Monday,
April 24, 2006

Part VIII

Department of
Health and Human
Services

Semiannual Regulatory Agenda
DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

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 agenda

SUMMARY: The Regulatory Flexibility Act of 1980 and Executive Order 12866 require this semi-annual publication inventorying all rulemaking actions under development by the Department. The purpose is to encourage public participation in the regulatory process by providing, at as early a stage as possible, summarized information about regulatory actions under consideration. Members of the public wishing to communicate to the Department their views on the potential rule-makings outlined below are invited to do so.

FOR FURTHER INFORMATION CONTACT: Ann C. Agnew, Executive Secretary, Department of Health and Human Services, Washington, DC 20201.

SUPPLEMENTARY INFORMATION: The capsulized information provided below presents for public scrutiny a forecast of the rulemaking activities that the Department expects to undertake over the foreseeable future. We focus primarily on those areas of work expected to result in publication of Notices of Proposed Rulemaking or Final Rules within the next 12 months.

We welcome the views of all concerned with regard to the planned rulemakings referenced below. Comments may be directed to the Agency officials cited in each of the summaries, or, if early attention at the Secretary’s level is seen as required, comments should be sent to: Ann C. Agnew, Executive Secretary to the Department, Room 603H, 200 Independence Avenue SW, Washington, DC 20201.


Ann C. Agnew,
Executive Secretary to the Department.

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<td>1046</td>
<td>Medicare Part B Competitive Acquisition of Outpatient Drugs and Biologicals (CMS-1325-F)</td>
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<td>1047</td>
<td>Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships; E-Prescribing Exceptions (CMS-1303-F)</td>
<td>0938–AN69</td>
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<td>1048</td>
<td>Medicare Integrity Program, Fiscal Intermediary and Carrier Functions, and Conflict of Interest Requirements (CMS-6030-F)</td>
<td>0938–AN72</td>
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<tr>
<td>1049</td>
<td>Health Care Infrastructure Improvement Program; Loan Program for Qualifying Hospitals Engaged in Cancer-Related Health Care (CMS-1287-F)</td>
<td>0938–AO03</td>
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<td>1050</td>
<td>Extending Sunset Date for the Interim Final Regulation on Mental Health Parity (CMS-4094-F4)</td>
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Centers for Medicare & Medicaid Services—Completed Actions

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<tr>
<td>1051</td>
<td>Standard Unique National Health Plan Identifier (CMS-6017-F)</td>
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<td>Medicare Outcome and Assessment Information Set (OASIS) Data Reporting Requirements (CMS-3006-F)</td>
<td>0938–AJ10</td>
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<td>1053</td>
<td>Hospice Care Amendments (CMS-1022-F)</td>
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<td>Electronic Medicare Claims Submission (CMS-0008-F)</td>
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<td>1055</td>
<td>Requirements for Long-Term Care Facilities; Nursing Services; Posting of Nurse Staffing Information (CMS-3121-F)</td>
<td>0938–AM55</td>
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<td>1056</td>
<td>Conditions for Coverage for Payment of Power Mobility Devices, Including Powered Wheelchairs and Power-Operated Vehicles (CMS-3017-F)</td>
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<td>1057</td>
<td>Payment for Respiratory Assist Devices With Bi-Level Capability and a Back-Up Rate (CMS-1167-F)</td>
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<td>1058</td>
<td>Update of the List of Covered Procedures for Ambulatory Surgical Centers for 2005 (CMS-1478-F)</td>
<td>0938–AN23</td>
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<td>Payment for Clinical Laboratory Tests (CMS-1494-F)</td>
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<td>Federal Enforcement in Group and Individual Health Insurance Markets (CMS-4091-F)</td>
<td>0938–AN35</td>
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<td>1061</td>
<td>Home Health Prospective Payment System Rate Update for Calendar Year 2006 (CMS-1301-F)</td>
<td>0938–AN44</td>
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<td>Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates (CMS-1501-FC)</td>
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<td>1063</td>
<td>Revised Civil Money Penalties, Assessments, Exclusions, and Related Appeals Procedures (CMS-6019-F)</td>
<td>0938–AN48</td>
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<td>Electronic Prescribing Standards (CMS-0011-F)</td>
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## HHS

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<td>Group Market Health Insurance Reform: Guaranteed Availability, Guaranteed Renewability, Disclosures to Small Employers (CMS-4102-F)</td>
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<td>1067</td>
<td>All Provider Bad Debt Payment (CMS-1126-F)</td>
<td>0938–AN75</td>
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<td>1068</td>
<td>Application of Inherent Reasonableness to All Medicare Part B Services (Other Than Physician Services) (CMS-1998-F)</td>
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<td>1069</td>
<td>Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006 (CMS-1502-FC)</td>
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<td>Electronic Submission of Cost Reports (CMS-1199-F)</td>
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<td>1071</td>
<td>Loan Forgiveness Criteria for the Health Care Infrastructure Loan Program (CMS-1320-F)</td>
<td>0938–AN93</td>
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<td>1072</td>
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<td>0938–AN99</td>
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<td>1073</td>
<td>State Allotments for Payment of Medicare Part B Premiums for Qualifying Individuals (CMS-2210-F)</td>
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<td>1074</td>
<td>Federal Government’s Adoption of Twenty (20) Healthcare Messaging and Vocabulary Standards Recommended by the Consolidated Health Informatics Initiative (CMS-0015-N)</td>
<td>0938–AO05</td>
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<td>1075</td>
<td>Revised Payment System for Services Furnished in Ambulatory Surgical Centers (ASCs) Effective January 1, 2008 (CMS-1517-P)</td>
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<td>1076</td>
<td>Fire Safety Requirements for Religious Non-Medical Health Care Institutions: Correction to Add Written Fire Control Plans &amp; Maintenance of Documentation (CMS-3183-IFC)</td>
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### Administration for Children and Families—Proposed Rule Stage

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<td>Developmental Disabilities and Bill of Rights Act</td>
<td>0970–AC07</td>
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<td>Administrative Cost Sharing Under TANF</td>
<td>0970–AC15</td>
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<td>1079</td>
<td>Care and Placement of Unaccompanied Alien Children</td>
<td>0970–AC20</td>
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<td>1080</td>
<td>Chafee National Youth in Transition Database</td>
<td>0970–AC21</td>
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<td>1081</td>
<td>Medical Support</td>
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<td>1082</td>
<td>Adoption and Foster Care Analysis and Reporting System</td>
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<td>1084</td>
<td>Privatizing Functions</td>
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<td>Head Start Transportation</td>
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### Administration for Children and Families—Final Rule Stage

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<td>Safeguarding Child Support and Expanded Federal Parent Locator Services (FPLS) Information</td>
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<td>1087</td>
<td>Child Care and Development Fund State Match Provisions</td>
<td>0970–AC18</td>
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<td>TANF Work Provisions of the Deficit Reduction Act</td>
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### Administration for Children and Families—Completed Actions

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<td>Administrative Costs for Children in Title IV-E Foster Care</td>
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<td>Head Start Transportation</td>
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### 833. REVISIONS TO REGULATIONS ADDRESSING THE OIG’S AUTHORITY TO IMPOSE CIVIL MONEY PENALTIES AND ASSESSMENTS

**Priority:** Substantive, Nonsignificant  
**Legal Authority:** 42 USC 1320a–7a; 42 USC 1395mm; 42 USC 1395w–27; 42 USC 1396b; 42 USC 1396–2  
**CFR Citation:** 42 CFR 1003  
**Legal Deadline:** None  
**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; modify the current definition for the term “claim;” update 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.

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### 834. SHARED RISK EXCEPTION TO THE SAFE HARBOR PROVISIONS

**Priority:** Substantive, Nonsignificant  
**Legal Authority:** 42 USC 1302; 42 USC 1320a–7b; 42 USC 1395bb; PL 104–191, sec 216(b)  
**CFR Citation:** 42 CFR 1001  
**Legal Deadline:** Final, Statutory, January 1, 1997.  
**Abstract:** This final rule establishes a new statutory exception 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.

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**Government Levels Affected:** None  
**Agency Contact:** Joel Jay Schaer, Regulations Officer, Department of Health and Human Services, Office of the Secretary, Office of Inspector General, 330 Independence Avenue SW., Washington, DC 20201  
Phone: 202 619–0089  
**Related RIN:** Related to 0991–AB06  
**RIN:** 0991–AA91

### 835. SAFE HARBOR FOR WAIVER OF BENEFICIARY COINSURANCE AND DEDUCTIBLE AMOUNTS FOR A MEDICARE SELECT POLICY

**Priority:** Substantive, Nonsignificant  
**Legal Authority:** PL 100–93, sec 14(a)  
**CFR Citation:** 42 CFR 1001  
**Legal Deadline:** None  
**Abstract:** This final rule will expand the existing safe harbor for certain waivers of beneficiary coinsurance and deductible amounts to benefit the Medicare program owing to the waiver is in accordance with section 1892(a)(1) of the Social Security Act. Specifically, the amended safe harbor will protect policyholders covered by a Medicare SELECT policy issued in accordance with section 1892(a)(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.

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**Government Levels Affected:** None  
**Agency Contact:** Joel Jay Schaer, Regulations Officer, Department of Health and Human Services, Office of the Secretary, Office of Inspector General, 330 Independence Avenue SW., Washington, DC 20201  
Phone: 202 619–0089  
**RIN:** 0991–AB06

### 836. CLARIFICATION OF TERMS AND APPLICATION OF PROGRAM EXCLUSION AUTHORITY FOR SUBMITTING CLAIMS CONTAINING EXCESSIVE CHARGES

**Priority:** Substantive, Nonsignificant  
**Legal Authority:** Social Security Act, sec 112B(6); Social Security Act, sec 112B(6)(A)  
**CFR Citation:** 42 CFR 1001  
**Legal Deadline:** None
HHS—OS

**Abstract:** This rule would amend the Office of Inspector General's exclusion regulations at 42 CFR 1001.701, addressing excessive claims, by including definitions for the terms “substantially in excess” and “usual charges,” and by clarifying the “good cause” exception set forth in this section.

**Timetable:**

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**Regulatory Flexibility Analysis Required:** No

**Government Levels Affected:** None

**Agency Contact:** Joel Jay Schaer, Regulations Officer, Department of Health and Human Services, Office of the Secretary, Office of Inspector General, 330 Independence Avenue SW., Washington, DC 20201 Phone: 202 619–0089

**RIN:** 0991–AB23

**837. MEDICARE AND STATE HEALTH CARE PROGRAMS: FRAUD AND ABUSE; SAFE HARBOR FOR FEDERALLY QUALIFIED HEALTH CENTERS UNDER THE ANTI–KICKBACK STATUTE**

**Priority:** Other Significant

**Legal Authority:** PL 100–93, sec 14(a); PL 108–173, sec 431

**CFR Citation:** 42 CFR 1001

**Legal Deadline:** Final, Statutory, December 8, 2004.

**Abstract:** This rule will establish a safe harbor with respect to the provision of nonmonetary remuneration—in the form of hardware, software, or information technology and training services—necessary and used solely to receive and transmit electronic prescription information in accordance with section 1860-D of the Social Security Act.

**Timetable:**

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**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** None

**Agency Contact:** Joel Jay Schaer, Regulations Officer, Department of Health and Human Services, Office of the Secretary, Office of Inspector General, 330 Independence Avenue SW., Washington, DC 20201 Phone: 202 619–0089

**RIN:** 0991–AB38

**838. MEDICARE AND STATE HEALTH CARE PROGRAMS: FRAUD AND ABUSE; SAFE HARBOR FOR CERTAIN ELECTRONIC PRESCRIBING ARRANGEMENTS UNDER THE ANTI–KICKBACK STATUTE**

**Priority:** Other Significant

**Legal Authority:** PL 100–93, sec 14(a); PL 108–173, sec 101(a)(4)(D)(6)

**CFR Citation:** 42 CFR 1001

**Legal Deadline:** None

**Abstract:** This rule will set forth standards for the new anti-kickback safe harbor addressing remuneration between federally qualified health centers and certain providers where significant community benefit exits.

**Timetable:**

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**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** None

**Agency Contact:** Joel Jay Schaer, Regulations Officer, Department of Health and Human Services, Office of the Secretary, Office of Inspector General, 330 Independence Avenue SW., Washington, DC 20201 Phone: 202 619–0089

**RIN:** Related to 0991–AB06, Related to 0991–AA91

**RIN:** 0991–AB39

Department of Health and Human Services (HHS)

Office of the Secretary (OS)

**839. DEBT COLLECTION**

**Priority:** Substantive, Nonsignificant

**Legal Authority:** 31 USC 3711; 31 CFR 900 to 904

**CFR Citation:** 45 CFR 30

**Legal Deadline:** None

**Abstract:** The Department will amend part 30 of title 45 of the Code of Federal Regulations (CFR) to reflect the amendments to the Federal Claims Collection Act made by the Debt Collection Improvement Act of 1996 (DCIA), Public Law 104-134, 110 Stat. 1321 to 1358, as implemented by the Department of the Treasury at 31 CFR 900-904. The proposed rule will prescribe the standards and procedures for the Department’s use in the administrative collection, offset, compromise, and suspension or termination of debts owed to the Department. The proposed rule is required in order to bring the Department’s claims collection provisions in compliance with the Department of the Treasury regulations.

**Timetable:**

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**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** None

**Agency Contact:** Jeffrey S. Davis, Associate General Counsel, Department of Health and Human Services, Office of the Secretary, HHS Cohen Building,
**840. SALARY OFFSET**

*Priority:* Substantive, Nonsignificant  
*Unfunded Mandates:* Undetermined  
*Legal Authority:* 5 USC 5514  
*CFR Citation:* 5 CFR 550; 45 CFR 33  
*Legal Deadline:* None  

**Abstract:** The Department will add a new part 33 to title 45 of the Code of Federal Regulations (CFR) to implement the salary offset provisions of the Debt Collection Improvement Act of 1996 (DCIA), Public Law 104-134, 110 Stat. 1321 to 1358, codified at 5 U.S.C. 5514, as implemented by the Office of Personnel Management at 5 CFR part 550, subpart K. The proposed rule is required in order to bring the Department’s salary offset provisions in compliance with Governmentwide regulations published by the Office of Personnel Management.

**Timetable:**

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**Legal Deadline:** None  

**Abstract:** In accordance with section 949 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, 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.

**Timetable:**

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**Regulatory Flexibility Analysis Required:** No  
**Small Entities Affected:** No  
**Government Levels Affected:** Federal  
**Agency Contact:** Joel Jay Schaer, Regulations Officer, Department of Health and Human Services, Office of the Secretary, Office of Inspector General, 330 Independence Avenue SW., Washington, DC 20201 Phone: 202 619–0089  
**RIN:** 0991–AB33

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**842. HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT—ENFORCEMENT**

*Priority:* Other Significant  
*CFR Citation:* 45 CFR 160, subparts C to E  

** Completed: **

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**Regulatory Flexibility Analysis Required:** No  
**Small Entities Affected:** Businesses  
**Government Levels Affected:** None  
**Agency Contact:** Carol Conrad  
**Phone:** 202 690–1840  
**RIN:** 0991–AB29

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

*Priority:* Other Significant. Major status under 5 USC 801 is undetermined.  
*Legal Authority:* PL 106–310  
*CFR Citation:* Not Yet Determined  

**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.

**Timetable:**

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</table>
HHS—SAMHSA

Health Services Administration, Room 13–103, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857

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844. MANDATORY GUIDELINES FOR THE FEDERAL WORKPLACE DRUG TESTING PROGRAM

Priority: Other Significant

Legal Authority: PL 100–71; 5 USC 7301

CFR Citation: None


Abstract: HHS is proposing to establish scientific and technical guidelines for the testing of hair, sweat, and oral fluid specimens in addition to urine specimens; scientific and technical guidelines for using on-site tests to test urine and oral fluids at the collection site; requirements for the certification of instrumented initial test facilities; and added standards for collectors, on-site testers, and medical review officers.

Timetable:

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Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: Federal

Agency Contact: Joseph Denis Faha,
Director, DLEA, SAMHSA, Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, 5600 Fishers Lane, Rockville, MD 20857
Phone: 301 443–7017
Fax: 301 443–1450
Email: jfaha@samhsa.gov

RIN: 0930–AA12

Department of Health and Human Services (HHS)

Centers for Disease Control and Prevention (CDC)

845. • FOREIGN QUARANTINE REGULATIONS, PROPOSED REVISION OF CDC ANIMAL IMPORTATION REGULATIONS

Priority: Other Significant. Major status under 5 USC 801 is undetermined.

Unfunded Mandates: Undetermined

Legal Authority: Not Yet Determined

CFR Citation: Not Yet Determined

Legal Deadline: None

Abstract: The Centers for Disease Control and Prevention (CDC) is issuing this Advance Notice of Proposed Rulemaking (ANPRM) to begin the process of revising the regulations for importation of dogs, cats and other animals into the United States (42 CFR 71.51 and 71.56).

The input received from stakeholders via the ANPRM with the aim of improving CDC's ability to prevent importation of communicable diseases. The scope of this ANPRM does not include the nonhuman primate regulations (42 CFR 71.53).

Timetable:

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Regulatory Flexibility Analysis Required: Undetermined

Federalism: Undetermined

Agency Contact: Jennifer Brooks, Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Infectious Diseases, 1600 Clifton Road NE., NE E–03, Atlanta, GA 30333
Phone: 404 639–7048

RIN: 0920–AA14

846. • AMENDMENTS TO POWERED AIR–PURIFYING RESPIRATOR REQUIREMENTS FOR APPROVAL OF RESPIRATORY PROTECTION DEVICES

Priority: Other Significant. Major status under 5 USC 801 is undetermined.

Unfunded Mandates: Undetermined

Legal Authority: 29 USC 651; 30 USC 3; 30 USC 7; 30 USC 11; 30 USC 842; 30 USC 844

CFR Citation: 42 CFR 84

Legal Deadline: None

Abstract: NIOSH plans to modify sections of 42 CFR Part 84 concerning performance testing and other specifications for the certification of powered air-purifying respirators. These respirators are used in a variety of workplace applications, including emergency response activities.

Timetable:

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Regulatory Flexibility Analysis Required: Undetermined

Federalism: Undetermined

Agency Contact: Jon Szalajada, Acting Chief, Policy and Standards Branch, HHS, CDC, NIOSH, Department of Health and Human Services, Centers for Disease Control and Prevention, P.O. Box 18070, 626 Cochrans Mill Road, Pittsburgh, PA 15236
Phone: 412 386–5200

RIN: 0920–AA16

847. • AMENDMENTS TO PERFORMANCE REQUIREMENTS FOR CHEMICAL BIOLOGICAL, RADIOLOGICAL, AND NUCLEAR (CBRN) APPROVAL OF RESPIRATORY PROTECTION DEVICES

Priority: Other Significant. Major status under 5 USC 801 is undetermined.

Legal Authority: 29 USC 651; 30 USC 3; 30 USC 5; 30 USC 7; 30 USC 11; 30 USC 842; 30 USC 844

CFR Citation: 42 CFR 84

Legal Deadline: None
**Department of Health and Human Services (HHS)**

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

### 848. AMENDMENTS TO QUALITY ASSURANCE AND ADMINISTRATIVE PROVISION FOR APPROVAL OF RESPIRATORY PROTECTIVE DEVICES

**Priority:** Other Significant. Major status under 5 USC 801 is undetermined.

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

**CFR Citation:** 42 CFR 84

**Legal Deadline:** None

**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; 3) revised approval label requirements; 4) updated and restructured fee schedule; and 5) fee retention in the respirator program.

