetermined
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Department of Health and Human Services (HHS)
Office of Consumer Information and Insurance Oversight (OCIIO) RIN: 0950-AA05

View Related Documents

Title: Pre-Existing Condition Insurance Plan

Abstract: The Affordable Care Act establishes a "temporary high risk health insurance pool program" to provide health insurance coverage to currently uninsured individuals with pre-existing conditions. The new Pre-Existing Condition Insurance Plan is a transitional program to make health coverage available to those who have a pre-existing condition and who have gone without coverage for at least six months.

Priority: Economically Significant
Agenda Stage of Rulemaking: Long-term Action
Major: Yes
Unfunded Mandates: No
CFR Citation: 45 CFR 152 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 111-148
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Final Action	00/00/0000	
Interim Final Rule	07/30/2010	75 FR 45014
Interim Final Rule Comment Period End	09/28/2010	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Office of Consumer Information and Insurance Oversight (OCIIO) RIN: 0950-AA09

View Related Documents

Title: Preventive Services Under the Affordable Care Act

Abstract: The Affordable Care Act requires that a group health plan and a health insurance issuer offering group or individual health insurance coverage provide benefits for and prohibit the imposition of cost-sharing requirements with respect to certain recommended evidence-based items or services. This rule would finalize the requirements and responds to any comments as the result of the interim final rule implementing this provision.

Priority: Economically Significant
Agenda Stage of Rulemaking: Long-term Action

Major: Yes Unfunded Mandates: No
CFR Citation: 45 CFR 156 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 111-148
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Final Action	00/00/0000	
Interim Final Rule	07/19/2010	75 FR 41726
Interim Final Rule Comment Period End	09/17/2010	
Interim Final Rule Effective	09/17/2010	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: Undetermined
Federalism: Undetermined
Energy Affected: Undetermined
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Department of Health and Human Services (HHS)
Office of Consumer Information and Insurance Oversight (OCIIO) RIN: 0950-AA12

View Related Documents

Title: Early Retiree Reinsurance Program
Abstract: The Affordable Care Act provides $5 billion in financial assistance to employers, unions and state and local governments to help them maintain coverage for early retirees age 55 and older who are not yet eligible for Medicare.

Priority: Economically Significant Agenda Stage of Rulemaking: Long-term Action
Major: Yes Unfunded Mandates: No
CFR Citation: 45 CFR 152 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 111-148
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Final Action	00/00/0000	
Interim Final Rule	05/05/2010	75 FR 24450
Interim Final Rule Comment Period End	06/04/2010	
Interim Final Rule Effective	09/01/2010	

Regulatory Flexibility Analysis Required: No Government Levels Affected: No
Federalism: No
Energy Affected: Undetermined
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Department of Health and Human Services (HHS)
Office of Consumer Information and Insurance Oversight (OCIIO) RIN: 0950-AA14

View Related Documents

Title: Dependent Coverage of Children to Age 26 Under the Patient Protection and Affordable Care Act

Abstract: The Affordable Care Act requires all plans in the individual market and new employer plans that offer dependent coverage to make the coverage available until the adult child reaches the age of 26. This rule would finalize the requirements for group health plans and health insurance coverage in the group and individual markets and respond to any comments as the result of the interim final rule implementing this provision.

Priority: Economically Significant
Agenda Stage of Rulemaking: Long-term Action
Major: Yes
Unfunded Mandates: No
CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 111-148
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Final Action	00/00/0000	
Interim Final Rule	05/13/2010	75 FR 27122
Interim Final Rule Effective	07/12/2010	
Interim Final Rule Comment Period End	08/11/2010	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: Undetermined
Federalism: Undetermined
Energy Affected: No

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Department of Health and Human Services (HHS)
Office of Consumer Information and Insurance Oversight (OCIIO) RIN: 0950-AA17

View Related Documents

Title: Status as a Grandfathered Health Plan Under the Affordable Care Act

Abstract: The Affordable Care Act protects the ability of individuals and businesses to keep their current plan while providing important consumer protections. The new regulation also provides stability and flexibility to insurers and businesses that offer health insurance coverage as the nation transitions to a more competitive marketplace. In 2014, businesses and consumers will have more affordable choices through exchanges. This rule would finalize the requirements for group health plans and health insurance coverage in the group and individual markets and respond to any comments as the result of the interim final rule implementing this provision.

Priority: Economically Significant
Agenda Stage of Rulemaking: Long-term Action
Major: Yes
Unfunded Mandates: Undetermined
CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 111-148
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Final Action	00/00/0000	
Interim Final Rule	06/17/2010	75 FR 34538
Interim Final Rule Effective	07/12/2010	
Interim Final Rule Comment Period End	08/16/2010	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: Undetermined

Federalism: Undetermined
Energy Affected: Undetermined
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Department of Health and Human Services (HHS)
Administration for Children and Families (ACF) RIN: 0970-AC36

View Related Documents

Title: Revised Head Start Performance Standards, Target Population, and Slot Conversion
Abstract: This proposed rule would modify Head Start program performance standards as necessary to reflect changes enacted in the Head Start for School Readiness Act of 2007. Changes could affect performance standards related to health, parental involvement, nutritional and social services, transitional and other services, education performance standards and measures, and standards related to family service workers, home visitors, and the condition and location of facilities. As required by statute, regulations will be drafted following consultations with experts and consideration of the National Academy of Sciences study on Developmental Outcomes and Assessments for Young Children. The proposed rule also will address provisions: (1) Allowing grantees to request conversion of Head Start slots to serve additional infant and toddler age children; (2) addressing children with disabilities; and (3) removing barriers to serving homeless children.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 9801 et seq
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	04/00/2011	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Administration for Children and Families (ACF) RIN: 0970-AC39