**Timetable:**

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**Regulatory Flexibility Analysis Required:** Undetermined

**Small Entities Affected:** Businesses

**Government Levels Affected:** None

**Agency Contact:** Jon Szalajada, Acting Chief, Policy and Standards Branch, HHS, CDC, NIOSH, Department of Health and Human Services, Centers for Disease Control and Prevention, P.O. Box 18070, 626 Cochran’s Mill Road, Pittsburgh, PA 15236

Phone: 412 386–5200

RIN: 0920–AA04

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**Department of Health and Human Services (HHS)**

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

### 849. AMENDMENTS TO SELF–CONTAINED BREATHING APPARATUS REQUIREMENTS FOR APPROVAL OF RESPIRATORY PROTECTIVE DEVICES

**Priority:** Other Significant

**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

**CFR Citation:** 42 CFR 84

**Legal Deadline:** None

**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.

**Timetable:**

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**Regulatory Flexibility Analysis Required:** Undetermined

**Small Entities Affected:** Businesses

**Government Levels Affected:** None

**Agency Contact:** Jon Szalajada, Acting Chief, Policy and Standards Branch, HHS, CDC, NIOSH, Department of Health and Human Services, Centers for Disease Control and Prevention, P.O. Box 18070, 626 Cochran’s Mill Road, Pittsburgh, PA 15236

Phone: 412 386–5200

RIN: 0920–AA10

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**Department of Health and Human Services (HHS)**

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

### 850. CONTROL OF COMMUNICABLE DISEASES, INTERSTATE AND FOREIGN QUARANTINE

**Priority:** Economically Significant. Major under 5 USC 801.

**Unfunded Mandates:** This action may affect the private sector under PL 104-4.

**Legal Authority:** Not Yet Determined

**CFR Citation:** 42 CFR 70; 42 CFR 71

**Legal Deadline:** None

**Abstract:** By statute, the Secretary of Health and Human Services (HHS) 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. Quarantine regulations are divided into two parts: Part 71 dealing with foreign arrivals and part 70 dealing with interstate matters. The Secretary has delegated the authority to prevent the introduction of diseases from foreign countries to the Director, CDC. Interstate authority is split between CDC and the Food and Drug Administration (FDA), with CDC delegated interstate authority as it pertains to humans. CDC maintains quarantine stations at eight major airports with quarantine inspectors who respond to reports of diseases from carriers. According to the statutory scheme, the President of the United States determines through Executive order which diseases may subject individuals to quarantine. The current disease list, which was last updated in April 2005, includes cholera, diphtheria, tuberculosis, plague, smallpox, yellow fever, viral hemorrhagic fevers, and Severe Acute Respiratory Syndrome (SARS) and influenza caused by novel or reemergent influenza virus that are
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causing, or have the potential to cause, a pandemic.

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Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Ram Koppaka M.D., Ph.D., Department of Health and Human Services, Centers for Disease Control and Prevention, MS–E–03, 1600 Clifton Road, Atlanta, GA 30333 Phone: 404 498–2308

RIN: 0920–AA12

851. AMENDMENTS TO REQUIREMENTS FOR COAL MINE DUST PERSONAL SAMPLER UNITS

Priority: Other Significant. Major status under 5 USC 801 is undetermined.

Unfunded Mandates: Undetermined

Legal Authority: Not Yet Determined

CFR Citation: Not Yet Determined

Legal Deadline: None

Abstract: NIOSH and MSHA jointly plan to modify 30 CFR part 74, which provides requirements for the approval by NIOSH and MSHA of coal mine dust personal sampler units that are worn by miners to determine the concentrations of respirable dust in coal mine atmospheres. The existing requirements are design-specific for a particular monitoring technology that has been available since the 1970's. The amendments would establish requirements that would promote the development and govern the testing and approval of new coal mine dust sampler designs and technology for use in coal mines.

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Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses

Government Levels Affected: None

Federalism: Undetermined

Agency Contact: John Breslin, Director, Science, Pittsburgh Research Laboratory, Department of Health and Human Services, Centers for Disease Control and Prevention, 626 Cochrans Mill Road, Pittsburgh, PA 15236 Phone: 412 386–6873

RIN: 0920–AA18

Department of Health and Human Services (HHS)

Centers for Disease Control and Prevention (CDC)

852. PROCEDURES FOR DESIGNATING CLASSES OF EMPLOYEES AS MEMBERS OF THE SPECIAL EXPOSURE COHORT UNDER THE ENERGY EMPLOYEES OCCUPATIONAL ILLNESS COMPENSATION PROGRAM ACT OF 2000; AMENDMENTS

Priority: Other Significant

Legal Authority: Not Yet Determined

CFR Citation: None

Legal Deadline: None


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Next Action Undetermined

RIN: 0920–AA13

Department of Health and Human Services (HHS)

Centers for Disease Control and Prevention (CDC)

853. CONTROL OF COMMUNICABLE DISEASES

Priority: Other Significant


CFR Citation: 42 CFR 70 and 71

Legal Deadline: None

Abstract: CDC is committed to protecting the health and safety of the American public by preventing the introduction of communicable disease into the United States. Having updated regulations in place is an important measure to ensure swift response to public health threats. CDC proposes to update existing regulations related to preventing the introduction, transmission, or spread of communicable diseases from foreign countries into the U.S. and from one State or possession into another.

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RIN: 0920–AA18

Regulatory Flexibility Analysis Required: No
854. MEDICAL DEVICES; CURRENT GOOD MANUFACTURING PRACTICE (CGMP) FINAL RULE; QUALITY SYSTEMS REGULATIONS (SECTION 610 REVIEW)

Priority: Routine and Frequent
Legal Authority: 5 USC 610
CFR Citation: 21 CFR 808; 21 CFR 812; 21 CFR 820
Legal Deadline: None

Abstract: FDA is initiating a review under section 610 of the Regulatory Flexibility Act for the regulations in part 820. The purpose of this review is to determine if any of the regulations in part 820 should be continued without change, or should be amended or rescinded, to minimize adverse economic impacts on small entities. FDA will consider and solicit comments on the following: (1) The continued need for a regulation in part 820; (2) the nature of complaints or comments received concerning a regulation in part 820; (3) the complexity of a regulation in part 820; (4) the extent to which a regulation in part 820 overlaps, duplicates, or conflicts with other Federal, State, or local government rules; and (5) the degree to which technology, economic conditions or other factors have changed in the area affected by a regulation in part 820.

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Regulatory Flexibility Analysis Required: No

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Myrna Hanna, Regulations Staff, Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, HFZ–215, 1350 Piccard Drive, PI50 RM150F, Rockville, MD 20850
Phone: 240 276–2347
Fax: 240 276–2352
Email: myrna.hanna@fda.hhs.gov
RIN: 0910–AF71

855. PACKAGE SIZE LIMITATION FOR SODIUM PHOSPHATES ORAL SOLUTION AND WARNING AND DIRECTION STATEMENTS FOR ORAL AND RECTAL SODIUM PHOSPHATES FOR OVER-THE-COUNTER LAXATIVE USE (SECTION 610 REVIEW)

Priority: Routine and Frequent. Major status under 5 USC 801 is undetermined.

Legal Authority: 5 USC 610
CFR Citation: 21 CFR 201.307
Legal Deadline: None

Abstract: Section 201.307 (21 CFR section 201.307) describes a final rule to limit the container size for sodium phosphates oral solution (dibasic sodium phosphate/monobasic sodium phosphate oral solution) to not greater than 90 milliliters (mL) (3 ounces (oz)) when used as an over-the-counter (OTC) laxative drug product. FDA limited the container size due to reports of deaths associated with an overdose of sodium phosphates when packaged in a larger size container and a larger than intended dose was ingested inadvertently. In addition, this final rule required warning and direction statements to inform consumers that exceeding the recommended dose of oral and rectal sodium phosphates products in a 24 hour period could be harmful.

FDA is initiating a review under section 610 of the Regulatory Flexibility Act for the regulation in section 201.307. The purpose of this review is to determine whether the regulation in section 201.307 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 201.307; (2) the nature of the complaints or comments received concerning the regulation in section 201.307; (3) the complexity of the regulation in section 201.307; (4) the extent to which the regulation in section 201.307 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 for the products still subject to the package size and labeling regulation in section 201.307.

The section 610 review will be carried out along with a regulatory review under section 5 of Executive Order 12866, which calls for agencies to periodically review existing regulations to determine whether any should be modified or eliminated so as to make the Agency’s regulatory program more effective in achieving its goals, less burdensome, or in greater alignment with the President’s priorities and the principles set forth in the Executive order.

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Regulatory Flexibility Analysis Required: No

Government Levels Affected: Local, State

Federalism: This action may have federalism implications as defined in EO 13132

Agency Contact: Walter Ellenberg, Regulatory Project Management Officer, Center for Drug Evaluation and Research, Department of Health and Human Services, Food and Drug Administration, WO22 RM 5489, HFD–569, Rockville, MD 20850
Phone: 301 796–0885
Fax: 301 796–9899
Email: walter.ellenberg@fda.hhs.gov
RIN: 0910–AF73
856. ● OVER-THE-COUNTER DRUG PRODUCTS CONTAINING ANALGESIC/ANTIPYRETIC ACTIVE INGREDIENTS FOR INTERNAL USE: REQUIRED ALCOHOL WARNING (SECTION 610 REVIEW)

Priority: Routine and Frequent. Major status under 5 USC 801 is undetermined.

Legal Authority: 5 USC 610

CFR Citation: 21 CFR 201.322

Legal Deadline: None

Abstract: Section 201.322 describes a regulation which requires an alcohol warning for all over-the-counter (OTC) drug products, labeled for adult use, containing internal analgesic/antipyretic active ingredients. The required warning statements advise consumers with a history of heavy alcohol use to consult a physician for advice about the use of OTC internal analgesic/antipyretic drug products.

FDA issued the final rule after considering comments on the Agency’s proposed regulation for OTC internal analgesic, antipyretic, and antirheumatic drug products: a proposed regulation to establish an alcohol warning; recommendations from its Nonprescription Drugs Advisory Committee (NDAC) and Arthritis Drugs Advisory Committee (ADAC); and data submitted to the agency.

FDA is initiating a review under section 610 of the Regulatory Flexibility Act for the regulation in section 201.322. The purpose of this review is to determine whether the regulation in section 201.322 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 201.322; (2) the nature of the complaints or comments received concerning the regulation in section 201.322; (3) the complexity of the regulation in section 201.322; (4) the extent to which the regulation in section 201.322 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 for the products still subject to the labeling regulation in section 201.322.

The section 610 review will be carried out along with a regulatory review under section 5 of Executive Order 12866, which calls for agencies to periodically review existing regulations to determine whether any should be modified or eliminated so as to make the Agency’s regulatory program more effective in achieving its goals, less burdensome, or in greater alignment with the President’s priorities and the principles set forth in the Executive order.

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Regulatory Flexibility Analysis

Required: No

Government Levels Affected: Local, State

Federalism: This action may have federalism implications as defined in EO 13132.

Agency Contact: Walter Ellenberg, Regulatory Project Management Officer, Center for Drug Evaluation and Research, Department of Health and Human Services, Food and Drug Administration, WO22 RM 5489, HFD–569, Rockville, MD 20850.

Phone: 301 796–0885

Fax: 301 796–9899

Email: walter.ellenberg@fda.hhs.gov

RIN: 0910-AP74

857. ● STATUS OF CERTAIN ADDITIONAL OVER-THE-COUNTER DRUG CATEGORY II AND III ACTIVE INGREDIENTS (SECTION 610 REVIEW)

Priority: Routine and Frequent. Major status under 5 USC 801 is undetermined.

Legal Authority: 5 USC 610

CFR Citation: 21 CFR 310.545

Legal Deadline: None

Abstract: Section 310.545 (21 CFR 310.545) codifies a final rule that was issued stating certain first aid antiseptic, vaginal contraceptive, and antimicrobial diaper rash ingredients in over-the-counter (OTC) drug products are not generally recognized as safe and effective and are misbranded. This rule took into consideration the reports and recommendations of various OTC drug advisory review panels and public comment on proposed Agency regulations. Based on the absence of substantive comments in opposition to the Agency’s proposed nonmonograph status for various ingredients, as well as the failure of interested parties to submit new data or information to FDA, the Agency determined that the presence of the subject ingredients in an OTC drug products would result in that product not being generally recognized as safe and effective and would result in misbranding.

FDA is initiating a review under section 610 of the Regulatory Flexibility Act for the regulation in section 310.545. The purpose of this review is to determine whether the regulation in section 310.545 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 310.545; (2) the nature of the complaints or comments received concerning the regulation in section 310.545; (3) the complexity of the regulations in section 310.545; (4) the extent to which the regulation in section 310.545 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 for the products still subject to the regulation in section 310.545.

The section 610 review will be carried out along with a regulatory review under section 5 of Executive Order 12866, which calls for agencies to periodically review existing regulations to determine whether any should be modified or eliminated so as to make the Agency’s regulatory program more effective in achieving its goals, less burdensome, or in greater alignment with the President’s priorities and the principles set forth in the Executive order.

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Regulatory Flexibility Analysis

Required: No

Government Levels Affected: Local, State
Federalism: This action may have federalism implications as defined in EO 13132.

Agency Contact: Walter Ellenberg, Regulatory Project Management Officer, Center for Drug Evaluation and Research, Department of Health and Human Services, Food and Drug Administration, WO22 RM 5489, HFD-569, Rockville, MD 20850
Phone: 301 796–0885
Fax: 301 796–9899
Email: walter.ellenberg@fda.hhs.gov

RIN: 0910–AF75

858. ● MEDICAL DEVICES: CLASSIFICATION/ RECLASSIFICATION; RESTRICTED DEVICES; ANALYTE SPECIFIC REAGENTS (SECTION 610 REVIEW)

Priority: Other Significant
Legal Authority: 21 USC 351; 21 USC 352; 21 USC 360j
CFR Citation: 21 CFR 809.10; 21 CFR 809.30
Legal Deadline: None
Abstract: FDA is initiating a review under section 610 of the Regulatory Flexibility Act for the regulations in part 809. The purpose of this review is to determine if any of the regulations in part 809 should be continued without change, or should be amended or rescinded, to minimize adverse economic impact on small entities. FDA will consider and solicit comments on the following: 1) The continued need for a regulation in part 809; 2) the nature of complaints or comments received concerning a regulation in part 809; 3) the complexity of a regulation in part 809; 4) the extent to which a regulation in part 809 overlaps, duplicates, or conflicts with other Federal, State, or Government rules; and 5) the degree to which technology economic conditions or other factors have changed in the area affected by a regulation in part 809.

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Regulatory Flexibility Analysis Required: No
Small Entities Affected: No

Government Levels Affected: None
Agency Contact: Myrna Hanna, Regulations Staff, Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, HFZ–215, 1350 Piccard Drive, PI50 RM150F, Rockville, MD 20850
Phone: 240 276–2347
Fax: 240 276–2352
Email: myrna.hanna@fda.hhs.gov

RIN: 0910–AF76

859. ● AMENDED ECONOMIC IMPACT ANALYSIS OF FINAL RULE ON USER LABELING ON NATURAL RUBBER–CONTAINING MEDICAL DEVICE (SECTION 610 REVIEW)

Priority: Other Significant. Major status under 5 USC 801 is undetermined.
Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351; 21 USC 352; 21 USC 357; 21 USC 360; 21 USC 360j; 21 USC 371; 21 USC 374
CFR Citation: 21 CFR 801.437
Legal Deadline: Other, Statutory, September 30, 2007, Planned Section 610 Review.
Abstract: FDA is initiating a review under section 610 of the Regulatory Flexibility Act for the regulations in part 801. The purpose of this review is to determine if any of the regulations in part 801 should be continued without change, or should be amended or rescinded, consistent with stated objectives and applicable statutes, to minimize any significant economic impact on a substantial number of small entities. FDA will consider and solicit comments on the following: 1) The continued need for a regulation in part 801; 2) the nature of complaints or comments received concerning a regulation in part 801; 3) the complexity of a regulation in part 801; 4) the extent to which a regulation in part 801 overlaps, duplicates, or conflicts with other Federal rules, and to the extent feasible, with State and local government rules; and 5) the degree to which technology, economic conditions or other factors have changed in the area affected by a regulation in part 801.

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<td>62 FR 51021</td>
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RIN: 0910–AF77

860. ● FINANCIAL DISCLOSURE BY CLINICAL INVESTIGATORS (SECTION 610 REVIEW)

Priority: Other Significant. Major status under 5 USC 801 is undetermined.
Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351; 21 USC 352; 21 USC 353; 21 USC 355; 21 USC 356; 21 USC 357; 21 USC 360; 21 USC 360c – 360j; 21 USC 371; 21 USC 372; 21 USC 373; 21 USC 374; 21 USC 375; 21 USC 376; 21 USC 379; 42 USC 262
Legal Deadline: Other, Statutory, February 2, 2006, Planned Section 610 Review.
Abstract: FDA is undertaking a review under section 610 of the Regulatory Flexibility Act. The purpose of this review is to determine whether the regulations in sections 54, 312.53, 312.47, 312.64, 314.50, 314.60, 314.94, 314.200, 314.300, 320.36, 330.10, 601.2, 807.31, 807.87, 807.100, 812.43, 812.110, 814.20, 814.42, 814.112 and 860.123 should be continued without change, or whether they should be 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 regulations in sections 54, 312.53, 312.47, 312.64, 314.50, 314.60, 314.94, 314.200, 314.300, 320.36, 330.10, 601.2, 807.31, 807.87, 807.100, 812.43, 812.110, 812.140, 814.112 and 860.123; (2) the nature of complaints or comments received concerning the regulations in sections 54, 312.53, 312.47, 312.64, 314.50, 314.60, 314.94, 314.200, 314.300, 320.36, 330.10, 601.2, 807.31, 807.87, 807.100, 812.43, 812.110, 812.140, 814.20, 814.42, 814.112 and 860.123; (3) the complexity of the regulations in sections 54, 312.53, 312.47, 312.64, 314.50, 314.60, 314.94, 314.200, 314.300, 320.36, 330.10, 601.2, 807.31, 807.87, 807.100, 812.43, 812.110, 812.140, 814.20, 814.42, 814.112 and 860.123; (4) the extent to which the regulations in sections 54, 312.53, 312.47, 312.64, 314.50, 314.60, 314.94, 314.200, 314.300, 320.36, 330.10, 601.2, 807.31, 807.87, 807.100, 812.43, 812.110, 812.140, 814.20, 814.42, 814.112 and 860.123; and (5) the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulations in sections 165.110 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 regulations in section 165.110; (2) the nature of complaints or comments received concerning the regulations in section 165.110; (3) the complexity of the regulations; (4) the extent to which the regulations in section 165.110 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 in the area affected by the regulations in section 165.110.

**Regulatory Flexibility Analysis**

**Required:** Undetermined

**Government Levels Affected:** Undetermined

**Agency Contact:** Richard A. Williams, Director, Division of Market Studies, OSAS, CFSAN, Department of Health and Human Services, Food and Drug Administration, HFS–725, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, College Park, MD 20740 Phone: 301 436–1989 Fax: 301 436–2626 Email: richard.williams@fda.hhs.gov

RIN: 0910–AF80

**Priority:** Other Significant. Major status under 5 USC 801 is undetermined.

**Unfunded Mandates:** Undetermined

**Legal Authority:** 21 USC 321; 21 USC 341; 21 USC 343; 21 USC 343–1; 21 USC 348; 21 USC 349; 21 USC 371; 21 USC 379e

**CFR Citation:** 21 CFR 165.110

**Legal Deadline:** Other, Statutory, November 13, 2005, Planned Section 610 Review.

**Abstract:** Section 165.110 (21 CFR 165.110) describes requirements for identity and quality standards for bottled water. FDA is undertaking a review of section 165.110 under section 610 of the Regulatory Flexibility Act. The purpose of this review is to determine whether the regulations in section 165.110 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 regulations in section 165.110; (2) the nature of complaints or comments received concerning the regulations in section 165.110; (3) the complexity of the regulations; (4) the extent to which the regulations in section 165.110 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 in the area affected by the regulations in section 165.110.