View Related Documents

Title: Interim Assistance for Trafficking Victims Under the Trafficking Victims Reauthorization Act of 2008
Abstract: The William Wilberforce Trafficking Victims Protection Reauthorization Act of 2008 (the Act), Public Law 110-457, revised and reauthorized the Trafficking Victims Protection Program. This rule would implement changes to the program that authorize interim assistance to child victims under section 212(a) of the Act.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 45 CFR 404 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 22 USC 7101 note, William Wilberfore Trafficking Victims Protection Reauthorization Act of 2008

Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	02/00/2011	

Regulatory Flexibility Analysis Required: No
Small Entities Affected: Governmental Jurisdictions; Organizations
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Government Levels Affected: Local; State
Federalism: No

Department of Health and Human Services (HHS)
Administration for Children and Families (ACF) RIN: 0970-AC42

View Related Documents

Title: Implementation of the Unaccompanied Alien Children (UAC) Provisions of the Trafficking Victims Reauthorization Act of 2008

Abstract: The William Wilberforce Trafficking Victims Protection Reauthorization Act of 2008 (the Act), Public Law 110-457, made significant changes concerning the care and placement of unaccompanied alien children while they are in the care of the Office of Refugee Resettlement (ORR). This rule would implement changes to the program under section 235 of the Act addressing issues like age determinations, placement determinations, suitability assessments, and home studies. This rule also will address provisions of the Flores settlement agreement that were not addressed in Public Law 110-457.

Priority: Other Significant
Major: No
Agenda Stage of Rulemaking: Proposed Rule
Unfunded Mandates: No
CFR Citation: 45 CFR 410 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 22 USC 7101 note, William Wilberforce Trafficking Victims Protection Reauthorization Act of 2008
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	06/00/2011	

Regulatory Flexibility Analysis Required: No
Small Entities Affected: No
Energy Affected: No
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Government Levels Affected: Federal
Federalism: No

Department of Health and Human Services (HHS)
Administration for Children and Families (ACF) RIN: 0970-AC43

View Related Documents

Title: Performance Standards for Runaway and Homeless Youth Grantees

Abstract: This rule would implement section VIII of the Reconnecting Homeless Youth Act of 2008, requiring the Secretary of Health and Human Services to issue rules that specify performance standards for public and nonprofit private entities that receive grants under the Runaway and Homeless Youth Program.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 45 CFR 1351 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: Reconnecting Homeless Youth Act, PL 110-378
Legal Deadline:

Action	Source	Description	Date
Other	Statutory	Statutory.	10/08/2009

Timetable:

Action	Date	FR Cite
NPRM	03/00/2011	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: Local; State; Tribal
Small Entities Affected: Organizations
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Administration for Children and Families (ACF)
RIN: 0970-AC44

View Related Documents

Title: Designation Renewal of Head Start Grantees

Abstract: This rule would implement provisions of the Improving Head Start for School Readiness Act of 2007 (Pub. L. 110-134), requiring the Secretary to develop a system that will evaluate each grantee's performance every 5 years to determine which grantees are providing services of such high quality that they should be given another 5-year grant without needing to recompete for the grant.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: Improving Head Start for School Readiness Act of 2007, PL 110-134
Legal Deadline: None

Regulatory Plan:

Statement of Need: The Administration for Children and Families will issue rules to amend 45 CFR chapter XIII by adding a new part 1307, Policies and Procedures for Designation Renewal of Head Start and Early Head Start Grantees, in order to respond to the statutory requirements of The Improving Head Start for School Readiness Act of 2007, which establishes that Head Start grantees will be awarded grants for a 5-year period and only grantees delivering high quality services will be given another 5-year grant non-competitively. These regulations will describe the proposed system for designation renewal, including a proposal to transition all current continuous grants into 5-year grants over a 3-year period. These regulations will encourage excellence, establish accountability for poor performance, and open up Head Start to new energetic organizations that may have great capacity to run high quality programs.

Legal Basis: Section 641 of the Head Start Act requires the Secretary of HHS to develop and implement a system for designation renewal (e.g., Designation Renewal System (DRS)) to determine if a Head Start agency is delivering a high-quality and comprehensive Head Start program that meets the educational, health, nutritional, and social needs of the children and families it serves and publish a notice in the Federal Register describing a proposed system for designation renewal, including a proposal for the transition to such system.

Alternatives: The Administration for Children and Families is statutorily mandated to develop and implement a system for designation renewal. As a precursor to developing the system, the Head Start Act required the Secretary to establish an

Advisory Committee to inform the development of a DRS and make recommendations to the Secretary. We are proposing to adopt the majority of the Advisory Committee's recommendations in whole or with minor modifications. In addition, we are considering additional and alternative criteria to be incorporated into the system for designation renewal, and ask for public comments regarding numerous provisions of the rule, as described in the preamble.

Costs and Benefits: The Agency estimates the costs of implementing the new reporting requirements described in the rule will be approximately $20,000 annually. In addition, at least 25 percent of grantees reviewed in a year will be required to submit a competitive application for a new 5-year grant, at an estimated cost of less than $1,500 for each grantee. In terms of benefits, the proposed system will fund only high-performing grantees in order to ensure the best services for Head Start children are provided and child outcomes are improved.

Risks:

Timetable:

Action	Date	FR Cite
NPRM	09/22/2010	75 FR 57704
NPRM Comment Period End	12/21/2010	
Final Action	09/00/2011	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No

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Department of Health and Human Services (HHS)
Administration for Children and Families (ACF) RIN: 0970-AC47

View Related Documents

Title: Adoption and Foster Care Analysis and Reporting System (AFCARS)

Abstract: This rule will amend the AFCARS regulations at 45 CFR part 1355.40 and the appendices to part 1355 to modify the requirements for States and Tribes to collect and report data to ACF on children in foster care and in subsidized adoption or guardianship arrangements with the State or Tribe. The rule also implements the AFCARS penalty requirements of the Adoption Promotion Act of 2003 (Pub. L. 108-145).

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 620 et seq; 42 USC 670 et seq; 42 USC 1302
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	06/00/2011	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: State; Tribal
Small Entities Affected: No
Federalism: No
Energy Affected: No

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Department of Health and Human Services (HHS)
Administration for Children and Families (ACF) RIN: 0970-AC48

View Related Documents

Title: Strengthen Medical Support in the Child Support Program

Abstract: Limited revisions will be made to medical support regulations to improve interoperability between Child Support and Medicaid and CHIP to be consistent with the CHIP Reauthorization Act of 2009, and the Secretary's public goal of enrolling all eligible uninsured children in Medicaid and CHIP by 2014.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 45 CFR 302 and 303; 45 CFR 308 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: Secs 452(f) and 466(a)(19) of the Social Security Act (Act); sec 1102 of the Act
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	09/00/2011	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: Federal; Local; State
Small Entities Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Administration for Children and Families (ACF) RIN: 0970-AC49

View Related Documents

Title: Improving Payment Processing in the Child Support Enforcement Program

Abstract: This proposed rule aims to address several significant barriers to effective payment processing experienced by employers, States and families. The Notice of Proposed Rulemaking (NPRM) will propose changes regarding the income withholding documentation; direction of income withholding payments from employers; state processing of all income withholding payments, including payments on non-IV-D orders, through the SDU; and SDU disbursement of payments.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 45 CFR 466(a) and 466(b) (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: secs 454A and 454B of the Act; sec 1102 of the Act
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	09/00/2011	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: Federal; Local; State
Small Entities Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Administration for Children and Families (ACF) RIN: 0970-AC50

View Related Documents

Title: Case Closure Improvements for State IV-D Programs

Abstract: The basic premise for development of the original case closure criteria was to establish clear and concise standards which precluded premature or inappropriate closing of cases, and to identify specific areas where case closure is permitted. As the child support program has evolved and the case types have changed, we have been asked by states to reevaluate case closure criteria in an effort to be responsive to administrative concerns for maintaining caseloads that may not be viable. This regulation will propose new case closure criteria to help states with case closure processes, while ensuring that all viable cases remain open.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 45 CFR 303.11 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: sec 1102 of the Act
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	09/00/2011	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: Federal; Local; State
Small Entities Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Administration for Children and Families (ACF) RIN: 0970-AC51

View Related Documents

Title: Case Closure Improvements for Tribal IV-D Programs

Abstract: When the tribal program regulation was published in 2004 it did not contain case closure criteria. The growth of the tribal IV-D program and the intergovernmental nature of the casework has made case closure criteria necessary. After appropriate tribal consultation, OCSE will propose case closure criteria for tribal IV-D cases. Once final, this regulation will help tribes with case closure processes, while ensuring that all viable cases remain open.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 45 CFR 309 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: sec 1102 of the Act, sec 455(f) of the Act
Legal Deadline: None

Timetable:

Action	Date	FR Cite

NPRM	09/00/2011	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: Federal; State; Tribal
Small Entities Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Administration for Children and Families (ACF)
RIN: 0970-AC33

View Related Documents

Title: Advance Planning Document Reform

Abstract: This rule updates existing regulations at 45 CFR 95 to make conforming changes reflecting transfer of HHS grant authority from 45 CFR 74 to part 92; to make technical updates to accurately reflect current terminology such as HCFA to CMS; and to make revisions designed to reduce the amount of Federal oversight and monitoring based on risk.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 45 CFR 95 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 5 USC 301, 42 USC 622(b); 42 USC 629(b); 42 USC 629b(a), 42 USC 652(a), 42 USC 654(a), 42 USC 671(a), 42 USC 1302, 42 USC 1396(a)
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	03/07/2008	73 FR 12341
NPRM Comment Period End	05/06/2008	
Final Action	12/00/2010	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: State
Small Entities Affected: No
Federalism: No
Energy Affected: No
RIN Information URL: regulations.acf.hhs.gov
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Department of Health and Human Services (HHS)
Administration for Children and Families (ACF)
RIN: 0970-AC41

View Related Documents

Title: Tribal Child Welfare

Abstract: This rule would implement title III, Tribal Foster Care and Adoption Access, of the Fostering Connections to Success and Increasing Adoptions Act of 2008 (the Act). Under section 301 of that Act, the Secretary is required to promulgate interim final regulations to carry out the title III provisions, including providing for transfer of responsibility for the placement and care of a child under a State plan approved under section 471 of the Social Security Act to a tribal plan. This rule also will

address in-kind expenditures from third-party sources for purposes of determining the non-Federal share of administrative and training expenditures as required in section 301 of the Act.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 45 CFR 1355 and 1356 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: Fostering Connections to Success and Increasing Adoptions Act of 2008
Legal Deadline:

Action	Source	Description	Date
Other	Statutory	Statutory.	10/09/2009

Timetable:

Action	Date	FR Cite
Interim Final Rule	03/00/2011	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: State; Tribal
Small Entities Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Administration for Children and Families (ACF)
RIN: 0970-AC45

View Related Documents

Title: Safeguarding Child Support Information
Abstract: This rule would modify provisions of the final rule published September 26, 2008 (73 FR 56422), to address legislation enacted subsequent to publication and other matters.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 45 CFR 302 and 303; 45 CFR 307 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 1302
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	06/07/2010	75 FR 32145
NPRM Comment Period End	08/06/2010	
Final Action	12/00/2010	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Administration for Children and Families (ACF) RIN: 0970-AC46

View Related Documents

Title: Head Start Eligibility Determinations

Abstract: This interim final regulation amends Head Start Program regulations to clarify and strengthen procedures to determine eligibility for Head Start program enrollment, including procedures to document and verify such eligibility. The intent of this rule is to reduce the risk of provision of Head Start services to persons who are not eligible for those services.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 9801 et seq
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Interim Final Rule	12/00/2010	
Interim Final Rule Comment Period End	02/00/2011	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No

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Department of Health and Human Services (HHS)
Administration for Children and Families (ACF) RIN: 0970-AC37

View Related Documents

Title: Intergovernmental Child Support Enforcement

Abstract: This regulation would revise Federal requirements for establishing and enforcing intergovernmental support obligations in child support enforcement program cases receiving services under title IV-D of the Social Security Act (the Act). The changes would: revise current interstate requirements to apply to case processing in all intergovernmental cases; require the responding State IV-D agency to pay the cost of genetic testing; clarify responsibility for determining in which State tribunal a controlling order determination is made where multiple support orders exist; recognize and incorporate electronic communication advancements; and make conforming changes to the Federal substantial-compliance audit and State self-assessment requirements.