**Regulatory Flexibility Analysis**

**Required:** Undetermined

**Government Levels Affected:** Undetermined

**Agency Contact:** Howard P. Muller, Office of Regulatory Policy, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, 515 Security Lane, Suite 1101 (HFD–7), Rockville, MD 20852 Phone: 301 594–2041 Fax: 301 827–5562 Email: howard.mullerjr@fda.hhs.gov

RIN: 0910–AF79

**Priority:** Substantive, Nonsignificant. Major status under 5 USC 801 is undetermined.

**Unfunded Mandates:** Undetermined

**Legal Authority:** 21 CFR 101.54; 21 CFR 101.60

**CFR Citation:** 21 CFR 165.110

**Legal Deadline:** Other, Statutory, September 23, 2007, Deadline for 610(c) Review.

**Abstract:** Section 165.110 (21 CFR 165.110) describes requirements for identity and quality standards for bottled water. FDA is undertaking a review of section 165.110 under section 610 of the Regulatory Flexibility Act. The purpose of this review is to determine whether the regulations in section 165.110 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 regulations in section 165.110; (2) the nature of complaints or comments received concerning the regulations in section 165.110; (3) the complexity of the regulations; (4) the extent to which the regulations in section 165.110 overlap, duplicate, or conflict with other Federal, State, or governmental rules, and (5) the degree
whether the regulations 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 regulations in sections 101.54 and 101.60; (2) the nature of complaints or comments received concerning the regulations; (3) the complexity of the regulations; (4) the extent to which the regulations in sections 101.54 and 101.60 overlap, duplicate, or conflict with other Federal rules, and to the extent feasible, with State, or governmental rules; and (5) the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulations in sections 101.54 and 101.60.

**Abstract:**

The proposed rule would require that the NDC number to newly listed drugs and take other steps to minimize the use of inaccurate NDC numbers on drug labels.

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<td>Government Levels Affected: None</td>
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**Agency Contact:**

Richard A. Williams, Director, Division of Market Studies, OSAS, CFSAN, Department of Health and Human Services, Food and Drug Administration, HFS–725, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, College Park, MD 20740

Phone: 301 436–1989
Fax: 301 436–2626
Email: richard.williams@fda.hhs.gov

RIN: 0910–AF83

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**863. FOREIGN AND DOMESTIC ESTABLISHMENT REGISTRATION AND LISTING REQUIREMENTS FOR HUMAN DRUGS, INCLUDING DRUGS THAT ARE REGULATED UNDER A BIOLOGICS LICENSE APPLICATION, AND ANIMAL DRUGS**

**Priority:** Other Significant

**Legal Authority:** 21 USC 321; 21 USC 331; 21 USC 351; 21 USC 352; 21 USC 355; 21 USC 360; 21 USC 360b; 21 USC 371; 21 USC 374; 42 USC 262; 42 USC 264; 42 USC 271


**Legal Deadline:** None

**Abstract:** The proposed rule would 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. The proposed rule would require that this information be submitted via the Internet into the FDA registration and listing database, instead of the current requirement to submit the information to FDA on paper forms. The proposed rule would also require that the NDC number appear on certain drug labels. In addition, FDA would assign the NDC number to newly listed drugs and take other steps to minimize the use of inaccurate NDC numbers on drug labels.

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**Agency Contact:**

Howard P. Muller, Office of Regulatory Policy, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, 5555 Security Lane, Suite 1101 (HFD–7), Rockville, MD 20852

Phone: 301 594–2041
Fax: 301 594–2041
Email: howard.mullerjr@fda.hhs.gov

RIN: 0910–AA49

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**864. MEDICAL DEVICES; ANESTHESIOLOGY DEVICES; PROPOSED RECLASSIFICATION OF PRESSURE REGULATORS FOR USE WITH MEDICAL OXYGEN**

**Priority:** Routine and Frequent

**Legal Authority:** 21 USC 351; 21 USC 352; 21 USC 360c; 21 USC 360h; 21 USC 371

**CFR Citation:** 21 CFR 863.2700

**Legal Deadline:** None

**Abstract:** The Food and Drug Administration (FDA) is proposing to reclassify pressure regulators for use with medical oxygen from class I to class II and to establish a special control for pressure oxygen regulators to address problems of fire and explosion associated with use of these devices. The special control will be a guidance document that includes standardized testing, performance, and labeling guidance for industry. Devices that meet the special control will be exempt from the premarket notification requirements of the Act. The Agency believes it is taking a least burdensome approach for industry. This proposed rule will phase-in a compliance approach that will minimize the cost. FDA seeks to reclassify these devices under section 513(e)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(e)(1)).

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**Federalism:** This action may have federalism implications as defined in EO 13132.

**Agency Contact:** Myrra Hanna, Regulations Staff, Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, HFZ–215, 1350 Piccard Drive, P150 RM150F, Rockville, MD 20850

Phone: 240 276–2347
Fax: 240 276–2352
865. ELECTRONIC SUBMISSION OF DATA FROM STUDIES EVALUATING HUMAN DRUGS AND BIOLOGICS

**Priority:** Other Significant. Major status under 5 USC 801 is undetermined.

**Legal Authority:** 21 USC 351 to 21 USC 353

**CFR Citation:** 21 CFR 201.161(a); 21 CFR 211.94; 21 CFR 211.125

**Legal Deadline:** None

**Abstract:** The Food and Drug Administration is proposing to amend 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 proposed 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 mixups, do not occur in the future.

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**Regulatory Flexibility Analysis Required:** Yes

**Small Entities Affected:** Businesses

**Agency Contact:** Martha Nguyen, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Office of Regulatory Policy, 5515 Security Lane, Suite 1101 (HFD–7), Rockville, MD 20852

**Phone:** 301 594–2041

**Fax:** 301–827–5562

**Email:** martha.nguyen@fda.hhs.gov

**RIN:** 0910–AC30

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866. MEDICAL GAS CONTAINERS AND CLOSURES: CURRENT GOOD MANUFACTURING PRACTICE REQUIREMENTS

**Priority:** Other Significant

**Legal Authority:** 21 USC 321; 21 USC 351 to 21 USC 353

**CFR Citation:** 21 CFR 201.161(a); 21 CFR 211.94; 21 CFR 211.125

**Legal Deadline:** None

**Abstract:** The Food and Drug Administration is proposing to amend 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 proposed 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 mixups, do not occur in the future.

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**Regulatory Flexibility Analysis Required:** Undetermined

**Government Levels Affected:** None

**Agency Contact:** Brian L. Pendleton, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, 5515 Security Lane, Suite 1101 (HFD–7), Rockville, MD 20852

**Phone:** 301 594–2041

**Fax:** 301 827–5562

**Email:** brian.pendleton@fda.hhs.gov

**Related RIN:** Previously reported as 0910–AC02

**RIN:** 0910–AC59

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867. REPORTING INFORMATION REGARDING FALSIFICATION OF DATA

**Priority:** Other Significant. Major status under 5 USC 801 is undetermined.

**Unfunded Mandates:** Undetermined

**Legal Authority:** 21 USC 321; 21 USC 341 to 343; 21 USC 348; 21 USC 349; 21 USC 351; 21 USC 352; 21 USC 355; 21 USC 360b; 21 USC 360c; 21 USC 360e; 21 USC 360f to 360k; 21 USC 361; 21 USC 371; 21 USC 379e; 42 USC 262

**CFR Citation:** 21 CFR 58.11; 21 CFR 71.1; 21 CFR 101.69; 21 CFR 101.70; 21 CFR 171.1; 21 CFR 190.6; 21 CFR 312.3; 21 CFR 312.56; 21 CFR 511.1; 21 CFR 812.46

**Legal Deadline:** None

**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.

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**Regulatory Flexibility Analysis Required:** Undetermined

**Government Levels Affected:** None

**Agency Contact:** Brian L. Pendleton, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, 5515 Security Lane, Suite 1101 (HFD–7), Rockville, MD 20852

**Phone:** 301 594–2041

**Fax:** 301 827–5562

**Email:** brian.pendleton@fda.hhs.gov

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868. CONTENT AND FORMAT OF LABELING FOR HUMAN PRESCRIPTION DRUGS AND BIOLOGICS; REQUIREMENTS FOR PREGNANCY AND LACTATION LABELING

**Priority:** Other Significant

**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 371; 21 USC 379e; 42 USC 262

**CFR Citation:** 21 CFR 201.161(a); 21 CFR 211.94; 21 CFR 211.125

**Legal Deadline:** None

**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.
870. CHARGING FOR INVESTIGATIONAL DRUGS

Priority: Substantive, Nonsignificant. Major status under 5 USC 801 is undetermined.

Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 371; 42 USC 282

CFR Citation: 21 CFR 312.7; 21 CFR 312.8

Legal Deadline: None

Abstract: The proposed rule would amend FDA's investigational new drug regulation concerning charging for investigational drugs. The proposed rule would clarify the circumstances in which charging for an investigational drug in a clinical trial is appropriate, set forth criteria for charging for an investigational drug for the different types of treatment uses to be described in the Agency's proposed rule on expanded access to investigational drugs for treatment use, and clarify what costs can be recovered for an investigational drug. The proposed rule is intended to permit charging for a broader range of investigational uses than is explicitly permitted in current regulations.

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871. EXPANDED ACCESS TO INVESTIGATIONAL DRUGS FOR TREATMENT USE

Priority: Other Significant

Legal Authority: 21 USC 355; 21 USC 360bb; 21 USC 371; 42 USC 262

CFR Citation: 21 CFR 312.42; 21 CFR 312.300; 21 CFR 312.305; 21 CFR 312.310; 21 CFR 312.315; 21 CFR 312.320

Legal Deadline: None

Abstract: To amend the regulations governing investigational new drugs to describe the ways patients may obtain investigational drugs for treatment use under expanded access programs. Such use of investigational drugs would be available to: (1) Individual patients, including in emergencies; (2) intermediate size patient populations; and (3) larger populations under a treatment protocol or IND.

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872. DISTRIBUTION OF BLOOD DERIVATIVES BY REGISTERED BLOOD ESTABLISHMENTS THAT QUALIFY AS HEALTH CARE ENTITIES; PDMA OF 1997; PDA OF 1992; POLICIES, REQUIREMENTS, AND ADMINISTRATIVE PROCEDURES

Priority: Substantive, Nonsignificant

Legal Authority: 21 USC 351 to 353; 21 USC 371; 21 USC 374

CFR Citation: 21 CFR 203.3(q); 21 CFR 203.22(h); 21 CFR 205.3(h)

Legal Deadline: None

Abstract: FDA is proposing to amend certain limited provisions of the implementing regulations of the Prescription Drug Marketing Act.
(PDMA) of 1987, as modified by the Prescription Drug Amendments (PDA) of 1992 and the FDA Modernization Act of 1997. Certain provisions of that final rule that published on December 3, 1999, (64 FR 67720), do not allow a registered blood establishment that provides health care services to concurrently distribute blood derivatives. The effective date of those provisions of that rule is December 1, 2006, as published on February 23, 2004, (69 FR 8105). FDA is amending the final rule to allow a registered blood establishment that concurrently provides health care services related to its activities as a blood establishment to also distribute blood derivatives.

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**Regulatory Flexibility Analysis**

**Required:** No

**Government Levels Affected:** None

**Additional Information:** Delayed effective date of portion of rule to 12/01/06, effective date of non-stayed portion of final rule, 64 FR 67720, December 3, 1999

**Agency Contact:** Kathleen E. Swisher, Supervisory Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Biologics Evaluation and Research, 1401 Rockville Pike, Suite 200N, (HFM–17), Rockville, MD 20852

Phone: 301 827–6210
Fax: 301 827–9434

**RIN:** 0910–AF16

873. BLOOD INITIATIVE—REQUIREMENTS FOR HUMAN BLOOD AND BLOOD COMPONENTS INTENDED FOR TRANSFUSION OR FOR FURTHER MANUFACTURING USE

**Priority:** Other Significant

**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; 42 USC 263; 42 USC 263a; 42 USC 264; 42 USC 271

**CFR Citation:** 21 CFR 606; 21 CFR 610; 21 CFR 630; 21 CFR 640; 21 CFR 660; 21 CFR 820; 21 CFR 1270

**Legal Deadline:** None

**Abstract:** The Food and Drug Administration (FDA) is proposing to amend 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 based on reports by the U.S. House of Representatives Committee on Government Reform and Oversight Subcommittee on House Resources and Intergovernmental Relations, the General Accounting Office, and the Institute of Medicine, and on public comments. These actions are intended to help ensure the continued safety of the Nation’s blood supply.

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**Regulatory Flexibility Analysis**

**Required:** No

**Small Entities Affected:** Businesses

**Government Levels Affected:** None

**Agency Contact:** Paula S. McKeever, Regulatory Policy Analyst, Department of Health and Human Services, Food and Drug Administration, Center for Biologics Evaluation and Research, HFM–17, 1401 Rockville Pike, Rockville, MD 20852–1448

Phone: 301 827–6210
Fax: 301 827–9434

Email: paula.mckeever@fda.hhs.gov

**Related RIN:** Split from 0910–AB26

**RIN:** 0910–AF25

874. OVER–THE–COUNTER (OTC) DRUG REVIEW—INTERNAL ANALGESIC PRODUCTS

**Priority:** Routine and Frequent

**Legal Authority:** 21 USC 321p; 21 USC 351 to 353; 21 USC 355; 21 USC 360a; 21 USC 371a; 21 USC 331; 21 USC 360; 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

**CFR Citation:** 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358

**Legal Deadline:** None

**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 labeling intended to better inform consumers of potential risks associated with these products. The second action addresses products marketed for children under 2 years old and weight- and age-based dosing for children’s products. The third action addresses combination products containing the analgesic acetaminophen or aspirin and sodium bicarbonate used as an antacid ingredient. The fourth action addresses products labeled to relieve upset stomach associated with overindulgence in food and drink and to relieve symptoms associated with a hangover. The Stevens Johnson and Cardiovascular Warnings Documents address new proposed product warnings.

**Regulatory Flexibility Analysis**

**Required:** Yes

**Small Entities Affected:** Businesses

**Government Levels Affected:** Local, State

**Federalism:** This action may have federalism implications as defined in EO 13132.

**Agency Contact:** Gerald M. Rachanow, Regulatory Counsel, Division of
Over-the-counter Drug Products, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, 5600 Fishers Lane, HFD–560, Rockville, MD 20857

Phone: 301 827–2241
Fax: 301 827–2315
Email: gerald.rachanow@fda.hhs.gov

Related RIN: Split from 0910–AA01
RIN: 0910–AF36

**875. OVER-THE-COUNTER (OTC) DRUG REVIEW—LABELING OF DRUG PRODUCTS FOR OTC HUMAN USE**

**Priority:** Routine and Frequent

**Legal Authority:** 21 USC 321p; 21 USC 351 to 353; 21 USC 355; 21 USC 360a; 21 USC 371a; 21 USC 331; 21 USC 360; 21 USC 371; 21 USC 358; 21 USC 360g to 360s; 21 USC 374; 21 USC 379e; 42 USC 216; 42 USC 241; 42 USC 262; 42 USC 264

**CFR Citation:** 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358

**Legal Deadline:** None

**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 emergency first aid eyewash products.

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**Regulatory Flexibility Analysis**

**Required:** Yes

**Small Entities Affected:** Businesses

**Government Levels Affected:** Local, State

**Federalism:** This action may have federalism implications as defined in EO 13132.

**Agency Contact:** Gerald M. Rachanow, Regulatory Counsel, Division of Over-the-Counter Drug Products, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, 5600 Fishers Lane, HFD–560, Rockville, MD 20857

Phone: 301 827–2241
Fax: 301 827–2315
Email: gerald.rachanow@fda.hhs.gov

Related RIN: Split from 0910–AA01
RIN: 0910–AF39

**876. OVER-THE-COUNTER (OTC) DRUG REVIEW—OPHTHALMIC PRODUCTS**

**Priority:** Routine and Frequent

**Legal Authority:** 21 USC 321p; 21 USC 351 to 353; 21 USC 355; 21 USC 360a; 21 USC 371a; 21 USC 331; 21 USC 360; 21 USC 371

**CFR Citation:** 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358

**Legal Deadline:** None

**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 emergency first aid eyewash products.

**Timetable:**

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<tr>
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<td>(Emergency First Aid Eyewashes)</td>
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**Regulatory Flexibility Analysis**

**Required:** Yes

**Small Entities Affected:** Businesses

**Government Levels Affected:** Local, State

**Federalism:** This action may have federalism implications as defined in EO 13132.

**Agency Contact:** Gerald M. Rachanow, Regulatory Counsel, Division of Over-the-Counter Drug Products, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, 5600 Fishers Lane, HFD–560, Rockville, MD 20857

Phone: 301 827–2241
Fax: 301 827–2315
Email: gerald.rachanow@fda.hhs.gov

Related RIN: Split from 0910–AA01
RIN: 0910–AF39

**877. OVER-THE-COUNTER (OTC) DRUG REVIEW—SUNSCREEN PRODUCTS**

**Priority:** Routine and Frequent

**Legal Authority:** 21 USC 321p; 21 USC 351 to 353; 21 USC 355; 21 USC 360a; 21 USC 371a; 21 USC 331; 21 USC 360; 21 USC 371

**CFR Citation:** 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358

**Legal Deadline:** None

**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 sunscreen formulation, labeling, and testing requirements for both ultraviolet B (UVB) and ultraviolet A (UVA) radiation protection, and the other action addresses combination products containing sunscreen and insect repellent ingredients.

**Timetable:**

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**Regulatory Flexibility Analysis**

**Required:** Yes

**Small Entities Affected:** Businesses

**Government Levels Affected:** Local, State

**Federalism:** This action may have federalism implications as defined in EO 13132.

**Agency Contact:** Gerald M. Rachanow, Regulatory Counsel, Division of Over-the-Counter Drug Products, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, 5600 Fishers Lane, HFD–560, Rockville, MD 20857

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Email: gerald.rachanow@fda.hhs.gov

Related RIN: Split from 0910–AA01
RIN: 0910–AF43
878. OVER–THE–COUNTER (OTC) DRUG REVIEW—WEIGHT CONTROL PRODUCTS  

**Priority:** Routine and Frequent  
**Legal Authority:** 21 USC 321p; 21 USC 351 to 353; 21 USC 359; 21 USC 360a; 21 USC 371a; 21 USC 331; 21 USC 360; 21 USC 371  

**CFR Citation:** 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358  

**Legal Deadline:** None  

**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 ingredient phenylpropanolamine, and the other action addresses the ingredient benzocaine.  