Priority: Other Significant
Agenda Stage of Rulemaking: Completed Action
Major: No
Unfunded Mandates: No
CFR Citation: 45 CFR 301 to 303; 45 CFR 305; 45 CFR 308 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 1302
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	12/08/2008	73 FR 74408
NPRM Comment Period End	02/06/2009	
Final Action	07/02/2010	75 FR 38612

Regulatory Flexibility Analysis Required: No
Government Levels Affected: Local; State; Tribal

Small Entities Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Administration for Children and Families (ACF) RIN: 0970-AC40

View Related Documents

Title: Use of TANF Funds Carried Over From Prior Year
Abstract: This rule would implement section 2103 of the American Recovery and Reinvestment Act of 2009 to provide that a State or Tribe may use reserve Temporary Assistance for Needy Families (TANF) grant funds for any benefit or service activity under the TANF program.

Priority: Other Significant
Agenda Stage of Rulemaking: Completed Action
Major: No
Unfunded Mandates: No
CFR Citation: 45 CFR 263 and 286 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: American Recovery and Reinvestment Act of 2009
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Interim Final Rule	05/27/2009	74 FR 25161
Interim Final Rule Comment Period End	07/27/2009	
Final Action	04/06/2010	75 FR 17313

Regulatory Flexibility Analysis Required: No
Government Levels Affected: Local; State; Tribal
Small Entities Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Administration on Aging (AOA) RIN: 0985-AA07

View Related Documents

Title: Community Living Assistance Services and Supports Enrollment and Eligibility Rules Under the Affordable Care Act
Abstract: The Department of Health and Human Services will issue rules to implement the Community Living Assistance Services and Supports (CLASS) program included in the Affordable Care Act. Specifically, the rules will define the enrollment and eligibility criteria for the program. Participation in the program is voluntary.

Priority: Economically Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: Yes
Unfunded Mandates: Undetermined
CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: PL 111-148, sec 8002
Legal Deadline: None

Regulatory Plan:

Statement of Need: About 14 million people spend more than $230 billion a year on long-term services and supports to assist them with daily living. Four times that many rely solely on unpaid care provided by family and friends. Medicare does not pay for long-term care, and while Medicaid is the largest public payer of these services, it is only available for people with few other resources. The CLASS program represents a significant new opportunity for all Americans to prepare themselves financially to remain as independent as possible under a variety of future health circumstances.

Legal Basis: Section 8002 of Public Law 111-148 (Affordable Care Act) requires the promulgation of regulations to implement the CLASS program. Specifically, the law states, "[t]he Secretary shall promulgate such regulations as are necessary to carry out the CLASS program in accordance with this title. Such regulations shall include provisions to prevent fraud and abuse under the program."

Alternatives: Under the law, the Secretary, in consultation with appropriate actuaries and other experts, will develop at least three actuarially sound benefit plans as alternatives for consideration for designation by the Secretary as the CLASS Independence Benefit Plan. Under the law, the Secretary will designate the final benefit plan by October 1, 2012.

Costs and Benefits: The program will help Americans prepare themselves financially to remain as independent as possible under a variety of future health circumstances and their financial independence may help reduce spending down to Medicaid. Costs to implement the proposed regulation have not yet been estimated.

Risks:

Timetable:

Action	Date	FR Cite
NPRM	09/00/2011	
Final Action	10/00/2012	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: No

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

RIN: 0991-AB03

View Related Documents

Title: Revisions to Regulations Addressing the OIG's Authority To Impose Civil Money Penalties and Assessments

Abstract: This proposed rule would revise part 1003, addressing the Office of Inspector General's authority to propose the imposition of civil money penalties and assessments by reorganizing and simplifying existing regulatory text and eliminating obsolete references contained in the current regulations. Among the proposed revisions, this rule would establish separate subparts within part 1003 for various categories of violations; clarify the availability of exclusion for certain violations in addition to civil money penalties and assessments; date various references to managed care organization authorities; and clarify the application of section 1140 of the Social Security Act with respect to the misuse of certain Departmental symbols, emblems, or names through Internet and e mail communications.

Priority: Substantive, Nonsignificant

Agenda Stage of Rulemaking: Proposed Rule

Major: No

Unfunded Mandates: No

CFR Citation: 42 CFR 1003 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: 42 USC 1320a-7a; 42 USC 1395mm; 42 USC 1395w-27; 42 USC 1396b; PL 99-660; PL 107-188

Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	04/00/2011	

NPRM Comment Period End	06/00/2011	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Office of the Secretary (OS)
RIN: 0991-AB33

View Related Documents

Title: Revisions to the Office of Inspector General's (OIG) Exclusion Authorities

Abstract: In accordance with section 949 of the Medicare Prescription Drug Improvement and Modernization Act of 2003, and section 6402 of the Affordable care Act 0f 2010, this rule would revise the OIG's exclusion authority to permit any Federal health care program to request a waiver of an OIG exclusion imposed under sections 1128(a)(1), 1128(a)(3), or 1128(a)(4) of the Social Security Act if the exclusion would impose a hardship on beneficiaries. In addition, in accordance with sections 6406 and 6408 of the Affordable Care Act, the proposed rule would revise the OIG's exclusion authority to grant testimonial subpoena authority in exclusion cases; to add a new permissive exclusion authority for making false statements or misrepreseentation of materials facts, and; to broaden the scope of certain permissive exclusion authorities. Finally, the proposed rule wouild revise current exclusion authorities in 42 CFR parts 1001, 1002, and 1005, to further clarify OIG's existing exclusion authorities.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 1001 and 1002; 42 CFR 1005 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 108-173, sec 949; PL 105-33, sec 4331; Social Security Act, sec 1128
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	04/00/2011	
NPRM Comment Period End	06/00/2011	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Office of the Secretary (OS)
RIN: 0991-AB41