**Timetable:**  
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**Regulatory Flexibility Analysis Required:** Yes  
**Small Entities Affected:** Businesses  
**Government Levels Affected:** Local, State  

**Federalism:** This action may have federalism implications as defined in EO 13132.  

**Agency Contact:** Gerald M. Rachanow, Regulatory Counsel, Division of Over–the–Counter Drug Products, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, 5600 Fishers Lane, HFD–560, Rockville, MD 20857  
Phone: 301 827–2241  
Fax: 301 827–2315  
Email: gerald.rachanow@fda.hhs.gov  

**Related RIN:** Split from 0910–AA01  
**RIN:** 0910–AF45

879. OVER–THE–COUNTER (OTC) DRUG REVIEW—SKIN BLEACHING PRODUCTS  

**Priority:** Routine and Frequent  
**Legal Authority:** 21 USC 321p; 21 USC 351 to 353; 21 USC 359; 21 USC 360a; 21 USC 371a; 21 USC 331  

**CFR Citation:** 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358  

**Legal Deadline:** None  

**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.  

**Timetable:**  
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**Regulatory Flexibility Analysis Required:** Yes  
**Small Entities Affected:** Businesses  
**Government Levels Affected:** Local, State  

**Federalism:** This action may have federalism implications as defined in EO 13132.  

**Agency Contact:** Gerald M. Rachanow, Regulatory Counsel, Division of Over–the–Counter Drug Products, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, 5600 Fishers Lane, HFD–560, Rockville, MD 20857  
Phone: 301 827–2241  
Fax: 301 827–2315  
Email: gerald.rachanow@fda.hhs.gov  

**RIN:** 0910–AF56

881. LABEL REQUIREMENT FOR FOOD THAT HAS BEEN REFUSED ADMISSION INTO THE UNITED STATES  

**Priority:** Other Significant  
**Legal Authority:** 15 USC 1453 to 1455; 21 USC 321; 21 USC 343; 21 USC 352; 21 USC 355; 21 USC 360b; 21 USC 362; 21 USC 371; 21 USC 374; 21 USC 381; 42 USC 216; 42 USC 264  

**CFR Citation:** 21 CFR 1.98  

**Legal Deadline:** None  

**Abstract:** The proposed rule would require owners or consignees to label imported food that is refused entry into the United States. The label would read, “UNITED STATES: REFUSED ENTRY.” The proposal would describe the label’s characteristics (such as its
883. BLOOD VESSELS RECOVERED WITH ORGANS AND INTENDED FOR USE IN ORGAN TRANSPLANTATION

**Priority:** Substantive, Nonsignificant

**Legal Authority:** 42 USC 216; 42 USC 243; 42 USC 263a; 42 USC 271; 42 USC 273 to 274d; 42 USC 1302; 42 USC 1306

**CFR Citation:** 21 CFR 1271; 42 CFR 121

**Legal Deadline:** None

**Abstract:** FDA and Health Resources and Services Administration (HRSA) are issuing a direct final rule and companion proposed rule to amend the regulations to consider as part of an organ (and regulated by HRSA) those blood vessels recovered with vascularized human organs that are intended for use in organ transplantation; and to exclude such blood vessels from the definition of human cells, tissues, and cellular and tissue-based products (regulated by FDA). We are taking this action to provide that blood vessels recovered with organs and intended for use in organ transplantation will be governed by the regulations pertaining to organs. We believe this change will eliminate unnecessary burden resulting from an organ procurement organization’s efforts to comply with both FDA and HRSA requirements with respect to vascular tissue (FDA jurisdiction) and organs (HRSA jurisdiction).

**Regulatory Flexibility Analysis Required:** Yes

**Small Entities Affected:** Businesses

**Government Levels Affected:** Federal

**Federalism:** This action may have federalism implications as defined in EO 13132.

**Agency Contact:** Walter Ellenberg, Regulatory Project Management Office, Center for Drug Evaluation and Research, Department of Health and Human Services, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20850
Phone: 301 796–0885
Fax: 301 796–9899
Email: walter.ellenberg@fda.hhs.gov

**Related RIN:** Related to 0910–AC82

**RIN:** 0910–AF63

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884. INDEX OF LEGALLY MARKETED UNAPPROVED NEW ANIMAL DRUGS FOR MINOR SPECIES

**Priority:** Other Significant

**Legal Authority:** 21 USC 360 ccc–1

**CFR Citation:** 21 CFR 516

**Legal Deadline:** NPRM, Statutory, February 2, 2006, Final, Statutory, August 2, 2007.

**Abstract:** This proposed rule is being issued in response to the Minor Use and Minor Species (MUMS) Animal Health Act of 2004. The proposed rule implements section 572 of the MUMS Act which provides for a public index listing of legally-marketed unapproved new animal drugs for minor species of animals (species other than cattle, horses, swine, chickens, turkeys, dogs, and cats). The drugs in this index will only be indicated for use in non-food minor species or for use in early non-food life stages to food-producing minor species. This proposed rule, will, among other things, specify the procedures for requesting eligibility for indexing and for requesting addition to the index as well as the reporting requirements for index holders. This rule will also describe the criteria requestors will use for assembling a qualified expert panel to evaluate for FDA the target animal safety and effectiveness of a new animal drug proposed for indexing.

**Regulatory Flexibility Analysis Required:** No

**Government Levels Affected:** None

**Agency Contact:** Paula S. McKeever, Regulatory Policy Analyst, Department of Health and Human Services, Food and Drug Administration, Center for Biologics Evaluation and Research, HFM–17, 1401 Rockville Pike, Rockville, MD 20852–1448
Phone: 301 827–6120
Fax: 301 827–9434
Email: paula.mckeever@fda.hhs.gov

**RIN:** 0910–AF65

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**Timetable:**

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**Federal Register** / Vol. 71, No. 78 / Monday, April 24, 2006 / Unified Agenda
### 885. OVER-THE-COUNTER (OTC) DRUG REVIEW—TOPICAL ANTIMICROBIAL DRUG PRODUCTS

**Priority:** Routine and Frequent  
**Legal Authority:** 21 USC 321p; 21 USC 351 to 353; 21 USC 355; 21 USC 360a; 21 USC 371a; 21 USC 331; 21 USC 360; 21 USC 371  
**CFR Citation:** 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358  
**Legal Deadline:** None  
**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 the consumer healthcare, food handlers and healthcare antiseptic products.  
**Timetable:**

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**Regulatory Flexibility Analysis Required:** No  
**Small Entities Affected:** No  
**Government Levels Affected:** None  
**Agency Contact:** Walter Kenneth Hailen, Veterinary Medical Officer, Department of Health and Human Services, Food and Drug Administration, 7519 Standish Place, Room 180, HFV–50, MPN–4, Rockville, MD 20855  
**Email:** andrew.beaulieu@fda.hhs.gov  
**RIN:** 0910–AF67

### 886. IMPORT TOLERANCES FOR ANIMAL DRUGS

**Priority:** Substantive, Nonsignificant  
**Legal Authority:** 21 USC 360b(a)(6)  
**CFR Citation:** Not Yet Determined  
**Legal Deadline:** None  
**Abstract:** 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 drug residue tolerances (import tolerances) for imported food products of animal origin for drugs that are used in other countries, but that are unapproved new animal drugs in the United States. Food products of animal origin that are in compliance with the import tolerances will not be considered adulterated under the Federal Food, Drug, and Cosmetic Act (the Act) and may be imported into the U.S.  
**Timetable:**

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**Regulatory Flexibility Analysis Required:** No  
**Small Entities Affected:** No  
**Government Levels Affected:** None  
**Agency Contact:** George Kenneth Hailen, Veterinary Medical Officer, Department of Health and Human Services, Food and Drug Administration, 7519 Standish Place, Room 169, MPN–4, HFV–6, Rockville, MD 20855  
**Phone:** 240 276–9019  
**Fax:** 240 276–9010  
**Email:** george.hailen@fda.hhs.gov  
**RIN:** 0910–AF69
888. POSTMARKET SAFETY REPORTING FOR COMBINATION PRODUCTS

Priority: Other Significant

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 360a to 360f; 21 USC 360h to 360j; 21 USC 360l; 21 USC 360hh to 360ss; 21 USC 360aa 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

CFR Citation: Not Yet Determined

Legal Deadline: None

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 and specify sponsors’ reporting requirements for each type of combination product. The proposed rule would clarify the circumstances in which following one set of postmarket safety reporting regulations generally would meet the requirements of another set, and the circumstances in which these requirements would be supplemented with specific reporting provisions applicable to the other constituent part of the combination product. The regulation would ensure the consistency and appropriateness of postmarket safety reporting for combination products while avoiding the need for duplicative reporting requirements.

Timetable:

Action | Date | FR Cite
--- | --- | ---
NPRM | 03/04/07 | 68 FR 12406
NPRM Comment Period Extended | 06/18/03 | |
NPRM Comment Period End | 07/14/04 | |
NPRM Comment Period Extension | 10/14/03 | |
Comment Review End | 10/06/06 | |
Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Undetermined

Agency Contact: Leigh Hayes, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Office of Combination Products, 15800 Crabbs Branch Way, Suite 200 (HFG–3), Rockville, MD 20855
Phone: 301 427–1934
Fax: 301 427–1935
Email: leigh.hayes@fda.hhs.gov

RIN: 0910–AF82

Department of Health and Human Services (HHS)

Food and Drug Administration (FDA)

889. SAFETY REPORTING REQUIREMENTS FOR HUMAN DRUG AND BIOLOGICAL PRODUCTS

Priority: Other Significant. Major status under 5 USC 801 is undetermined.

Unfunded Mandates: Undetermined

Legal Authority: 21 USC 216; 21 USC 241; 42 USC 242a; 42 USC 262; 21 USC 263; 42 USC 263a to 263–n; 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

CFR Citation: 21 CFR 310; 21 CFR 312; 21 CFR 314; 21 CFR 320; 21 CFR 600; 21 CFR 601; 21 CFR 606

Legal Deadline: None

Abstract: This regulation is one component of the Secretary’s initiative to reduce medical errors. The final rule would amend the 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 propose other revisions to these regulations to enhance the quality of safety reports received by FDA.

Timetable:

Action | Date | FR Cite
--- | --- | ---
NPRM | 03/14/03 | 68 FR 12406
NPRM | 07/20/04 | 69 FR 43357
Final Action | 10/06/06 | |
Regulatory Flexibility Analysis Required: No

Small Entities Affected: None

Agency Contact: Carol Drew, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, 5515 Security Lane, Suite 1101 (HFD–7), Rockville, MD 20852
Phone: 301 594–2041
Fax: 301 827–5562
Email: james.cohen@fda.hhs.gov

RIN: 0910–AF81

890. APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG; COMPLETE RESPONSE LETTER; AMENDMENTS TO UNAPPROVED APPLICATIONS

Priority: Substantive, Nonsignificant. Major status under 5 USC 801 is undetermined.

Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 371; 21 USC 374; 21 USC 379e

CFR Citation: 21 CFR 312; 21 CFR 314

Legal Deadline: None

Abstract: The rule would amend the regulations on marketing approval of new drugs to discontinue the use of approvable and not approvable letters when taking action on a marketing application and instead use complete response letters. The rule would also amend the regulations on extension of the review clock because of amendments to applications.

Timetable:

Action | Date | FR Cite
--- | --- | ---
NPRM | 07/20/04 | 69 FR 43357
Final Action | 10/06/06 | |
Government Levels Affected: None

Agency Contact: Brian L. Pendleton, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, 5553 Security Lane, Suite 1101 (HFD–7), Rockville, MD 20852
Phone: 301 594–2041
Fax: 301 827–5562
Email: brian.pendleton@fda.hhs.gov

RIN: 0910–AB34

891. CGMPS FOR BLOOD AND BLOOD COMPONENTS: NOTIFICATION OF CONSIGNEES AND TRANSFUSION RECIPIENTS RECEIVING BLOOD AND BLOOD COMPONENTS AT INCREASED RISK OF TRANSMITTING HCV INFECTION (LOOKBACK)

Priority: Other Significant

Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 360c; 21 USC 360d; 21 USC 360h to 360j; 21 USC 371; 21 USC 374; 42 USC 216; 42 USC 262; 42 USC 263 to 263a; 42 USC 264; 21 USC 372; 21 USC 381

CFR Citation: 21 CFR 606; 21 CFR 610

Legal Deadline: None

Abstract: This rulemaking is one of a number of actions being taken to amend the biologics regulations to remove, revise, or update the regulations applicable to blood, blood components, and blood derivatives. These actions are based on FDA’s comprehensive review of the biologics regulations and on reports by the U.S. House of Representatives Committee on Government Reform and Oversight’s, Subcommittee on House Resources and Intergovernmental Relations, the General Accounting Office, and the Institute of Medicine, as well as on public comments. In this rulemaking, FDA will amend the biologics regulations to require that blood establishments prepare and follow written procedures for appropriate action when it is determined that blood and blood components pose an increased risk for transmitting hepatitis C virus (HCV) infection because they have been collected from a donor who, at a later date, tested reactive for evidence of HCV. The HIV lookback regulations will be amended for consistency.

Timetable:

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Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Paula S. McKeever, Regulatory Policy Analyst, Department of Health and Human Services, Food and Drug Administration, Center for Biologics Evaluation and Research, HFM–17, 1401 Rockville Pike, Rockville, MD 20852–1448
Phone: 301 827–6210
Fax: 301 827–9434
Email: paula.mckeever@fda.hhs.gov

Related RIN: Related to 0910–AB26

RIN: 0910–AB76

892. CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKING, OR HOLDING DIETARY INGREDIENTS AND DIETARY SUPPLEMENTS

Priority: Economically Significant. Major under 5 USC 801.

Unfunded Mandates: This action may affect the private sector under PL 104–4.

Legal Authority: 21 USC 321; 21 USC 342; 21 USC 343; 21 USC 348; 21 USC 371; 21 USC 374; 21 USC 381; 21 USC 393; 42 USC 264

CFR Citation: 21 CFR 111

Legal Deadline: None

Abstract: The Food and Drug Administration proposed in the Federal Register of March 13, 2003 (68 FR 12158), current good manufacturing practice (CGMP) regulations for dietary ingredients and dietary supplements. The proposed rule was published to establish the minimum CGMPs necessary to ensure that, if firms engage in activities related to manufacturing, packaging, or holding dietary ingredients or dietary supplements, they do so in a manner that will not adulterate and misbrand such dietary ingredients or dietary supplements. FDA also proposed to require manufacturers to evaluate the identity, purity, quality, strength, and composition of their dietary ingredients and dietary supplements. The proposed rule also responds to concerns that such regulations are necessary to ensure that consumers are provided with dietary supplement products which have not been adulterated as a result of manufacturing, packing, or holding, e.g., which have the identity and provide the quantity of dietary ingredients declared in labeling.

Timetable:

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Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Linda Kahl, Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, HFS–024, College Park, MD 20740
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Fax: 301 436–2964
Email: linda.kahl@fda.hhs.gov

RIN: 0910–AB88

893. ADDITIONAL SAFEGUARDS FOR CHILDREN IN CLINICAL INVESTIGATIONS OF FDA–REGULATED PRODUCTS

Priority: Other Significant. Major status under 5 USC 801 is undetermined.

Unfunded Mandates: Undetermined

Legal Authority: 21 USC 321; 21 USC 343; 21 USC 346; 21 USC 346a; 21 USC 348; 21 USC 350a; 21 USC 350b; 21 USC 351 to 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; 41 USC 216; 41 USC 241; 41 USC 262; 41 USC 263b to 263n

CFR Citation: 21 CFR 50; 21 CFR 56

Legal Deadline: None

Abstract: The final rule will finalize the interim rule that published in April 2001, providing additional protections for children involved as subjects in clinical investigations of FDA-regulated products.
products, as required by the Children’s Health Act of 2000.

**Timetable:**

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**Regulatory Flexibility Analysis**

Required: No

**Small Entities Affected:** No

**Government Levels Affected:** None

**Agency Contact:** Carol Drew, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, 5515 Security Lane, Suite 1101 (HFĐ–7), Rockville, MD 20852

Phone: 301 594–2041
Fax: 301 827–5562

RIN: 0910–AC07

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**894. PREVENTION OF SALMONELLA ENTERITIDIS IN SHELL EGGS**

**Priority:** Economically Significant. Major under 5 USC 801.

**Unfunded Mandates:** This action may affect the private sector under PL 104-4.

**Legal Authority:** 21 USC 321; 21 USC 342; 21 USC 371; 21 USC 381; 21 USC 393; 42 USC 243; 42 USC 264; 42 USC 271; . . .

**CFR Citation:** 21 CFR 16; 21 CFR 116; 21 CFR 118

**Legal Deadline:** None

**Abstract:** In July 1999, the Food and Drug Administration (FDA) and the Food Safety Inspection Service (FSIS) committed to developing an action plan to address the presence of salmonella enteritidis (SE) in shell eggs and egg products using a farm-to-table approach. FDA and FSIS held a public meeting on August 26, 1999, to obtain stakeholder input on the draft goals, as well as to further develop the objectives and action items for the action plan. The Egg Safety Action Plan was announced on December 11, 1999. The goal of the Action Plan is to reduce egg-related SE illnesses by 50 percent by 2005 and eliminate egg-related SE illnesses by 2010.

The Egg Safety Action Plan consists of eight objectives covering all stages of the farm-to-table continuum as well as support functions. On March 30, 2000 (Columbus, OH), April 6, 2000 (Sacramento, CA), and July 31, 2000 (Washington, DC), joint public meetings were held by FDA and FSIS to solicit and discuss information related to the implementation of the objectives in the Egg Safety Action Plan.

On September 22, 2004, FDA published a proposed rule that would require egg safety measures to prevent the contamination of shell eggs with SE during egg production. This proposal would reduce SE prevalence in the egg production environment and consequently in the eggs themselves. Most SE contamination of eggs is a result of SE infection in the laying hen’s reproductive tract, called transovarian contamination. The proposed measures are designed to reduce the likelihood of this transovarian contamination and include: (1) Provisions for procurement of chicks and pullets; (2) a biosecurity program; (3) a rodent and pest control program; (4) cleaning and disinfection of poultry houses that have had an environmental or egg test positive for SE; (5) egg testing when an environmental test is positive; and (6) refrigerated storage of eggs held at the farm.

Additionally, to verify that the measures have been effective, the rule proposes that producers test the poultry house environment for SE. If the environmental test is positive, eggs from that environment must be tested for SE, and if the egg test is positive, the eggs must be diverted to egg products processing or a treatment process that achieves at least a 5-log destruction of SE.

The proposed rule is one step in a broader farm-to-table egg safety effort that includes FDA's requirements for safe handling statements on egg cartons and refrigerated storage of shelf eggs at retail and egg safety education for consumers and retail establishments. The rule had a 90-day comment period, which ended December 21, 2004. To discuss the proposed rule and solicit comments from interested stakeholders, FDA held three public meetings: October 28, 2004, in College Park, MD; November 9, 2004, in Chicago, IL; and November 16, 2004, in Los Angeles, CA.

The comment period was reopened until July 25, 2005 to solicit further comments and information on industry practices and programs that prevent SE monitored chicks from becoming infected by SE during the period of pullet rearing until placement into laying hen houses.

**Timetable:**

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<td>09/22/04</td>
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**Regulatory Flexibility Analysis**

Required: Yes

**Small Entities Affected:** Businesses

**Government Levels Affected:** State

**Federalism:** This action may have federalism implications as defined in EO 13132.

**Agency Contact:** John Sheehan, Supervisory Food Technologist, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition (HFS–032), 5100 Paint Branch Parkway, College Park, MD 20740

Phone: 301 436–4488
Fax: 301 436–2632
Email: john.sheehan@fda.hhs.gov

RIN: 0910–AC14

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**895. INSTITUTIONAL REVIEW BOARDS: REGISTRATION REQUIREMENTS**

**Priority:** Info./Admin./Other

**Legal Authority:** 21 USC 321; 21 USC 346 to 21 USC 346a; 21 USC 348; 21 USC 351 to 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

**CFR Citation:** 21 CFR 56.106

**Legal Deadline:** None

**Abstract:** The final rule would require institutional review boards (IRB) to register with the Department of Health and Human Services. The registration information would include the name of the IRB, the name of the institution operating the IRB, and names, addresses, phone numbers, facsimile (fax) numbers, and electronic mail (e-mail) addresses of the senior officer of the institution and IRB chair or contact, the number of active protocols involving FDA-regulated products reviewed in the previous calendar year, and a description of the types of FDA-regulated products reviewed. The final rule would make it easier for FDA to inspect IRBs and to convey information to IRBs.
Abstract: This interim final rule will add an 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.

Timetable:

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Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Catherine Lorraine, Director, Policy Development and Coordination Group, Office of Policy and Planning, Department of Health and Human Services, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857

Phone: 301 827–3360
Fax: 301 594–6777

RIN: 0910–AC17

898. TOLL–FREE NUMBER FOR REPORTING ADVERSE EVENTS ON LABELING FOR HUMAN DRUGS

Priority: Other Significant
Legal Authority: 21 USC 355b
CFR Citation: 21 CFR 201; 21 CFR 208; 21 CFR 209

Abstract: To require the labeling of human drugs approved under section 505 of the Federal Food, Drug, and Cosmetic Act to include a toll-free number for reports of adverse events, and a statement that the number is to be used for reporting purposes only and not to receive medical advice.

Timetable:

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Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Carol Drew, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, 5515 Security Lane, Suite 1101 (HFD–7), Rockville, MD 20852

Phone: 301 594–2041
Fax: 301 827–5562

RIN: 0910–AC35

899. PRIOR NOTICE OF IMPORTED FOOD UNDER THE PUBLIC HEALTH SECURITY AND BIOTERRORISM PREPAREDNESS AND RESPONSE ACT OF 2002

Priority: Other Significant. Major under 5 USC 801.
Legal Authority: PL 107–188, sec 307
CFR Citation: 21 CFR 1.276 et seq

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002, section 307, directs the Secretary, through FDA, to issue final regulations establishing prior notice requirements for all imported food by December 12, 2003. If FDA fails to issue final regulations by this date,
the statute is self-executing on this date, and requires FDA to receive prior notice of not less than eight hours, nor more than five days until final regulations are issued.

Abstract: This rulemaking is one of a number of actions being taken to improve FDA’s ability to respond to threats of bioterrorism. Section 801(m) of the Federal Food, Drug, and Cosmetic Act (FFDCA), which was added by section 307 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), requires notification to FDA prior to the entry of imported food. The required prior notice would provide the identity of the article of food; the manufacturer; the shipper; the grower, if known at the time of notification; the originating country; the shipping country; and the anticipated port of entry. The regulation identifies the parties responsible for providing the notice and explains the information that the prior notice is required to contain, the method of submission of the notice, and the minimum and maximum period of advance notice required. Section 307 also states that if FDA does not receive prior notice or receives inadequate prior notice, the imported food shall be refused admission and held at the port of entry until proper notice is provided.

Section 307 authorizes the Secretary, through FDA, to promulgate final regulations by December 12, 2003. FDA and CBP issued an interim final rule (IFR) on October 10, 2003 (68 FR 58974). The IFR originally provided a 75-day comment period to ensure that those that comment on the IFR have the benefit of our outreach and educational efforts and have the experience with the systems, timeframes, and data elements. We reopened the comment period for an additional 90 days in April through July 2004 to allow for additional comment on the industry’s experience with the prior notice system, and comment on the Joint FDA-CBP Plan for Increasing Integration and Assessing the Coordination of Prior Notice Timeframes. The final rule currently is under development, and it will confirm or amend the IFR, as appropriate. This final rule is not expected to have a significant impact on a substantial number of small entities.

**Timetable:**

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**Regulatory Flexibility Analysis**

**Required:** Yes

**Small Entities Affected:** Businesses

**Government Levels Affected:** Federal

**Agency Contact:** May Nelson, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, College Park, MD 20740

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Fax: 301 436–2637
Email: may.nelson@fda.hhs.gov

**RIN:** 0910–AC41

**900. POSITRON EMISSION TOMOGRAPHY DRUGS; CURRENT GOOD MANUFACTURING PRACTICES**

**Priority:** Other Significant

**Legal Authority:** PL 105–115, sec 121

**CFR Citation:** 21 CFR 212

**Legal Deadline:** Final, Statutory, November 21, 1999.

**Abstract:** Section 121 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105-115) directs FDA to establish requirements for current good manufacturing practices (CGMPs) for positron emission tomography (PET) drugs, a type of radiopharmaceutical. The proposed rule would adopt CGMPs that reflect the unique characteristics of PET drugs.

**Timetable:**

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**Regulatory Flexibility Analysis**

**Required:** Yes

**Small Entities Affected:** Governmental Jurisdictions

**Government Levels Affected:** Federal, State

**URL For More Information:**

www.fda.gov/cder/regulatory/pet

**Agency Contact:** Brian L. Pendleton, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, 5515 Security Lane, Suite 1101 (HFD–7), Rockville, MD 20852

Phone: 301 594–2041

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Email: brian.pendleton@fda.hhs.gov

**Related RIN:** Previously reported as 0910–AB63

**RIN:** 0910–AC55

**901. HUMAN SUBJECT PROTECTION; FOREIGN CLINICAL STUDIES NOT CONDUCTED UNDER AN INVESTIGATIONAL NEW DRUG APPLICATION**

**Priority:** Substantive, Nonsignificant.

Major status under 5 USC 801 is undetermined.

**Legal Authority:** 21 USC 355(d)(5); 21 USC 355(i); 21 USC 371(a); 42 USC 262(a)(2)(A); 42 USC 262(a)(2)(B)(i)(l)

**CFR Citation:** 21 CFR 312.120

**Legal Deadline:** None

**Abstract:** This final rule follows a proposed rule, which proposed to update the standards for the acceptance of foreign clinical studies not conducted under an investigational new drug application (IND) as support for an IND or marketing application for a drug or biological product. We proposed to replace the requirement in 21 CFR 312.120 that non-IND foreign clinical studies be conducted in accordance with ethical principles stated in the Declaration of Helsinki or with the laws and regulations of the country that is the research site, whichever provide greater protection to subjects. We would replace that with a requirement that such studies be conducted in accordance with good clinical practice (GCP), including review and approval by an independent ethics committee. The proposed GCP standard is consistent with the standard of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use for GCP and is sufficiently flexible to accommodate differences in how countries regulate the conduct of clinical research and obtain the informed consent of patients.
902. REVOCATION OF THE STATUS OF SPECIFIC PRODUCTS; GROUP A STREPTOCOCCUS

Priority: Info./Admin./Other

Legal Citation: 21 CFR 610.19

Legal Deadline: None

Abstract: FDA issued a direct final rule and companion proposed rule to revoke 21 CFR 610.19, Status of specific products; Group A streptococcus. The products had been licensed by the National Institutes of Health prior to 1972, when regulatory authority over these products was transferred to FDA. The regulation prohibits the use of Group A streptococcus organisms and derivatives of Group A streptococcus as ingredients in Bacterial Vaccines and Bacterial Antigens with “No U.S. Standard of Potency.” The regulation was written to apply to a group of products that are no longer on the market, namely, streptococcus vaccines and antigens with “No U.S. Standard of Potency” that were not purified. The regulation was never intended to refer to purified streptococcus vaccines, which were not developed at that time. Therefore, the regulation is being revoked.

Timetable:

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903. OBSTETRICAL AND GYNECOLOGICAL DEVICES; DESIGNATION OF SPECIAL CONTROL FOR CONDOMS AND CONDOMS WITH SPERMICIDAL LUBRICANT

Priority: Other Significant

Legal Authority: 21 USC 360c

CFR Citation: 21 CFR 884.5300; 21 CFR 884.5310

Legal Deadline: None

Abstract: The classification regulations for male condoms would be amended to specify a labeling guidance document as a special control for condoms made from natural rubber latex. The new special control guidance document would identify issues presented by these devices, and would provide detailed recommendations for labeling to address these issues. FDA believes that compliance with the recommendations in the guidance, or with some equivalent means of addressing the identified issues together with the general controls, will provide a reasonable assurance of the safety and effectiveness of these devices. These labeling recommendations are also consistent with the labeling requirements of 21 CFR 801. The rule will demonstrate how the Agency is moving forward to meet the congressional directive of Public Law 106-554 that FDA review condom labeling to assure that the information regarding the overall effectiveness or lack of effectiveness of condoms in preventing sexually transmitted diseases is medically accurate.

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Valerie Butler, Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, Center for Biologics Evaluation and Research, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852

Phone: 301 827–6210

Fax: 301 827–9434

RIN: 0910–AF20

904. BLOOD INITIATIVE—REVISIONS TO LABELING REQUIREMENTS FOR BLOOD AND BLOOD COMPONENTS, INCLUDING SOURCE PLASMA; AND TECHNICAL AMENDMENT

Priority: Other Significant

Legal Authority: 21 USC 321; 21 USC 360j; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371; 21 USC 374; 42 USC 216; 42 USC 262; 42 USC 263; 42 USC 263a; 42 USC 264; 42 USC 300aa to 25; 21 USC 331; 21 USC 310

CFR Citation: 21 CFR 606; 21 CFR 610; 21 CFR 640

Legal Deadline: None

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 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.

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Myrna Hanna, Regulations Staff, Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, HFZ–215, 1350 Piccard Drive, P150 RM150F, Rockville, MD 20850

Phone: 240 276–2347

Fax: 240 276–2352

Email: myrna.hanna@fda.hhs.gov

RIN: 0910–AF21
HHS—FDA

Final Rule Stage

Regulatory Flexibility Analysis

Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Melissa Scales, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, HFS–024, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, College Park, MD 20740

Phone: 301 436–1720

Email: melissa.scales@fda.hhs.gov

Related RIN: Split from 0910–AA04

RIN: 0910–AF28

907. OVER–THE–COUNTER (OTC) DRUG REVIEW—COUGH/COLD (BRONCHODILATOR) PRODUCTS

Priority: Routine and Frequent

Legal Authority: 21 USC 321p; 21 USC 351 to 353; 21 USC 355; 21 USC 360a; 21 USC 371a; 21 USC 331; 21 USC 360; 21 USC 371

CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358

Legal Deadline: None

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 these products.

Timetable:

Action | Date | FR Cite
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NPRM | 07/09/96 | 61 FR 36154
NPRM Comment Period End | 12/06/96 | 
NPRM Comment Period Reopened | 04/28/03 | 68 FR 22341
NPRM Comment Period Extended | 06/27/03 | 68 FR 38247
NPRM Comment Period End | 08/26/03 | 
Final Action | 12/00/06 | 

Regulatory Flexibility Analysis

Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Local, State

Federalism: This action may have federalism implications as defined in EO 13132.

Agency Contact: Gerald M. Rachanow, Regulatory Counsel, Division of Over–the–Counter Drug Products, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, 5600 Fishers Lane, HFD–560, Rockville, MD 20857

Phone: 301 827–2241

Fax: 301 827–2315

Email: gerald.rachanow@fda.hhs.gov

Related RIN: Split from 0910–AA04

RIN: 0910–AF28

905. INFANT FORMULA: CURRENT GOOD MANUFACTURING PRACTICES; QUALITY CONTROL PROCEDURES; NOTIFICATION REQUIREMENTS; RECORDS AND REPORTS

Priority: Other Significant

Legal Authority: 21 USC 321; 21 USC 350a; 21 USC 371; …

CFR Citation: 21 CFR 106; 21 CFR 107

Legal Deadline: None

Abstract: 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, and 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 period was extended on June 27, 2003, to end on August 26, 2003.

Timetable:

Action | Date | FR Cite
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NPRM | 07/09/96 | 61 FR 36154
NPRM Comment Period End | 12/06/96 | 
NPRM Comment Period Reopened | 04/28/03 | 68 FR 22341
NPRM Comment Period Extended | 06/27/03 | 68 FR 38247
NPRM Comment Period End | 08/26/03 | 
Final Action | 12/00/06 | 

Regulatory Flexibility Analysis

Required: No

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Melissa Scales, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, HFS–024, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, College Park, MD 20740

Phone: 301 436–1720

Email: melissa.scales@fda.hhs.gov

Related RIN: Split from 0910–AA04

RIN: 0910–AF27

RIN: 0910–AF28

RIN: 0910–AF29
908. OVER–THE–COUNTER (OTC) DRUG REVIEW—COUGH/COLD (COMBINATION) PRODUCTS

Priority: Routine and Frequent
Legal Authority: 21 USC 321p; 21 USC 351 to 353; 21 USC 355; 21 USC 360a; 21 USC 371a; 21 USC 331; 21 USC 360; 21 USC 371
CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358

Legal Deadline: None

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 ingredient phenylephrine bitartrate, and the other action addresses the ingredient phenylpropanolamine.

Timetable:

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Regulatory Flexibility Analysis
Required: Yes
Small Entities Affected: Businesses
Government Levels Affected: Local, State

Federalism: This action may have federalism implications as defined in EO 13132.

Agency Contact: Gerald M. Rachanow, Regulatory Counsel, Division of Over–the–Counter Drug Products, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, 5600 Fishers Lane, HFD–560, Rockville, MD 20857 Phone: 301 827–2241 Fax: 301 827–2315 Email: gerald.rachanow@fda.hhs.gov
Related RIN: Split from 0910–AA01
RIN: 0910–AF33

909. OVER–THE–COUNTER (OTC) DRUG REVIEW—COUGH/COLD (NASAL DECONGESTANT) PRODUCTS

Priority: Routine and Frequent
Legal Authority: 21 USC 321p; 21 USC 351 to 353; 21 USC 355; 21 USC 360a; 21 USC 371a; 21 USC 331; 21 USC 360; 21 USC 371

910. OVER–THE–COUNTER (OTC) DRUG REVIEW—LAXATIVE DRUG PRODUCTS

Priority: Routine and Frequent
Legal Authority: 21 USC 321p; 21 USC 351 to 353; 21 USC 355; 21 USC 360a; 21 USC 371a; 21 USC 331; 21 USC 360; 21 USC 371

CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358

Legal Deadline: None
### 912. OVER–THE–COUNTER (OTC) DRUG REVIEW—VAGINAL CONTRACEPTIVE PRODUCTS

**Priority:** Routine and Frequent

**Legal Authority:** 21 USC 321p; 21 USC 351 to 353; 21 USC 353; 21 USC 360a; 21 USC 371a; 21 USC 331; 21 USC 358; 21 USC 360; 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

**CFR Citation:** 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358

**Legal Deadline:** None

**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 labeling for products formulated and marketed as skin protectants. The second action addresses skin protectant products to protect and treat fever blisters and cold sores.

**Timetable:**

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### 914. USE OF MATERIALS DERIVED FROM CATTLE IN HUMAN FOOD AND COSMETICS

**Priority:** Other Significant

**Legal Authority:** 21 USC 342; 21 USC 361; 21 USC 371

**CFR Citation:** 21 CFR 189.5; 21 CFR 700.27

**Legal Deadline:** None

**Abstract:** On July 14, 2004, FDA issued an interim final rule (IFR), effective immediately, to prohibit the use of certain cattle origin materials in the food or feed of all animals to help strengthen existing safeguards to prevent the spread of bovine spongiform encephalopathy (BSE) in U.S. cattle. The discovery of a BSE-positive dairy cow in December 2003 has caused FDA to review its policies for prevention of BSE which resulted in this rulemaking.

**Timetable:**

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**Regulatory Flexibility Analysis**

**Required:** Yes

**Small Entities Affected:** Businesses

**Government Levels Affected:** None

**Agency Contact:** Burt Pritchett, Biologist, Department of Health and Human Services, Food and Drug Administration, Center for Veterinary Medicine, HFV–222, 7519 Standish Place, MPN–4, Rockville, MD 20855 Phone: 240 453–6860 Fax: 240 453–6882 Email: burt.pritchett@fda.hhs.gov

**Related RIN:** Split from 0910–AA01

**RIN:** 0910–AF46

### 913. SUBSTANCES PROHIBITED FROM USE IN ANIMAL FOOD OR FEED

**Priority:** Other Significant

**Legal Authority:** 21 USC 321; 21 USC 342; 21 USC 343; 21 USC 349; 21 USC 371

**CFR Citation:** 21 CFR 589.2001

**Legal Deadline:** None

**Abstract:** On October 6, 2005, the Food and Drug Administration (FDA) proposed to amend its regulations to prohibit the use of certain cattle origin materials in the food or feed of all animals to help strengthen existing safeguards to prevent the spread of bovine spongiform encephalopathy (BSE) in U.S. cattle. The discovery of a BSE-positive dairy cow in December 2003 has caused FDA to review its policies for prevention of BSE which resulted in this rulemaking.
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. After reviewing comments received to the interim final rule, FDA intends to issue a final rule.

On September 7, 2005, FDA amended the IFR to permit the use of small intestine in human food and cosmetics if it is effectively removed from the distal ileum. The amendment also clarified that milk and milk products, hides, and tallow derivatives are not prohibited for use in human food and cosmetics.

**Timetable:**

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**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** No

**Agency Contact:** Morris E. Potter, Lead Scientist for Epidemiology, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition, HFS–032, 60 Eighth St., NE, Atlanta, GA 30309

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Fax: 404–253–1218
Email: morris.potter@fda.hhs.gov

**RIN:** 0910–AF47

915. RECORDKEEPING REQUIREMENTS FOR HUMAN FOOD AND COSMETICS MANUFACTURED FROM, PROCESSED WITH, OR OTHERWISE CONTAINING MATERIAL FROM CATTLE

**Priority:** Other Significant

**Legal Authority:** 21 USC 342; 21 USC 361; 21 USC 371; 21 USC 381

**CFR Citation:** 21 CFR 189.5; 21 CFR 700.27

**Legal Deadline:** None

**Abstract:** On July 14, 2004, FDA proposed to require that manufacturers and processors of human food and cosmetics that are manufactured from, processed with, or otherwise contain, material from cattle must establish and maintain records sufficient to demonstrate the food or cosmetic is not manufactured from, processed with, or does not otherwise contain, prohibited cattle materials. This is a companion rulemaking to FDA’s interim final rule entitled “Use of Materials Derived From Cattle in Human Food and Cosmetics.” FDA intends to finalize this proposal after reviewing any comments received.

**Timetable:**

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**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** Businesses

**Government Levels Affected:** None

**Agency Contact:** Rebecca Buckner, Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, HFS–366, College Park, MD 20740

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Fax: 301 436–2632
Email: rebecca.buckner@fda.hhs.gov

**RIN:** 0910–AF48

916. OVER–THE–COUNTER (OTC) DRUG REVIEW—OVERINDULGENCE IN FOOD AND DRINK PRODUCTS

**Priority:** Routine and Frequent

**Legal Authority:** 21 USC 321p; 21 USC 351 to 353; 21 USC 355; 21 USC 360a; 21 USC 371; 21 USC 371a; 21 USC 371a

**CFR Citation:** 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358

**Legal Deadline:** None

**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 combinations containing coal tar solution and menthol in a shampoo product.

**Timetable:**

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**Regulatory Flexibility Analysis Required:** Yes

**Small Entities Affected:** Businesses

**Government Levels Affected:** Local, State

**Federalism:** This action may have federalism implications as defined in EO 13132.

**Agency Contact:** Gerald M. Rachanow, Regulatory Counsel, Division of Over-the-Counter Drug Products, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, 5600 Fishers Lane, HFD–560, Rockville, MD 20857

Phone: 301 827–2241
Fax: 301 827–2315
Email: gerald.rachanow@fda.hhs.gov

**RIN:** 0910–AF49
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.

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**Other Significant**

**Priority:** Routine and Frequent

**Legal Authority:** 21 USC 321p; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 360a; 21 USC 371a; 21 USC 331

**CFR Citation:** 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358

**Legal Deadline:** None

**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.

**Regulatory Flexibility Analysis Required:** Yes

**Small Entities Affected:** Businesses

**Government Levels Affected:** Local, State

**Federalism:** This action may have federalism implications as defined in EO 13132.

**Agency Contact:** Gerald M. Rachanow, Regulatory Counsel, Division of Over-the-Counter Drug Products, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, 5600 Fishers Lane, HFD–560, Rockville, MD 20857 Phone: 301 827–2241 Fax: 301 827–2315 Email: gerald.rachanow@fda.hhs.gov

**RIN:** 0910–AF51

919. SUPPLEMENTS AND OTHER CHANGES TO APPROVED NEW ANIMAL DRUG APPLICATIONS

**Priority:** Substantive, Nonsignificant

**Legal Authority:** 21 USC 356a

**CFR Citation:** 21 CFR 25; 21 CFR 500; 21 CFR 514; 21 CFR 558

**Legal Deadline:** None

**Abstract:** The Food and Drug Administration (FDA) is amending its regulations on supplements and other changes to approved new animal drug applications (NADAs) or abbreviated new animal drug applications (ANADAs) to implement the manufacturing changes provision of the Food and Drug Modernization Act of 1997. The final rule requires manufacturers to assess the effect of a manufacturing change on the identity, strength, quality, purity, and potency of a drug as those factors relate to the safety or effectiveness of the drug. The final rule sets forth requirements for changes requiring submission and approval of a supplement before the distribution of the drug made using the change, changes requiring the submission of a supplement at least 30 days prior to the distribution of the drug, changes requiring the submission of a supplement at the time of distribution of the drug, and changes to be described in an annual report.