View Related Documents

Title: Revisions to OIG Regulations Governing State Medicaid Fraud Control Units

Abstract: This proposed rule would revise and update part 1007, addressing the Office of Inspector General's authority regarding the requirements and procedures for establishing and operating a State Medicaid Fraud Control Unit. The current regulations were originally promulgated in 1978, and recodified in 1992.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: Undetermined
CFR Citation: 42 CFR 1007 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 1302; 42 USC 1396b(a)(6) and 1396b(b)(3); 42 US 1396b(q)
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	03/00/2011	
NPRM Comment Period End	05/00/2011	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: State
Small Entities Affected: No
Federalism: Undetermined
Energy Affected: No
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Department of Health and Human Services (HHS)
Office of the Secretary (OS)
RIN: 0991-AB59

View Related Documents

Title: Establishment of the Permanent Certification Program for Health Information Technology
Abstract: Under the authority granted to the National Coordinator for Health Information Technology (the National Coordinator) by section 3001(c)(5) of the Public Health Service Act (PHSA), the National Coordinator issued a proposed rule proposing the establishment of two certification programs for the purposes of voluntarily testing and certifying health information technology. A final rule establishing a temporary certification program was issued on June 24, 2010 (75 FR 36158). The National Coordinator intends to issue a final rule establishing a permanent certification program by the end of 2010.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 45 CFR 170 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 300jj-11
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	12/00/2010	
NPRM Comment Period End	01/00/2011	
Final Action Effective	02/00/2011	
Final Action	02/00/2011	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: Undetermined
Federalism: No
Energy Affected: Undetermined
Related RINs: Related to 0991-AB58
Related Agencies: Common: CMS
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Department of Health and Human Services (HHS)
Office of the Secretary (OS) RIN: 0991-AB61

View Related Documents

Title: Revision to Prohibition on FFP for "Data Mining" by Medicaid Fraud Control Units

Abstract: This notice proposes modifications to current regulations that prohibit State Medicaid Fraud Control Units (MFCUs) from using Federal matching funds to conduct efforts to identify situations in which a question of fraud may exist, including the screening of claims, analysis of patterns of practice, or routine verification with recipients of whether services billed by providers were actually received. The modifications would allow data mining to be conducted by MFCUs under limited circumstances.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 1007 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 1302; 42 USC 1396b(a)(6); 42USC 1396(b)(3); 42 USC 1396b(q)
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	01/00/2011	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: State
Federalism: No
Energy Affected: Undetermined
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Department of Health and Human Services (HHS)
Office of the Secretary (OS) RIN: 0991-AB62

View Related Documents

Title: HIPAA Privacy Rule Accounting of Disclosures Under the Health Information Technology for Economic and Clinical Health Act

Abstract: The Department of Health and Human Services Office for Civil Rights will issue rules to modify the HIPAA Privacy rule as necessary to implement the accounting of disclosures provisions of section 13405(c) of the Health Information Technology for Economic and Clinical Health Act (Title XIII of the American Recovery and Reinvestment Act of 2009).

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: Undetermined
Unfunded Mandates: Undetermined
CFR Citation: 45 CFR 164 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 111-5, sec 13405(c)
Legal Deadline:

Action	Source	Description	Date
NPRM	Statutory		06/00/2010

Timetable:

Action	Date	FR Cite
NPRM	02/00/2011	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: Undetermined
Federalism: Undetermined
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Department of Health and Human Services (HHS)
Office of the Secretary (OS) RIN: 0991-AB72

View Related Documents

Title: Safe Harbors to the Anti-Kickback Statute for Certain Arrangements

Abstract: This proposed rule would add safe harbors under the anti-kickback statute addressing arrangements in the following areas (subject to certain conditions): waivers of Federal health care program beneficiary cost-sharing amounts in the context of certain government sponsored clinical trials and in the context of certain emergency medical services furnished by suppliers owned or operated by States or municipalities; certain local transportation provided to Federal health care program beneficiaries; certain waived or reduced cost-sharing amounts under Medicare Part D (codifying in regulations section 101(e) of the Medicare Prescription Drug Improvement and Modernization Act of 2003); and certain discounts in the price of “applicable drugs” of manufacturers furnished to “applicable beneficiaries” under the Medicare Coverage Gap Discount Program (pursuant to section 3301 of the Affordable Care Act of 2010). In addition, this rule would re-propose expanding the existing safe harbor for certain waivers of beneficiary co-insurance and deductible amounts for Part A or Part B services for Medicare SELECT policyholders in accordance with an agreement between the Medicare SELECT issuer and a provider or supplier, in certain contexts.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: Undetermined
Unfunded Mandates: No
CFR Citation: 42 CFR 1001.952 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 100–93, sec 14(a); PL 111–148, sec 3301; PL 108–173, sec 101(e)
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	04/00/2011	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: Undetermined
Energy Affected: Undetermined
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Department of Health and Human Services (HHS)
Office of the Secretary (OS) RIN: 0991-AB73

View Related Documents

Title: Exceptions to the Beneficiary Inducement Prohibition for Certain Arrangements

Abstract: This proposed rule will codify section 6402(d)(2)(B) of the Affordable Care Act of 2010, entitled “Clarification of Treatment of Certain Charitable and Other Innocuous Programs.” Section 1128A(a)(5) of the Social Security Act provides for a civil monetary penalty for certain inducements offered to Medicare and Medicaid beneficiaries. Section 6402(d)(2)(B) of the ACA adds four exceptions to the definition of remuneration at section 1128A(i)(6) of the Social Security Act for purposes of section 1128A(a)(5): certain remuneration which promotes access to care and poses a low risk of harm to patients and Federal health care programs (as defined in section 1128(f) of the Social Security Act and designated by the Secretary under regulations); certain offers or transfers in connection with retail rewards programs; certain unadvertised transfers of items or services to beneficiaries experiencing financial need; and certain waivers by PDP sponsors of Part D plans or MA organizations offering