**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** Businesses

**Government Levels Affected:** None

**Agency Contact:** Dennis Bensley Jr., Chemist, Department of Health and Human Services, Food and Drug Administration, 7500 Standish Place, MPN–2, Room 320, HFV–140, Rockville, MD 20855 Phone: 301 827–6956 Email: dennis.bensley@fda.hhs.gov

**RIN:** 0910–AF59

920. DESIGNATION OF NEW ANIMAL DRUGS FOR MINOR USES OR MINOR SPECIES

**Priority:** Other Significant

**Legal Authority:** 21 USC 360ccc–2

**CFR Citation:** 21 CFR 516

**Legal Deadline:** NPRM, Statutory, August 2, 2005. Final, Statutory, August 2, 2006.

**Abstract:** The proposed rule was published on September 27, 2005, in response to the Minor Use and Minor Species (MUMS) Animal Health Act of 2004. The proposed rule would implement section 573 of the MUMS Act which sets forth the requirements for drug sponsors requesting MUMS designation for proposed new animal drugs. MUMS designation of a new animal drug allows drug sponsors to be granted seven years of exclusive marketing rights for these limited demand new animal drugs once the drugs are approved or conditionally approved. This regulation would define content and format requirements for designation, requests changing designation ownership, and annual reporting requirements. This rule would also describe the criteria CVM will use for granting or denying these requests. Specific sections of the rule
are dedicated to documentation of MUMS status in a request, granting MUMS designation, and revocation of MUMS designation. FDA intends to finalize this proposal after reviewing any comments received. This is a voluntary program for animal drug sponsors. While we do not have estimates of the impact on the animal drug industry, we expect that this rule will have a net beneficial impact on the industry with those firms participating who hope to profit as a result of the market exclusivity provided by the MUMS Act. A large number of these drug companies are classified as small businesses.

**Timetable:**

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**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** Businesses

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**Government Levels Affected:** None

**Agency Contact:** Andrew J. Beaulieu, Director, Office of Minor Use and Minor Species Animal Drug Development, Department of Health and Human Services, Food and Drug Administration, Center for Veterinary Medicine, 7519 Standish Place, Room 10855, Phone: 240 276–9090, Fax: 240–276–9001, Email: andrew.beaulieu@fda.hhs.gov

**RIN:** 0910–AF60

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**Department of Health and Human Services (HHS)**

**Food and Drug Administration (FDA)**

### 921. CHRONIC WASTING DISEASE: CONTROL OF FOOD PRODUCTS AND COSMETICS DERIVED FROM EXPOSED ANIMAL POPULATIONS

**Priority:** Other Significant

**Legal Authority:** 42 USC 264; 21 USC 301 et seq

**CFR Citation:** Not Yet Determined

**Legal Deadline:** None

**Abstract:** The Food and Drug Administration (FDA) is proposing to prohibit the use of cervids (deer, elk) for food, including dietary supplements, and cosmetics if the cervids have been exposed to chronic wasting disease (CWD). FDA is proposing this regulation because of potential risks to health.

CWD is a type of transmissible spongiform encephalopathy (TSE), a group of fatal, neurodegenerative diseases that include bovine spongiform encephalopathy (BSE) in cattle, scrapie in sheep and goats, and Creutzfeldt-Jakob disease (CJD) in humans. The disease has been identified in wild and farmed elk and wild deer populations.

CWD has been found in cervid populations in certain areas of Wisconsin, Colorado, Nebraska, Wyoming, Kansas, Montana, Oklahoma, South Dakota, New Mexico, Minnesota, and Canada. In 1999, the World Health Organization said there is no evidence that CWD transmits to humans. However, it also suggested any part of a deer or elk believed to be diseased should not be eaten. Results of some studies using in vitro techniques have suggested that transmission to humans could possibly occur. However, if it does occur, it is likely to be through a very inefficient process.

Currently, there are no validated analytical tests to identify animals in the preclinical phase of CWD, or any other TSE. In addition, no test exists to ensure food safety. CWD typically exhibits a long incubation period, during which time animals appear normal but are potentially infectious. Therefore, DA is proposing to require that food or cosmetic products derived from animals exposed to CWD not enter into commerce.

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis Required:** Yes

**Small Entities Affected:** Businesses

**Government Levels Affected:** Undetermined

**Federalism:** Undetermined

**Agency Contact:** Rebecca Buckner, Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, HFS–366, College Park, MD 20740, Phone: 301 436–486, Fax: 301 436–2632, Email: rebecca.buckner@fda.hhs.gov

**RIN:** 0910–AC21

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**922. REQUIREMENTS FOR SUBMISSION OF IN VIVO BIOEQUIVALENCE DATA**

**Priority:** Substantive, Nonsignificant

**Legal Authority:** 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355;

21 USC 355a; 21 USC 356; 21 USC 356a to 356c; 21 USC 371; 21 USC 374; 21 USC 379

**CFR Citation:** 21 CFR 314.96(a)(1); 21 CFR 314.94(a)(7); 21 CFR 320.21(b)(1)

**Legal Deadline:** None

**Abstract:** The Food and Drug Administration (FDA) is proposing to amend its regulations on submission of bioequivalence (BE) data to require an abbreviated new drug application (ANDA) applicant to submit data from all BE studies the applicant conducts on a drug product formulation submitted for approval. In the past, ANDA applicants have submitted BE studies demonstrating that a generic product meets BE criteria for FDA to approve the ANDA but have not typically submitted additional BE studies conducted on the same drug product formulation. FDA is proposing to require ANDA applicants to submit information, in either a complete or summary report, from all additional passing and nonpassing BE studies conducted on the same drug product formulation submitted for approval.

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**Regulatory Flexibility Analysis Required:** Yes

**Small Entities Affected:** Businesses

**Government Levels Affected:** None

**Agency Contact:** Christine F. Rogers, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug
923. FOOD LABELING: TRANS FATTY ACIDS IN NUTRITION LABELING: CONSUMER RESEARCH TO CONSIDER NUTRIENT CONTENT AND HEALTH CLAIMS AND POSSIBLE FOOTNOTE OR DISCLOSURE STATEMENTS

Priority: Other Significant
Legal Authority: 21 USC 321; 21 USC 336; 21 USC 371
CFR Citation: 21 CFR 101

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.

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924. FOOD STANDARDS: GENERAL PRINCIPLES AND FOOD STANDARDS MODERNIZATION

Priority: Other Significant
Legal Authority: 21 USC 321; 21 USC 336; 21 USC 341; 21 USC 343; 21 USC 371
CFR Citation: 21 CFR 130.5

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.

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925. CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PROCESSING, PACKING, OR HOLDING OF DRUGS; REVISION OF CERTAIN LABELING CONTROLS

Priority: Substantive, Nonsignificant. Major status under 5 USC 801 is undetermined.

Unfunded Mandates: Undetermined
Legal Authority: 21 USC 351
CFR Citation: 21 CFR 211.122
Legal Deadline: None

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.

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Regulatory Flexibility Analysis
Required: Undetermined
Small Entities Affected: Businesses
Government Levels Affected: None
Federalism: Undetermined

Agency Contact: Howard P. Muller, Office of Regulatory Policy, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, 5515 Security Lane, Suite 1101 (HFD–7), Rockville, MD 20852
Phone: 301 594–2041
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Email: howard.mullerjr@fda.hhs.gov
RIN: 0910–AF08

926. HEALTH CLAIMS

Priority: Other Significant
Unfunded Mandates: Undetermined
Legal Authority: 21 USC 343; 21 USC 371
CFR Citation: Not Yet Determined
Legal Deadline: None

Abstract: On November 25, 2003 (68 FR 66040), FDA issued an advance notice of proposed rulemaking (ANPRM) to request comments on alternatives for regulating qualified health claims in the labeling of conventional human foods and dietary supplements. FDA also solicited comments on various other issues related to health claims and on the appropriateness and nature of dietary guidance statements on conventional food and dietary supplement labels. This ANPRM was signaled in the July 11, 2003 (68 FR 41387) notice that announced the availability of the final report of the FDA Task Force on the Consumer Health Information for Better Nutrition Initiative.

Comments on the regulatory alternatives and additional topics identified in the ANPRM will inform FDA decisions about regulation of qualified health claims.

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Regulatory Flexibility Analysis
Required: Yes
Small Entities Affected: Businesses
Government Levels Affected: None
Federalism: Undetermined

Agency Contact: Nancy Crane, Department of Health and Human Services, Food and Drug Administration, HFS–830, 5100 Paint Branch Parkway, College Park, MD 20740
Phone: 301 436–1456
Fax: 301 436–2636
Email: nancy.crane@fda.hhs.gov
RIN: 0910–AF09

927. FOOD LABELING; PROMINENCE OF CALORIES

Priority: Other Significant
Legal Authority: 21 USC 321; 21 USC 343; 21 USC 371
CFR Citation: 21 CFR 101.9

Legal Deadline: None

Abstract: In response to the Report of the Working Group on Obesity (OWG) that FDA issued on March 12, 2004, the Agency issued on April 4, 2005, an advance notice of proposed rulemaking (ANPRM) in its efforts to combat the Nation’s obesity problem. The ANPRM requested comments on ways to give more prominence to “calories” on the food label.

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928. 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

Priority: Other Significant
Legal Authority: 21 USC 321; 21 USC 343; 21 USC 371
CFR Citation: 21 CFR 101.9; 21 CFR 101.12; 21 CFR 101.60(b)

Legal Deadline: None

Abstract: In response to the Report of the Working Group on Obesity that FDA issued on March 12, 2004, the Agency issued on April 4, 2005, an advance notice of proposed rulemaking (ANPRM) in its efforts to combat the Nation’s obesity problem. The ANPRM requested comments on ways to give more prominence to “calories” on the food label.

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Regulatory Flexibility Analysis
Required: Undetermined
929. OVER–THE–COUNTER (OTC) DRUG REVIEW—COUGH/COLD (ANTIHISTAMINE) PRODUCTS

Priority: Routine and Frequent

Legal Authority: 21 USC 321p; 21 USC 351 to 353; 21 USC 355; 21 USC 360a; 21 USC 371a; 21 USC 331; 21 USC 360; 21 USC 371

CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358

Legal Deadline: None

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

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Local, State

Federalism: This action may have federalism implications as defined in EO 13132.

Agency Contact: Gerald M. Rachanow, Regulatory Counsel, Division of Over–the–Counter Drug Products, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, 5600 Fishers Lane, HFD–560, Rockville, MD 20857 Phone: 301 827–2241 Fax: 301 827–2315 Email: gerald.rachanow@fda.hhs.gov

Related RIN: Split from 0910–AA01

RIN: 0910–AF23

930. OVER–THE–COUNTER (OTC) DRUG REVIEW—EXTERNAL ANALGESIC PRODUCTS

Priority: Routine and Frequent

Legal Authority: 21 USC 321p; 21 USC 351 to 353; 21 USC 355; 21 USC 360a; 21 USC 371a; 21 USC 331; 21 USC 360; 21 USC 371

CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358

Legal Deadline: None

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

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Local, State

Federalism: This action may have federalism implications as defined in EO 13132.

Agency Contact: Gerald M. Rachanow, Regulatory Counsel, Division of Over–the–Counter Drug Products, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, 5600 Fishers Lane, HFD–560, Rockville, MD 20857 Phone: 301 827–2241 Fax: 301 827–2315 Email: gerald.rachanow@fda.hhs.gov

Related RIN: Split from 0910–AA01

RIN: 0910–AF31

931. OVER–THE–COUNTER (OTC) DRUG REVIEW—ORAL HEALTH CARE PRODUCTS

Priority: Routine and Frequent

Legal Authority: 21 USC 321p; 21 USC 351 to 353; 21 USC 355; 21 USC 360a; 21 USC 371a; 21 USC 331; 21 USC 360; 21 USC 371

CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358

Legal Deadline: None

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e. final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action will address oral health care products used to reduce or prevent dental plaque and gingivitis.

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Local, State

Federalism: This action may have federalism implications as defined in EO 13132.

Agency Contact: Gerald M. Rachanow, Regulatory Counsel, Division of Over–the–Counter Drug Products, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, 5600 Fishers Lane, HFD–560, Rockville, MD 20857 Phone: 301 827–2241 Fax: 301 827–2315 Email: gerald.rachanow@fda.hhs.gov

Related RIN: Split from 0910–AA01

RIN: 0910–AF40

932. USE OF MATERIALS DERIVED FROM CATTLE IN MEDICAL PRODUCTS INTENDED FOR USE IN HUMANS AND DRUGS INTENDED FOR USE IN RUMINANTS

Priority: Other Significant

Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351; 21 USC 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

CFR Citation: 21 CFR 211; 21 CFR 300; 21 CFR 500; 21 CFR 530; 21 CFR 600; 21 CFR 895.102; 21 CFR 1271.465; 21 CFR 1271.470

Email: gerald.rachanow@fda.hhs.gov

Related RIN: Split from 0910–AA01

RIN: 0910–AF35
### 933. OVER-THE-COUNTER (OTC) DRUG REVIEW—POISON TREATMENT DRUG PRODUCTS

**Priority:** Routine and Frequent. Major status under 5 USC 801 is undetermined.

**Legal Deadline:** None

**Abstract:** The regulation would prohibit the use of certain cattle material in the manufacture of medical products for humans and 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 rules. 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.

**Timetable:**

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**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** None

**Agency Contact:** Eric Flamm, Senior Policy Advisor, Office of Policy, Department of Health and Human Services, Food and Drug Administration, Office of the Commissioner, 5600 Fishers Lane, Room 14C–17, HF–23, Rockville, MD 20857

Phone: 301 827–0591
Fax: 301 827–4774

Email: eric.flamm@fda.hhs.gov

**Related RIN:** Merged with 0910–AF55

**RIN:** 0910–AF54

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### 934. OVER-THE-COUNTER (OTC) DRUG REVIEW—URINARY ANALGESIC DRUG PRODUCTS

**Priority:** Routine and Frequent. Major status under 5 USC 801 is undetermined.

**Legal Deadline:** None

**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.

**Timetable:**

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**Regulatory Flexibility Analysis Required:** Yes

**Small Entities Affected:** Businesses

**Government Levels Affected:** Local, State

**Federalism:** This action may have federalism implications as defined in EO 13132.

**Agency Contact:** Walter Ellenberg, Regulatory Project Management Officer, Center for Drug Evaluation and Research, Department of Health and Human Services, Food and Drug Administration, WO22 RM 5489, HFD–569, Rockville, MD 20850

Phone: 301 796–0885
Fax: 301 796–9899
Email: walter.ellenberg@fda.hhs.gov

**RIN:** 0910–AF70
935. INVESTIGATIONAL NEW DRUGS: EXPORT REQUIREMENTS FOR UNAPPROVED NEW DRUG PRODUCTS

Priority: Other Significant

CFR Citation: 21 CFR 312.110

Completed:

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Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Philip L. Chao
Phone: 301 827–0587
Fax: 301 827–4774
Email: philip.chao@fda.hhs.gov

RIN: 0910–AA61

936. REQUIREMENTS ON CONTENT AND FORMAT OF LABELING FOR HUMAN PRESCRIPTION DRUGS AND BIOLOGICAL PRODUCTS

Priority: Other Significant

CFR Citation: 21 CFR 201

Completed:

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Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Elizabeth J. Sadove
Phone: 301 594–2041
Fax: 301 827–5562
Email: elizabeth.sadove@fda.hhs.gov

RIN: 0910–AA94

937. BIOLOGICAL PRODUCTS; BACTERIAL VACCINES AND TOXOIDS; IMPLEMENTATION OF EFFICACY REVIEW

Priority: Substantive, Nonsignificant

CFR Citation: 21 CFR 610.21

Completed:

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Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Richard A. Williams
Phone: 301 436–1989
Fax: 301 436–2626
Email: richard.williams@fda.hhs.gov

RIN: 0910–AF64

938. LOWFAT AND SKIM MILK AND LOWFAT AND NONFAT YOGURT PRODUCTS, LOWFAT COTTAGE CHEESE: REV. OF STAND. OF IDENT.; FOOD LAB., NUTRIENT CONT. CLAIMS FOR FAT, FATTY ACIDS, AND CHOLESTEROL CONT. OF FOODS (SECTION 610 REVIEW)

Priority: Other Significant

CFR Citation: 21 CFR 101; 21 CFR 131; 21 CFR 133

Completed:

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Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Astrid L. Szeto
Phone: 301 827–6210
Fax: 301 827–9434
Email: astrid.szeto@fda.hhs.gov

RIN: 0910–AF62

939. DESIGNATION OF MEDICALLY UNDERSERVED POPULATIONS AND HEALTH PROFESSIONAL SHORTAGE AREAS

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 254b; 42 USC 254e

CFR Citation: 42 CFR 5; 42 CFR 51c

Legal Deadline: None

Abstract: This rule would consolidate the process for designating areas of health professional shortage and medical underservice that apply in several Department programs, and would improve the criteria for designating medically underserved populations and Primary Care Health Professional Shortage Areas. This notice of proposed rulemaking (NPRM) will address issues raised by comments received in a previous NPRM, dated September 1, 1998.

Timetable:

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Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Andy Jordan, Chief, Shortage Designation Branch, Department of Health and Human Services, Health Resources and Services Administration, 5600 Fishers Lane, Room 8C–26, Rockville, MD 20857
Phone: 301 594–0197
Email: dsd@hrsa.gov

RIN: 0906–AA44

940. NATIONAL PRACTITIONER DATA BANK FOR ADVERSE INFORMATION ON PHYSICIANS AND OTHER HEALTH CARE PRACTITIONERS: REPORTING ADVERSE AND NEGATIVE ACTIONS

Priority: Other Significant

Legal Authority: 42 USC 1396r–2

CFR Citation: 45 CFR 60

Legal Deadline: None

Abstract: Public Law 100-93 amended section 1921 of the Social Security Act to require that each State have in effect a system of reporting disciplinary licensure actions taken against all licensed health care practitioners and entities. It also requires States to report any negative action or finding that a peer review organization, private accreditation entity, or a State has concluded against a health care practitioner or entity. Section 1921 directs the Secretary to provide for maximum appropriate coordination in the implementation of these reporting requirements with those of the Health...
Care Quality Improvement Act of 1986 (title IV of Pub. L. 99-660). Section 1921 requirements will be incorporated into the National Practitioner Data Bank.

**Timetable:**

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**Regulatory Flexibility Analysis**

**Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** State

**Agency Contact:** Mark S. Pincus, Director, Division of Practitioner Data Banks, Department of Health and Human Services, Health Resources and Services Administration, 5600 Fishers Lane, Room 8–103, Rockville, MD 20857

Phone: 301 443–2300

RIN: 0906–AA57

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**941. NATIONAL VACCINE INJURY COMPENSATION PROGRAM: CALCULATION OF AVERAGE COST OF A HEALTH INSURANCE POLICY**

**Priority:** Info./Admin./Other

**Legal Authority:** Section 2115 of the Public Health Service Act, 42 USC, 300aa–15

**CFR Citation:** 42 CFR 100, sec 100.2

**Legal Deadline:** None

**Abstract:** The Department of Health and Human Services (HHS) is proposing to revise the current method for calculating the average cost of a health insurance policy, which is an amount deducted from the award of compensation in certain cases. According to the Final Rule published on June 24, 1992, which established the current calculation, “If, over time, the average cost of health insurance, as calculated by the method described above, significantly differs from subsequent HIAA survey results or other authoritative sources then available, the Secretary of HHS will consider appropriate revisions of this rule.” 57 FR 28098 (June 24, 1992). When the latest average monthly cost of an individual health insurance policy was calculated based on the current methodology, it was significantly different from the Kaiser Family Foundation/Health Research and Educational Trust average monthly cost of an individual health insurance policy for the same time period. Therefore, the Secretary is proposing a new methodology to calculate the average cost of a health insurance policy.