MA-PD plans of copayments otherwise owed by their enrollees for the first fill of a covered Part D drug that is a generic drug.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: Undetermined
CFR Citation: 42 CFR 1003.101 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 111-148, sec 6402
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	04/00/2011	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Federalism: Undetermined
Energy Affected: Undetermined
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Department of Health and Human Services (HHS)
Office of the Secretary (OS)
RIN: 0991-AB74

View Related Documents

Title: Individual Access to Protected Health Information Held by CLIA Laboratories
Abstract: The Department of Health and Human Services Office for Civil Rights will modify the HIPAA Privacy Rule to conform the access provisions to be consistent with new Centers for Medicare and Medicaid Services regulations that will require laboratories subject to the Clinical Laboratory Improvements Amendments of 1988, to provide individuals with access to their protected health information.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Proposed Rule
Major: Undetermined
Unfunded Mandates: Undetermined
CFR Citation: 45 CFR 164 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 104-191 sec 264
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	01/00/2011	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: Undetermined
Federalism: Undetermined
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Department of Health and Human Services (HHS)
Office of the Secretary (OS)
RIN: 0991-AB75

View Related Documents

Title: Nondiscrimination Under the Patient Protection and Affordable Care Act

Abstract: The Department of Health and Human Services Office for Civil Rights will issue rules for covered entities with respect to prohibitions against discrimination on the basis of race, color, national origin, sex, age, and disability, as provided in section 1557 of the Patient Protection and Affordable Care Act (Pub. L. 111-148).

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: Undetermined
Unfunded Mandates: Undetermined
CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 111-148, sec 1557
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	09/00/2011	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: Undetermined
Federalism: Undetermined
Energy Affected: Undetermined
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Department of Health and Human Services (HHS)
Office of the Secretary (OS)
RIN: 0991-AB54

View Related Documents

Title: Standards for Privacy of Individually Identifiable Health Information; Modifications to the HIPAA Privacy Rule Required by the Genetic Information Nondiscrimination Act of 2008

Abstract: The Department of Health and Human Services Office for Civil Rights will issue final rules to implement the modifications to the HIPAA Privacy Rule required by section 105 of the Genetic Information Nondiscrimination Act of 2008. These rules will prohibit certain health plans from using or disclosing genetic information about an individual for underwriting purposes.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 45 CFR 160; 45 CFR 164 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 1320d-9
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		05/21/2009

Timetable:

Action	Date	FR Cite
NPRM	10/07/2009	74 FR 51698
NPRM Comment Period End	12/07/2009	
Final Action	12/00/2010	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Federalism: No
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Department of Health and Human Services (HHS)
Office of the Secretary (OS) RIN: 0991-AB55

View Related Documents

Title: HIPAA Administrative Simplification; Modifications to the HIPAA Enforcement Rule

Abstract: The Department of Health and Human Services will issue final rules to modify the HIPAA Enforcement Rule to reflect the revised penalty structure and certain provisions of section 13410 of the Health Information Technology for Economic and Clinical Health Act (Title XIII of the American Recovery and Reinvestment Act of 2009) that were effective February 17, 2009.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 45 CFR 160 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 111-5, sec 13410
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		02/17/2009

Timetable:

Action	Date	FR Cite
Interim Final Rule	10/30/2009	74 FR 56123
Interim Final Rule Comment Period End	12/29/2009	
Final Action	12/00/2010	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Federalism: No
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Department of Health and Human Services (HHS)
Office of the Secretary (OS) RIN: 0991-AB56

View Related Documents

Title: HIPAA Administrative Simplification; Notification in the Case of Breach

Abstract: The Department will issue final rules for HIPAA covered entities and business associates with respect to breach notification of unsecured protected health information, as required by section 13402 of the Health Information Technology for Economic and Clinical Health Act (title XIII of the American Recovery and Reinvestment Act of 2009).

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 45 CFR 160; 45 CFR 164 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 111-5, sec 13402
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		08/17/2009

Timetable:

Action	Date	FR Cite

Interim Final Rule	08/24/2009	74 FR 42740
Interim Final Rule Comment Period End	10/24/2009	
Final Action	12/00/2010	

Regulatory Flexibility Analysis Required: No Government Levels Affected: No
Federalism: No

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Department of Health and Human Services (HHS)
Office of the Secretary (OS) RIN: 0991-AB57

View Related Documents

Title: Modifications to the HIPAA Privacy, Security, and Enforcement Rules Under the Health Information Technology for Economic and Clinical Health Act

Abstract: The Department of Health and Human Services Office for Civil Rights will issue rules to modify the HIPAA Privacy, Security, and Enforcement Rules as necessary to implement the privacy, security, and certain enforcement provisions of subtitle D of the Health Information Technology for Economic and Clinical Health Act (title XIII of the American Recovery and Reinvestment Act of 2009).

Priority: Economically Significant Agenda Stage of Rulemaking: Final Rule
Major: Yes Unfunded Mandates: No
CFR Citation: 45 CFR 160; 45 CFR 164 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 111-5, secs 13400 to 13410
Legal Deadline:

Action	Source	Description	Date
NPRM	Statutory		02/17/2010

Regulatory Plan:

Statement of Need: The Office for Civil Rights will issue rules to modify the HIPAA Privacy, Security, and Enforcement Rules to implement the privacy and security provisions in sections 13400 to 13410 of the Health Information Technology for Economic and Clinical Health Act (title XIII of Division A of the American Recovery and Reinvestment Act of 2009, Pub. L. 111-5). These regulations will improve the privacy and security protection of health information.

Legal Basis: Subtitle D of the Health Information Technology for Economic and Clinical Health Act (title XIII of the American Recovery and Reinvestment Act of 2009) requires the Office for Civil Rights to modify certain provisions of the HIPAA Privacy and Security Rules to implement sections 13400 to 13410 of the Act.

Alternatives: The Office for Civil Rights is statutorily mandated to make modifications to the HIPAA Privacy and Security Rules to implement the privacy provisions at sections 13400 to 13410 of the Health Information Technology for Economic and Clinical Health Act (title XIII of the American Recovery and Reinvestment Act of 2009).

Costs and Benefits: These modifications to the HIPAA Privacy, Security, and Enforcement Rules will benefit health care consumers by strengthening the privacy and security protections afforded their health information by HIPAA covered entities and their business associated. The Agency believe the primary cost associate with this regulation will be for covered entities to revise and redistribute their notices of privacy practices to ensure health care consumers are informed of their new rights and protections. The Agency estimates the cost of revising and redistributing these notices to total approximates $166.1 million over the first year following the effective date of the regulation. Of this total, the cost heal care providers is estimated to be approximately $46 million and to health plans to be approximately $120.1 million. The Agency does not believe that the additional modification to Privacy, Security, or Enforcement Rules required by this regulation will significantly increase covered entity or business associates and in some cases will reduce burden. Further, it is expected that the costs of modifying business associate contracts will be mitigated both by the additional one-year transition period which will allow the costs of modifying contracts to be incorporated into the normal renegotiation of contracts as the contracts expire, as well as sample business associate contract language to be provided by the Agency.

Risks:

Timetable:

Action	Date	FR Cite
Final Action	03/00/2011	

Regulatory Flexibility Analysis Required: Business; Governmental Jurisdictions; Organizations

Government Levels Affected: Federal; Local; State; Tribal

Federalism: No

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

RIN: 0991-AA91

View Related Documents

Title: Shared Risk Exception to the Safe Harbor Provisions

Abstract: This final rule establishes a new safe harbor for risk-sharing arrangements under the Federal health care programs' anti-kickback provisions. The rule sets forth an exception from liability for remuneration between an eligible organization and an individual or entity providing items or services in accordance with a written agreement between these parties. The rule allows remuneration between an organization and an individual or entity if a written agreement places the individual or entity at "substantial financial risk" for the cost or utilization of the items or services that the individual or entity is obligated to provide.

Priority: Substantive, Nonsignificant

Agenda Stage of Rulemaking: Long-term Action

Major: No

Unfunded Mandates: No

CFR Citation: 42 CFR 1001 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: 42 USC 1302; 42 USC 1320a-7b; 42 USC 1395hh; PL 104-191, sec 216(b)

Legal Deadline:

Action	Source	Description	Date
Other	Statutory		01/01/1997

Timetable:

Action	Date	FR Cite
Final Action	00/00/0000	
ANPRM	05/23/1997	62 FR 28410
ANPRM Comment Period End	06/09/1997	
Interim Final Rule	11/19/1999	64 FR 63504
Interim Final Rule Comment Period End	01/18/2000	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: No

Federalism: No

Related RINs: Related to 0991-AB06

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

RIN: 0991-AB49

View Related Documents

Title: Rescission of the Regulation Entitled Ensuring That Department of Health and Human Services Funds Do Not Support Coercive of Discriminatory Policies or Practices in Violation of Federal Law

Abstract: The Department of Health and Human Services proposes to rescind the December 19, 2008 final rule entitled "Ensuring That Department of Health and Human Services Funds Do Not Support Coercive or Discriminatory Policies or Practices in Violation of Federal Law," 73 FR 78072.

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: Not Yet Determined
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Next Action Undetermined		
NPRM	03/10/2009	74 FR 10207
NPRM Comment Period End	04/09/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No

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Department of Health and Human Services (HHS)
Office of the Secretary (OS)
RIN: 0991-AB51

View Related Documents

Title: Principles for Determining Costs at Hospitals Under Federal Grants, Contracts, and Cooperative Agreements

Abstract: This notice of proposed rulemaking will publish for a 30-day comment period revisions to 45 CFR part 74, appendix E: Principles for Determining Costs at Hospitals Under Federal Grants, Contracts, and Cooperative Agreements (hereinafter referred to as the Hospital Cost Principles or HCP). It is the culmination of a comprehensive review process begun in 2005, and incorporates relevant elements of the Office of Management and Budget circulars for Colleges and Universities (OMB Circular A-21), Non-Profit Institutions (OMB Circular A-122), and State and Local Governments (OMB Circular A-87). These other principles were revised by OMB in the early 1990s, but the Hospital Cost Principles were not.

Priority: Routine and Frequent
Agenda Stage of Rulemaking: Long-term Action
Major: Undetermined
Unfunded Mandates: No
CFR Citation: 45 CFR 74, app E (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: Not Yet Determined
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	00/00/0000	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: Local; State
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Office of the Secretary (OS) RIN: 0991-AB52

View Related Documents

Title: Rescission of Interest Prohibition in the Principles for Determining Costs at Hospitals Under Federal Grants, Contracts, and Cooperative Agreements

Abstract: This Notice of Proposed Rulemaking (NPRM) would rescind the current prohibition against interest as an allowable expense. The recision applies only to interest endured for new construction, facility acquisitions, and interest debt to acquire or replace facility acquisitions. It makes the Hospital Cost Principles consistent with the Office of Management and Budget circulars for Colleges and Universities (OMB Circular A-21), Non-Profit Institutions (OMB Circular A-122), and State and Local Governments (OMB Circular A-87) concerning the allowance of interest debt. These other principles were revised in the early 1990s, but the Hospital Cost Principles were not. In 2000, the current interest request waiver process was established as a temporary practice to align the Hospital Cost Principles with A-21 and A-87 until a permanent revision could be published. Since then, 12 such waivers have been granted by the Department. The standards in this NPRM would be the same as those in A-21 and A-87. This NPRM establish the Department of Health and Human Services as the proponent agency for appendix E of 45 CFR part 74 with inherent responsibility to review, approve, and deny requests for waiver to Hospital Cost Principles.