Subtitle 2 of title XXI of the Public Health Service Act, as enacted by the National Childhood Vaccine Injury Act of 1986, as amended, governs the National Vaccine Injury Compensation Program (VICP). The VICP, administered by the Secretary of Health and Human Services (the Secretary) provides that a proceeding for compensation for a vaccine-related injury or death shall be initiated by service upon the Secretary, and the filing of a petition with the United States Court of Federal Claims. In some cases, the injured individual may receive compensation for future lost earnings, less appropriate taxes and the “average cost of a health insurance policy, as determined by the Secretary.” The elements of compensation that may be awarded to a successful petitioner are set out in section 2115 of the Public Service Act, 42 U.S.C. section 300aa-15. Subsection (a)(3)(B) specifically provides for compensation for lost earnings for a person who has sustained a vaccine-related injury at age 18 and beyond. The injured person will be eligible to receive compensation for loss of earnings, after the age of 18, which are calculated on the basis of the average gross weekly earnings of workers in the private, non-farm sector, less appropriate taxes and the “average cost of a health insurance policy, as determined by the Secretary.” The wage data are taken from the Employment and Earnings survey done by the Department of Labor, Bureau of Labor Statistics.

Subsection (a)(3)(A) specifically provides for payment of actual and anticipated lost earnings for individuals injured after reaching age 18 and does not include deductions for taxes and the cost of health insurance. This new methodology is expected to result in a more accurate reflection of the actual average cost of a health insurance policy as compared to the figure reached under the methodology that is currently used which results in a number that is too high. Because the amount of compensation for lost wages is reduced by this figure for some petitioners receiving compensation under the VICP, such petitioners are likely to receive a greater amount of compensation if the amendment is adopted.

**Timetable:**

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**Regulatory Flexibility Analysis**

**Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** None

**Agency Contact:** Dr. Geoffrey S. Evans, Acting Director, Division of Vaccine Injury Compensation, Department of Health and Human Services, Health Resources and Services Administration, Room 11C–26, 5600 Fishers Lane, Rockville, MD 20857

Phone: 301 443–6593

Fax: 301 443–8196

Email: gevanar@hrsa.gov

RIN: 0906–AA68
### 942. SMALLPOX EMERGENCY PERSONNEL PROTECTION PROGRAM: SMALLPOX (VACCINIA) VACCINE INJURY TABLE

**Priority:** Substantive, Nonsignificant. Major status under 5 USC 801 is undetermined.

**Legal Authority:** PL 108–20, 117 Stat 638

**CFR Citation:** 42 CFR 102

**Legal Deadline:** None

**Abstract:** To establish a table identifying adverse effects (including injuries, disabilities, conditions, and deaths) that shall be presumed to result from the administration of, or exposure to, the smallpox vaccine, and the time interval in which the first symptom or manifestation of each listed injury must manifest in order for such presumption to apply.

**Timetable:**

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**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** None

**Agency Contact:** Mr. Paul T. Clark, Director, Smallpox Vaccine Injury Compensation Program, Department of Health and Human Services, Health Resources and Services Administration, 11th Floor, 5600 Fishers Lane, Rockville, MD 20857

Phone: 301 443–5255

Email: smallpox@hrsa.gov

**Related RIN:** Related to 0906–AA60

**RIN:** 0906–AA61

### 944. INTESTINES ADDED TO THE DEFINITION OF ORGANS COVERED BY THE RULES GOVERNING THE OPERATION OF THE ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK (OPTN)

**Priority:** Other Significant

**Legal Authority:** 42 USC 274e, sec 301; 42 USC 273 to 274d, sec 371 to 376; 42 USC 1320b–8, sec 1138

**CFR Citation:** 42 CFR 121

**Legal Deadline:** None

**Abstract:** The Department of Health and Human Services proposes to add intestines to the definition of organs covered by the rules governing the operation of the OPTN. After a review of intestinal transplants, HHS believes that intestines should now be included within the definition. The notice of proposed rulemaking provides the history of intestinal transplants, the factors that have persuaded HHS of the advisability of including intestines within the scope of the regulations governing the operation of the OPTN, and the anticipated consequences of this proposal.

As the field of intestinal transplantation evolves, it becomes more critical that intestinal organ allocation policies keep pace with the advances in the field; that policy development include performance indicators to assess how well the policies achieve the goals of an equitable transplant system; that those policies are enforceable; and that patients and physicians have timely access to accurate data that will assist them in making decisions regarding intestinal transplantation.

**Timetable:**

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**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** No

**Agency Contact:** Dr. Laura St. Martin, Chief Medical Officer, Department of Health and Human Services, Health Resources and Services Administration, 5600 Fishers Lane, Room 12C–04, Parklawn Bldg., Rockville, MD 20857

Phone: 301 443–4423

Email: lstmartin@hrsa.gov

**Related RIN:** Related to 0906–AA60

**RIN:** 0906–AA61

### 945. REQUIREMENTS ESTABLISHING A LIMITATION ON ADMINISTRATIVE EXPENSES; RYAN WHITE CARE ACT TITLE IV GRANTS FOR COORDINATED SERVICES AND ACCESS TO RESEARCH

**Priority:** Other Significant. Major status under 5 USC 801 is undetermined.

**Legal Authority:** 42 USC 300ff–71

**CFR Citation:** Not Yet Determined

**Legal Deadline:** None

**Abstract:** This rule finalizes the determination to establish a limitation on administrative expenses for Ryan White Comprehensive AIDS Resources Emergency (CARE) Act title IV Grants for Coordinated Services and Access to Research for Women, Infants, Children, and Youth. The rule establishes the limitation on administrative expenses as a percentage of the grant award, provides guidance on the procedures and processes for implementation of the limitation on administrative expenses, and clarifies the individual expenses that shall be categorized as administrative. The rule specifies the date for implementation as grants funded using fiscal year 2005 grant dollars.
946. HEALTH TOMORROW’S PARTNERSHIP FOR CHILDREN (HTPC) PROGRAM

Priority: Other Significant

Legal Authority: Social Security Act, title V, sec. 501(a)(1); Social Security Act, title V, sec. 502(a)(1); 42 USC 701

CFR Citation: 42 CFR 51(a)

Legal Deadline: None

Abstract: In this rule, the HTPC is proposing to formally add a cost participation component to its grant program. This would require the grantees to have non-Federal matching funds and/or in-kind resources that are equal to or greater than $100,000 in years 2 through 5 of the 5-year project period. For example, in years 2-5, a project awarded $50,000 (i.e., the maximum annual award) of HTPC funds yearly would be expected to have, at a minimum, $100,000 in non-Federal matching funds each funding year. In this example, the $100,000 must come from alternate non-Federal funds, including, but not limited to, individuals, corporations, foundations, in-kind resources, or State and local agencies. Documentation of matching funds would be required (i.e., specific sources, funding level, in-kind contributions).

Timetable:

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Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Jose Rafael Morales, Acting Director, Division of Community Based Programs, Department of Health and Human Services, Health Resources and Services Administration, 5600 Fishers Lane, Room 7A–21, Rockville, MD 20857

Phone: 301 443–3650

Email: jmorales@hrsa.gov

RIN: 0906–AA65

947. NATIONAL PRACTITIONER DATA BANK FOR ADVERSE INFORMATION ON PHYSICIANS AND OTHER HEALTH CARE PRACTITIONERS: MEDICAL MALPRACTICE PAYMENTS REPORTING REQUIREMENTS

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 11131

CFR Citation: 45 CFR 60.7

Legal Deadline: None

Abstract: This notice of proposed rulemaking (NPRM) proposes to require that, in addition to reporting to the National Practitioner Data Bank, medical malpractice payments made where physicians or other health care practitioners are named in medical malpractice actions or claims, judgments, or settlements, payments be reported where they are made for the benefit of physicians or other health care practitioners not named in the judgments or settlements but who furnished or failed to furnish the health care services upon which the actions or claims were based. The purpose of this NPRM is to prevent the evasion of the medical malpractice payment reporting requirement of the Data Bank through the agreement of the parties to a lawsuit to use the corporate health care entity to “shield” practitioners. It would also require malpractice payers, in very limited circumstances, when it is impossible to identify the practitioner who furnished or failed to furnish the health care services upon which the actions or claims were based, to report why the practitioner could not be identified, and to provide the name of the corporate health care entity.

Timetable:

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Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Jose Belardo, Director, Healthy Tomorrow’s Partnership for Children Program, Department of Health and Human Services, Health Resources and Services Administration, 5600 Fishers Lane, Room 18A–55, Rockville, MD 20857

Phone: 301 443–0757

Email: jbelardo@hrsa.gov

RIN: 0906–AA70

948. OPERATION OF THE ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK (OPTN)

Priority: Other Significant. Major status under 5 USC 801 is undetermined.

Legal Authority: 42 USC 274e, sec 301, 1984; 42 USC 273 to 274d, sec 371 to 376; 42 USC 1320b–8, sec 1138

CFR Citation: 42 CFR 121

Legal Deadline: None

Abstract: The Department of Health and Human Services (HHS) proposes to amend the final rule governing the operation of the OPTN.

This notice of proposed rulemaking provides the legislative and regulatory history of the current rule, the factors that persuaded HHS of the advisability of amending the final rule governing the operation of the OPTN, and the
anticipated consequences of this proposal. As required rapid changes in response to better understanding of the clinical scientific issues have become evident, HHS has determined that the current process for approving and enforcing policies must be amended.

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** None

**Agency Contact:** Dr. Hui–Hsing Wong, Medical Officer, Department of Health and Human Services, Health Resources and Services Administration, 5600 Fishers Lane, Mail Stop 16C–17, Parklawn Bldg., Rockville, MD 20857

Phone: 301 443–8104

Fax: 301 594–6095

Email: hwong@hrsa.gov

RIN: 0906–AA63

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**Department of Health and Human Services (HHS)**

**Health Resources and Services Administration (HRSA)**

**949. PUBLIC HEALTH SERVICE (PHS) GRANT APPEALS PROCEDURE**

**Priority:** Other Significant

**CFR Citation:** 42 CFR 50.402

**Completed Actions**

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**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** None

**Agency Contact:** Gail Ellen Lipton

Phone: 301 443–6509

Email: glipton@hrsa.gov

RIN: 0906–AA69

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**Department of Health and Human Services (HHS)**

**Indian Health Service (IHS)**

**950. SECTION 506—LIMITATION ON CHARGES FOR SERVICES FURNISHED BY MEDICARE—PARTICIPATING INPATIENT HOSPITAL TO INDIANS**

**Priority:** Substantive, Nonsignificant. Major status under 5 USC 801 is undetermined.

**Legal Authority:** MMA, sec 506; PL 108–173

**CFR Citation:** 42 CFR 135, subpart D; 42 CFR 489, subpart B

**Legal Deadline:** None

**Abstract:** This provision requires that as a condition of participation in the Medicare Program, providers accept payment at rates established by the Secretary in regulations as payment in full for services provided in an inpatient hospital to American Indians/Alaskan Natives (AI/AN) beneficiaries referred or authorized by the Indian Health Service, Tribes or Tribal organizations, or Urban Indian Organization (I/T/U).

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**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** None

**Government Levels Affected:** None

**Agency Contact:** Betty Z. Gould, Regulations Officer, Department of Health and Human Services, Indian Health Service, 12300 Twinbrook Parkway, Suite 450, Rockville, MD 20852

Phone: 301 443–1116

Email: bgould@hqe.ihs.gov

RIN: 0917–AA07

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**Department of Health and Human Services (HHS)**

**National Institutes of Health (NIH)**

**951. GRANTS FOR RESEARCH PROJECTS**

**Priority:** Substantive, Nonsignificant

**Legal Authority:** 42 USC 216

**CFR Citation:** 42 CFR 52

**Legal Deadline:** None

**Abstract:** NIH proposes to amend the regulations governing grants for research projects by revising the definition of Principal Investigator to mean one or more individuals designated by the grantee in the grant application and approved by the Secretary, who is or are responsible for the scientific and technical direction of the project, rather than limiting the role of principal investigator to one single individual when that more accurately reflects the management needs of a research project.

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**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** None

**Agency Contact:** Jerry Moore, NIH Regulations Officer, Department of Health and Human Services, National Institutes of Health, 6011 Executive Boulevard, Rockville, MD 20852

Phone: 301 496–4606

Fax: 301 402–0169
HHS—NIH

### 952. NATIONAL INSTITUTES OF HEALTH LOAN REPAYMENT PROGRAMS

**Priority:** Substantive, Nonsignificant

**Legal Authority:** 42 USC 216; 42 USC 288–5a; 42 USC 287c–3; 42 USC 288–6; 42 USC 288–1; 42 USC 288–3 42 USC 288–5; 42 USC 288–5a; 42 USC 288–6

**CFR Citation:** 42 CFR 68

**Legal Deadline:** None

**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 68a and at 42 CFR 68c replaced by the new consolidated set of LRP regulations. This action will also include withdrawing the previously announced planned actions concerning NIH LRP authorities.

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**Regulatory Flexibility Analysis**

**Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** None

**Agency Contact:** Jerry Moore, NIH Regulations Officer, Department of Health and Human Services, National Institutes of Health, 6011 Executive Boulevard, Rockville, MD 20852

**Phone:** 301 496–4606

**Fax:** 301 402–0169

**Email:** jm40z@nih.gov

**RIN:** 0925–AA42

### 953. NATIONAL LIBRARY OF MEDICINE TRAINING GRANTS

**Priority:** Substantive, Nonsignificant

**Legal Authority:** 42 USC 216; 42 USC 286b–3

**CFR Citation:** 42 CFR 64

**Legal Deadline:** None

**Abstract:** NIH proposes to amend the regulations governing National Library of Medicine training grants by revising the definition of Program Director to mean one or more individuals designated by the grantee in the grant application and approved by the Secretary, who is or are responsible for the scientific and technical direction of the project, rather than limiting the role of the program director to one single individual when that more accurately reflects the management needs of a research project.

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**Regulatory Flexibility Analysis**

**Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** None

**Agency Contact:** Jerry Moore, NIH Regulations Officer, Department of Health and Human Services, National Institutes of Health, 6011 Executive Boulevard, Rockville, MD 20852

**Phone:** 301 496–4606

**Fax:** 301 402–0169

**Email:** jm40z@nih.gov

**RIN:** 0925–AA43

### 954. MINORITY BIOMEDICAL RESEARCH SUPPORT PROGRAM

**Priority:** Substantive, Nonsignificant

**Legal Authority:** 42 USC 216 42 USC 241(a) (3)

**CFR Citation:** 42 CFR 52c

**Legal Deadline:** None

**Abstract:** NIH proposes to amend the regulations governing Minority Biomedical Research Support Program grants by revising the definition of Program Director to mean one or more individuals designated by the grant application and approved by the Secretary, who is or are responsible for the scientific and technical direction of the program, rather than limiting the role of the program director to one single individual when that more accurately reflects the management needs of a research project.

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**Regulatory Flexibility Analysis**

**Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** None

**Agency Contact:** Jerry Moore, NIH Regulations Officer, Department of Health and Human Services, National Institutes of Health, 6011 Executive Boulevard, Rockville, MD 20852

**Phone:** 301 496–4606

**Fax:** 301 402–0169

**Email:** jm40z@nih.gov

**RIN:** 0925–AA44

### 955. NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES HAZARDOUS SUBSTANCES BASIC RESEARCH AND TRAINING GRANTS

**Priority:** Substantive, Nonsignificant

**Legal Authority:** 42 USC 216; 42 USC 9660(a)

**CFR Citation:** 42 CFR 65a

**Legal Deadline:** None

**Abstract:** NIH proposes to amend the regulations governing National Institute of Environmental Health Sciences Hazardous Substances Basic Research and Training grants by revising the definition of Program Director to mean one or more individuals designated by the grantee in the grant application and approved by the Secretary, who is or are responsible for the scientific and technical direction of the project, rather than limiting the role of the program director to one single individual when that more accurately reflects the management needs of a research project.

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**Regulatory Flexibility Analysis**

**Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** None

**Agency Contact:** Jerry Moore, NIH Regulations Officer, Department of Health and Human Services, National Institutes of Health, 6011 Executive Boulevard, Rockville, MD 20852

**Phone:** 301 496–4606

**Fax:** 301 402–0169

**Email:** jm40z@nih.gov

**RIN:** 0925–AA45

### 956. ENDOWMENT PROGRAM

**Priority:** Substantive, Nonsignificant

**Legal Authority:** 42 USC 216; 42 USC 287c–31

**CFR Citation:** Not Yet Determined

**Legal Deadline:** None
**957. UNDERGRADUATE SCHOLARSHIP PROGRAM REGARDING PROFESSIONS NEEDED BY THE NATIONAL INSTITUTES OF HEALTH**

**Priority:** Substantive, Nonsignificant. Major status under 5 USC 801 is undetermined.

**Legal Authority:** 42 USC 216; 42 USC 288–4

**CFR Citation:** 42 CFR 68b

**Legal Deadline:** NPRM 09/00/06

**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** None

**Agency Contact:** Jerry Moore, NIH

**Email:** jm40z@nih.gov

**RIN:** 0925–AA47

**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 service (employment) after graduation, at NIH, for one year. Additionally, the individual agrees to 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.

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**Department of Health and Human Services (HHS) Final Rule Stage**

**958. NATIONAL INSTITUTES OF HEALTH TRAINING GRANTS**

**Priority:** Substantive, Nonsignificant

**Legal Authority:** 42 USC 216; 42 USC 285g–10

**CFR Citation:** 42 CFR 63a

**Legal Deadline:** None

**Abstract:** NIH proposes to amend the training grants regulations to implement the new authority under section 452G of the Public Health Service (PHS) Act. This action is necessitated by enactment of the Children’s Health Act of 2000. Section 1002 of this Act adds a new section 452G to the PHS Act that authorizes the Director of the National Institute of Child Health and Human Development, in consultation with the Administrator of the Health Resources and Services Administration, to support activities to provide for an increase in the number and size of institutional training grants supporting pediatric training.

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**959. STANDARDS FOR A NATIONAL CHIMPANZEE SANCTUARY SYSTEM**

**Priority:** Other Significant

**Legal Authority:** 42 USC 287a–3a

**CFR Citation:** 42 CFR 9

**Legal Deadline:** NPRM, Statutory, June 18, 2001.

**Abstract:** NIH proposes to establish standards for operating a national chimpanzee sanctuary system to provide for the retirement of federally-owned or supported chimpanzees no longer needed for research.

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960. HUMAN SUBJECTS PROTECTION REGULATIONS: ADDITIONAL PROTECTIONS FOR ADULT INDIVIDUALS WITH IMPAIRED DECISIONMAKING CAPACITY

Priority: Substantive, Nonsignificant. Major status under 5 USC 801 is undetermined.

Legal Authority: 5 USC 301; 42 USC 289

CFR Citation: 45 CFR 46

Legal Deadline: None

Abstract: Through this advance notice of proposed rulemaking (ANPRM), the Office for Human Research Protections (OHRP), Office of Public Health and Science, and the Food and Drug Administration (FDA) of the Department of Health and Human Services (HHS) are seeking comment on whether it is necessary to develop additional safeguards to help protect adult individuals with impaired decisionmaking capacity who are potential subjects in research, and if so, suggestions for appropriate safeguards. This ANPRM stems from the recommendation of an HHS working group, generated in response to the report published by the National Bioethics Advisory Commission entitled “Research Involving Persons with Mental Disorders That May Affect Decisionmaking Capacity” (December 1998), and from subsequent recommendations by the National Human Research Protections Advisory Committee. The goal of these efforts is to maximize the safety and welfare of adult subjects with impaired decisionmaking capacity who participate in research supported, conducted, or regulated by HHS.