Priority: Routine and Frequent
Agenda Stage of Rulemaking: Long-term Action
Major: Undetermined
Unfunded Mandates: No
CFR Citation: 42 CFR 74 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: Not Yet Determined
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	00/00/0000	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: Local; State
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Office of the Secretary (OS) RIN: 0991-AB16

View Related Documents

Title: Safe Harbor for Waiver of Beneficiary Co-Insurance and Deductible Amounts for a Medicare SELECT Policy

Abstract: This final rule would expand the existing safe harbor for certain waivers of beneficiary co-insurance and deductible amounts to benefit the policyholders of Medicare SELECT supplemental insurance. Specifically, the amended safe harbor would protect waivers of co-insurance and deductible amounts under part A or part B of the Medicare program owed by beneficiaries covered by a Medicare SELECT policy issued in accordance with section 1882(t)(1) of the Social Security Act, if the waiver is in accordance with a price reduction agreement covering such policyholders between the Medicare SELECT issuer and the provider or supplier offering the waiver. We plan to solicit additional public input before taking Final action.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Completed Action
Major: No
Unfunded Mandates: No

CFR Citation: 42 CFR 1001 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 100-93, sec 14(a)
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	09/25/2002	67 FR 60202
NPRM Comment Period End	10/25/2002	
Withdrawn	07/26/2010	

Regulatory Flexibility Analysis Required: No
Small Entities Affected: No
Government Levels Affected: No
Federalism: No

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Department of Health and Human Services (HHS)
Office of the Secretary (OS)
RIN: 0991-AB58

View Related Documents

Title: Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology

Abstract: The Department of Health and Human Services (HHS), Office of the National Coordinator for Health Information Technology, will issue an interim final rule with a request for comments to adopt an initial set of standards, implementation specifications, and certification criteria, as required by section 3004(b)(1) of the Public Health Service Act. The certification criteria adopted in this initial set establish the technical capabilities and related standards that certified electronic health record (EHR) technology will need to include in support of the Medicare and Medicaid EHR Incentive Programs.

Priority: Other Significant
Major: No
Agenda Stage of Rulemaking: Completed Action
Unfunded Mandates: No
CFR Citation: 45 CFR 170 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 300jj-14
Legal Deadline:

Action	Source	Description	Date
Other	Statutory	Interim final rule.	12/31/2009

Timetable:

Action	Date	FR Cite
Interim Final Rule	01/13/2010	75 FR 2014
Interim Final Rule Effective	02/12/2010	
Interim Final Rule Comment Period End	03/15/2010	
Final Action	07/28/2010	75 FR 44590

Regulatory Flexibility Analysis Required: No
Small Entities Affected: No
Energy Affected: No
Related RINs: Related to 0991-AB59
Government Levels Affected: Federal
Federalism: No
Related Agencies: Common: OS; Common: CMS

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Department of Health and Human Services (HHS)
Office of the Secretary (OS) RIN: 0991-AB69

View Related Documents

Title: Requirements for Group Health Plans and Health Insurance Issuers Relating to Preexisting Condition Exclusions, Lifetime and Annual Limits, Rescissions and Patient Protections

Abstract: This document contains interim final regulations implementing the rules for group health plans and health insurance coverage in the group and individual markets under provisions of the Patient Protection and Affordable Care Act regarding preexisting condition exclusions, lifetime and annual dollar limits on benefits, rescissions, prohibition on discrimination in favor of highly compensated individuals, and patient protections.

Priority: Economically Significant
Agenda Stage of Rulemaking: Completed Action
Major: Yes
Unfunded Mandates: No
CFR Citation: 26 CFR 54.9815-2704T; 29 CFR 2590.715-2704; 45 CFR 147.108 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 111-148
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Interim Final Rule	06/28/2010	75 FR 37188
Interim Final Rule Comment Period End	08/27/2010	
Merged With 0950-AA00	09/16/2010	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Office of the Secretary (OS) RIN: 0991-AB70

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Title: Group Health Plans and Health Insurance Issuers Relating to Internal Claims and Appeals and External Review Processes Under the Patient Protection and Affordable Care Act

Abstract: The Affordable Care Act provides consumers with the right to appeal decisions made by their health carrier to an outside, independent decision-maker, regardless of the state of residence or type of health insurance. Under the interim final regulations plans and issuers must comply with a State external review process or the federal external review process.

Priority: Economically Significant
Agenda Stage of Rulemaking: Completed Action
Major: Yes
Unfunded Mandates: No
CFR Citation: 45 CFR 147 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 111-148
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Interim Final Rule	07/23/2010	75 FR 43330
Merged With 0950-AA01	09/16/2010	
Interim Final Rule Comment Period End	09/21/2010	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: State

Federalism: Yes
Energy Affected: Undetermined
Agency Contact: Ellen Kuhn Department of Health and Human Services
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Department of Health and Human Services (HHS)
Office of the Secretary (OS) RIN: 0991-AB71

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Title: Pre-Existing Condition Insurance Plan Program

Abstract: Section 1101 of title I of the Patient Protection and Affordable Care Act of 2010, (Affordable Care Act) requires that the Secretary establish, either directly or through contracts with States or nonprofit private entities, a temporary high risk health insurance pool program to provide affordable health insurance coverage to uninsured individuals with pre-existing conditions. This program will continue until January 1, 2014, when American Health Benefit Exchanges established under sections 1311 and 1321 of the Affordable Care Act will be available for individuals to obtain health insurance coverage. This interim final rule implements requirements in section 1101 of the Affordable Care Act.

Priority: Economically Significant
Agenda Stage of Rulemaking: Completed Action
Major: Yes
Unfunded Mandates: No
CFR Citation: None (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 111-148
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Interim Final Rule	07/30/2010	75 FR 45010
Merged With 0950-AA05	09/16/2010	
Interim Final Rule Comment Period End	09/28/2010	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No
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