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Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Julie A. Kaneshiro, Department of Health and Human Services, Office of Public Health and Science, The Tower Building, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852 Phone: 240 452–6900 Fax: 301 402–2071 Email: jakaneshiro@ophs.dhhs.gov

RIN: 0940–AA11

961. HUMAN SUBJECTS PROTECTION REGULATIONS: INSTITUTIONAL REVIEW BOARDS REGISTRATION REQUIREMENTS

Priority: Substantive, Nonsignificant

Legal Authority: 5 USC 301; 42 USC 289

CFR Citation: 45 CFR 46

Legal Deadline: None

Abstract: This notice of proposed rulemaking proposes to add subpart F to Department of Health and Human Services (HHS) regulations for protection of human subjects, 45 CFR part 46, to require registration of institutional review boards (IRBs) with HHS. The registration information would include contact information, approximate numbers of active protocols involving research conducted or supported by HHS, accreditation status, IRB membership, and staffing for the IRB. The proposed registration requirements will make it easier for the Office for Human Research Protections (OHRP) to convey information to IRBs, and will support the current IRB registration operated by OHRP. Under the current OHRP IRB registration system, the submission of certain registration information is required by human subjects protection regulations, and certain other information may be submitted voluntarily. This proposed information collection was submitted to the Office of Management and Budget under the Paperwork Reduction Act. Under the proposed rule, all registration information will be required, making the IRB registration system uniform with IRB registration requirements of the Food and Drug Administration (FDA), and creating a single, HHS IRB Registration system. FDA simultaneously published a proposed rule regarding FDA IRB registration requirements.

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Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Irene Stith–Coleman Ph.D, Department of Health and Human Services, Office of Public Health and Science, The Tower Building, 1101 Wootton Parkway, Rockville, MD 20852 Phone: 240 453–6900 Fax: 301 402–2071

RIN: 0940–AA06
962. PUBLIC HEALTH SERVICE STANDARDS FOR THE PROTECTION OF RESEARCH MISCONDUCT WHISTLEBLOWERS

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 216; 42 USC 241; 42 USC 289b

CFR Citation: 42 CFR 94

Legal Deadline: None

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.

Regulatory Flexibility Analysis
Required: No
Small Entities Affected: No
Government Levels Affected: None

Agency Contact: Chris Pascal, Director, Office of Research Integrity, Department of Health and Human Services, Office of Public Health and Science, 1101 Wootten Parkway, Rockville, MD 20852 Phone: 240 453–8200 Fax: 301 443–5351

Related RIN: Related to 0940–AA04
RIN: 0940–AA01

963. HUMAN SUBJECTS PROTECTION REGULATIONS: TRAINING AND ED. REQUIREMENTS FOR INSTITUTIONAL OFFICIALS, INSTITUTIONAL REVIEW BOARD MEMBERS AND STAFF, HUMAN PROTECTIONS ADMINISTRATORS, AND INVESTIGATORS

Priority: Other Significant. Major status under 5 USC 801 is undetermined.

Legal Authority: 5 USC 301; 42 USC 289

CFR Citation: 45 CFR 46

Legal Deadline: None

Abstract: This notice of proposed rulemaking proposes to add subpart E to the Department of Health and Human Services (HHS) regulations for protection of human subjects, 45 CFR part 46, and would require that institutions engaged in human subjects research covered by an assurance of compliance filed with the Office for Human Research Protections ensure that institutional officials, institutional review board (IRB) chairpersons, and human protection administrators receive appropriate training and education about the institution’s assurance and that IRB chairpersons and members, IRB staff, investigators, and other personnel involved in the conduct or oversight of human subjects research receive appropriate training and education about relevant human subjects protection requirements. The proposed training and education requirements will help to ensure that responsible individuals at assured institutions understand and meet their regulatory responsibilities for human subjects protection.

Regulatory Flexibility Analysis
Required: No
Small Entities Affected: No
Government Levels Affected: None


RIN: 0940–AA08
965. INNOVATIONS IN FEE–FOR–SERVICE PAYMENT SYSTEMS TO IMPROVE QUALITY AND OUTCOMES (CMS–1298–ANPR)

**Priority:** Other Significant  
**Legal Authority:** None  
**CFR Citation:** None  
**Legal Deadline:** None

**Abstract:** This advance notice of proposed rulemaking explores the concept of “paying for performance” as a means of promoting better quality of care in Medicare fee-for-service payment systems. It explains the concept in general and reports on a number of activities of the Center for Medicare and Medicaid Services measuring and reporting and possible ways these results could be used to create financial incentives for high quality care. The notice seeks public comments on these ideas.

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**RIN:** 0938–AN91

966. HOME HEALTH AGENCY (HHA) CONDITIONS OF PARTICIPATION (COPs) (CMS–3819–P) (SECTION 610 REVIEW)

**Priority:** Other Significant  
**Legal Authority:** 42 USC 1302; 42 USC 1395x; 42 USC 1395cc(a); 42 USC 1395hh; 42 USC 1395bb  
**CFR Citation:** 42 CFR 484  
**Legal Deadline:** None

**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 requirements 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.

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**RIN:** 0938–AG81

967. APPEALS OF CMS OR CONTRACTOR DETERMINATIONS WHEN A PROVIDER OR SUPPLIER FAILS TO MEET OR MAINTAIN THE REQUIREMENTS FOR MEDICARE BILLING PRIVILEGES (CMS–6003–P2)

**Priority:** Substantive, Nonsignificant  
**Legal Authority:** 42 USC 1302; 42 USC 1395u(b)(3)(C); 42 USC 1395ff(b)  
**CFR Citation:** 42 CFR 405.874  
**Legal Deadline:** None

**Abstract:** This proposed rule would extend appeal rights to all suppliers whose enrollment applications for Medicare billing privileges are disallowed by a carrier or whose Medicare billing privileges are revoked, except for those suppliers covered under other existing appeals provisions of our regulations. In addition, certain appeal provisions are revised to correspond with the existing appeal provisions in those other sections of our regulations. The rule would also extend appeal rights to all suppliers not covered by existing regulations to ensure they have a full and fair opportunity to be heard. This rule would incorporate provisions from section 936 of the Medicare Modernization Act.

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**RIN:** 0938–AI49
968. RURAL HEALTH CLINICS: AMENDMENTS TO PARTICIPATION REQUIREMENTS AND PAYMENT PROVISIONS AND ESTABLISHMENT OF A QUALITY ASSESSMENT AND IMPROVEMENT PROGRAM (CMS–1910–P2)

Priority: Other Significant
Legal Authority: 42 USC 1302; 42 USC 1395hh
CFR Citation: 42 CFR 405; 42 CFR 491
Legal Deadline: None

Abstract: This rule proposes to amend the Medicare certification and payment requirements for rural health clinics (RHCs), as required by section 4205 of the Balanced Budget Act of 1997. It proposes to change the definition of a qualifying rural shortage area in which a Medicare RHC must be located; establish criteria for identifying RHCs essential to delivery of primary care services that we can continue to approve as Medicare RHCs in areas no longer designated as medically underserved; and limit nonphysician practitioner staffing requirements. This rule proposes to impose payment limits on provider-based RHCs and prohibit the use of RHC space, professional staff, equipment, and other RHC resources by another Medicare entity. The rule also proposes to require RHCs to establish a quality assessment and performance improvement program. In light of the fact that section 902 of MMA of 2003 requires the Secretary to issue regulations within 3 years, CMS is republishing the provisions of the final RHC rule as a proposed rule to provide the public with an opportunity to formally comment on the new policies established under the December 24, 2003 rule. In addition, we are proposing new policy revisions to the RHC and FQHC program to improve and strengthen this rural safety net benefit.

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Regulatory Flexibility Analysis
Required: No
Small Entities Affected: Businesses
Government Levels Affected: Federal
Agency Contact: Carla McGregor, Health Insurance Specialist, Hospital and Ambulatory Policy Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop C4–15–18, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–5919
Email: carla.mcgregor@cms.hhs.gov
RIN: 0938–AJ17

969. USE OF RESTRAINTS AND SECLUSION IN MEDICARE AND MEDICAID PARTICIPATING FACILITIES THAT PROVIDE INPATIENT OR RESIDENTIAL CARE (CMS–2130–P)

Priority: Other Significant. Major status under 5 USC 801 is undetermined.
Legal Authority: PL 106–554, (BIPA 2000 of the Children’s Health Act)
CFR Citation: 42 CFR 101; 42 CFR 418; 42 CFR 482 to 483; 42 CFR 485
Legal Deadline: None

Abstract: This proposed rule would implement provisions of the Children’s Health Act of 2000 (CHA) related to the use of restraints or seclusion for individuals receiving services in health care facilities that receive Federal funding. The rule would establish common terminology and basic expectations for the use of restraints and seclusion for health care facilities that furnish inpatient or residential care and receive Medicare or Medicaid funding.

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Regulatory Flexibility Analysis
Required: Undetermined
Small Entities Affected: Businesses
Government Levels Affected: Undetermined
Federalism: Undetermined
Agency Contact: Joan Brooks, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Clinical Standards Group, Mailstop S3–02–01, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–5526
Email: joan.brooks@cms.hhs.gov
RIN: 0938–AL80

970. REVISIONS TO CONDITIONS FOR COVERAGE FOR AMBULATORY SURGICAL CENTERS (CMS–3887–P)

Priority: Other Significant. Major under 5 USC 801.
Legal Authority: Not Yet Determined
CFR Citation: None
Legal Deadline: None

Abstract: This proposed rule would revise the ambulatory surgical center conditions for coverage to reflect current innovations in healthcare delivery, quality assessment, and performance improvement. The focus would be to improve outcomes of health care and satisfaction for Medicare beneficiaries, while streamlining structural and procedural requirements when possible.

Timetable:

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Regulatory Flexibility Analysis
Required: No
Small Entities Affected: Businesses
Government Levels Affected: State
Agency Contact: Jacqueline Morgan, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Clinical Standards Group, Mailstop S3–02–01, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–4282
Email: jacqueline.morgan@cms.hhs.gov
RIN: 0938–AL26

971. MODIFICATIONS TO ELECTRONIC TRANSACTIONS AND CODE SETS (CMS–0099–P)

Priority: Other Significant. Major status under 5 USC 801 is undetermined.
Unfunded Mandates: Undetermined
Legal Authority: Sec 1171 to 1179 of the Social Security Act
CFR Citation: Not Yet Determined
Legal Deadline: None
### 972. REQUIREMENTS FOR LONG-TERM CARE FACILITIES: HOSPICE SERVICES (CMS–3140–P)

**Priority:** Economically Significant. Major status under 5 USC 801 is undetermined.

**Unfunded Mandates:** Undetermined

**Legal Authority:** 42 USC 1395i–3; 42 USC 1396r

**CFR Citation:** 42 CFR 483

**Legal Deadline:** None

**Abstract:** This proposed rule establishes requirements that hospice agencies and long-term care (LTC) facilities must meet to participate in the Medicare and Medicaid programs. We are proposing these new requirements to ensure that quality hospice care is provided to eligible residents.

**Timetable:**

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### 973. COMPETITIVE ACQUISITION FOR CERTAIN DURABLE MEDICAL EQUIPMENT (DME), PROSTHETICS, ORTHOTICS, AND SUPPLIES (CMS–1270–P)

**Priority:** Economically Significant. Major under 5 USC 801.

**Legal Authority:** PL 108–173, MMA; Deficit Reduction Act of 2005, PL 109–171, sec 5101

**CFR Citation:** 42 CFR 414.200; 42 CFR 405.502(g); 42 CFR 424.57; 42 CFR 410.38

**Legal Deadline:** Final, Statutory, December 31, 2007.

**Abstract:** Section 302 of the Medicare Modernization Act establishes DME competitive bidding. National competitive bidding will provide a program for using market forces to set Medicare payment amounts. This will also create incentives for suppliers to provide quality items and services while at the same time providing Medicare with reasonable prices for payment. This rule also incorporates provisions from section 5105 of the DRA of 2005, which concerns beneficiary ownership of certain DMEs. (The statute requires competitive bidding be implemented by 2007).

**Timetable:**

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### 974. REVISIONS TO HIPAA CODE SETS (CMS–0013–P)

**Priority:** Economically Significant.

**Unfunded Mandates:** Undetermined

**Legal Authority:** PL 104–191

**CFR Citation:** 45 CFR 162

**Legal Deadline:** None

**Abstract:** This proposed rule would revise some of the adopted transaction and code set standards detailed in regulations published by HHS on August 17, 2000, and February 20, 2003.

**Timetable:**

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### 975. LIMITATION ON RECOUPMENT OF OVERPAYMENTS (CMS–6025–P)

**Priority:** Other Significant. Major status under 5 USC 801 is undetermined.

**Legal Authority:** Section 1893 (f) (2) of the Social Security Act added by Section 935 of the MMA
This proposed rule would implement one provision of section 935 of the Medicare Modernization Act which added a new subsection to section 1893 of the Social Security Act. It would limit recoupment where a provider or supplier has appealed an overpayment determination until the reconsideration-level appeal is decided. The proposed rule also changes how interest is to be paid to a provider or supplier whose overpayment is reversed at the third or subsequent levels of administrative appeal or through judicial review.

**Abstract:** This proposed rule would implement one provision of section 935 of the Medicare Modernization Act which added a new subsection to section 1893 of the Social Security Act. It would limit recoupment where a provider or supplier has appealed an overpayment determination until the reconsideration-level appeal is decided. The proposed rule also changes how interest is to be paid to a provider or supplier whose overpayment is reversed at the third or subsequent levels of administrative appeal or through judicial review.

**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** None

**Agency Contact:** Nancy Braymer, Health Insurance Specialist, Centers for Medicare & Medicaid Services, Mailstop C3–14–21, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786–4323

Email: nancy.braymer@cms.hhs.gov

**RIN:** 0938–AN42

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**976. REVISIONS TO THE OVERSIGHT AND VALIDATION PROGRAM FOR ACCREDITING ORGANIZATIONS APPROVED FOR DEEMING AUTHORITY (CMS–2255–P)**

**Priority:** Other Significant. Major under 5 USC 801.

**Legal Authority:** Medicare Act of 2005, PL 109–171, sec 5101 to 5201

**CFR Citation:** 42 CFR 484

**Legal Deadline:** Final, Statutory, January 1, 2007, Effective Date.

**Abstract:** This notice sets forth an update to the 60-day national episode rates and the national per-visit amounts under the Medicare prospective payment system for home health agencies, effective on January 1, 2007. This rule would also incorporate provisions from the Deficit Reduction Act of 2005, which affects Home Health payments.

**Regulatory Flexibility Analysis Required:** Undetermined

**Small Entities Affected:** Undetermined

**Agency Contact:** Captain Arnold C. Farley, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of Clinical Standards and Quality, Improvement Group, Mail Stop S3–02–01, 7500 Security Boulevard, Baltimore, MD 21244–1850

Phone: 410 786–1154

Email: amber.wolfe@cms.hhs.gov

**RIN:** 0938–AN73

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**978. HOME HEALTH PAYMENT SYSTEM RATE UPDATE FOR CALENDAR YEAR 2007 (CMS–1304–P)**

**Priority:** Economically Significant. Major under 5 USC 801.

**Legal Authority:** Social Security Act, sec 1895; Deficit Reduction Act of 2005, PL 109–171, sec 5101 to 5201

**CFR Citation:** 42 CFR 484

**Legal Deadline:** Final, Statutory, January 1, 2007, Effective Date.

**Abstract:** This notice sets forth an update to the 60-day national episode rates and the national per-visit amounts under the Medicare prospective payment system for home health agencies, effective on January 1, 2007. This rule would also incorporate provisions from the Deficit Reduction Act of 2005, which affects Home Health payments.

**Regulatory Flexibility Analysis Required:** Undetermined

**Small Entities Affected:** None

**Government Levels Affected:** None

**Agency Contact:** Captain Arnold C. Farley, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of Clinical Standards and Quality, Improvement Group, Mail Stop S3–02–01, 7500 Security Boulevard, Baltimore, MD 21244–1850

Phone: 410 786–1154

Email: amber.wolfe@cms.hhs.gov

**RIN:** 0938–AN73

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**976. REVISIONS TO THE OVERSIGHT AND VALIDATION PROGRAM FOR ACCREDITING ORGANIZATIONS APPROVED FOR DEEMING AUTHORITY (CMS–2255–P)**

**Priority:** Other Significant. Major under 5 USC 801.

**Legal Authority:** Social Security Act, sec 1864; Social Security Act, sec 1865; Social Security Act, sec 1875

**CFR Citation:** 42 CFR 484.1 to 488.9

**Legal Deadline:** None

**Abstract:** This proposed rule would add a provision to the existing Quality Improvement Organization (QIO) confidentiality regulations allowing the release of Medicare beneficiary-specific information, with patient consent, from the QIO to practitioners and providers in a treatment relationship with the beneficiary. This release may only be permitted after the beneficiary has consented to the release and has been provided notice of the release. The new provisions will also permit the release of Medicare beneficiary-specific information, with patient consent, from the QIO to other QIOs, subcontractors to QIOs, and CMS for educational and quality improvement purposes. Additionally, the rule would add provisions for the Medicare beneficiary complaint system that is required by the statute and administered by the QIOs.

**Regulatory Flexibility Analysis Required:** Undetermined

**Small Entities Affected:** Undetermined

**Agency Contact:** Nancy Braymer, Health Insurance Specialist, Centers for Medicare & Medicaid Services, Mailstop C3–14–21, 7500 Security Boulevard, Baltimore, MD 21244–1850

Phone: 410 786–4323

Email: nancy.braymer@cms.hhs.gov

**RIN:** 0938–AN42

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**976. REVISIONS TO THE OVERSIGHT AND VALIDATION PROGRAM FOR ACCREDITING ORGANIZATIONS APPROVED FOR DEEMING AUTHORITY (CMS–2255–P)**

**Priority:** Other Significant. Major under 5 USC 801.

**Legal Authority:** Social Security Act, sec 1864; Social Security Act, sec 1865; Social Security Act, sec 1875

**CFR Citation:** 42 CFR 484.1 to 488.9

**Legal Deadline:** None

**Abstract:** This proposed rule would add a provision to the existing Quality Improvement Organization (QIO) confidentiality regulations allowing the release of Medicare beneficiary-specific information, with patient consent, from the QIO to practitioners and providers in a treatment relationship with the beneficiary. This release may only be permitted after the beneficiary has consented to the release and has been provided notice of the release. The new provisions will also permit the release of Medicare beneficiary-specific information, with patient consent, from the QIO to other QIOs, subcontractors to QIOs, and CMS for educational and quality improvement purposes. Additionally, the rule would add provisions for the Medicare beneficiary complaint system that is required by the statute and administered by the QIOs.

**Regulatory Flexibility Analysis Required:** Undetermined

**Small Entities Affected:** Undetermined

**Agency Contact:** Nancy Braymer, Health Insurance Specialist, Centers for Medicare & Medicaid Services, Mailstop C3–14–21, 7500 Security Boulevard, Baltimore, MD 21244–1850

Phone: 410 786–4323

Email: nancy.braymer@cms.hhs.gov

**RIN:** 0938–AN42
979. FIRE SAFETY REQUIREMENTS FOR LONG–TERM CARE FACILITIES: SPRINKLER SYSTEMS (CMS–3191–P)

Priority: Other Significant
Legal Authority: 42 USC 1302; 42 USC 1395hh
CFR Citation: 42 CFR 483
Legal Deadline: None
Abstract: This proposed rule would require all long-term care facilities to be equipped with sprinkler systems. This proposed rule requests public comment, including comment on the duration of a phase-in period, to allow long-term care facilities to install such systems.

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980. PAYMENTS FOR SERVICE PROVIDED WITHOUT CHARGE (CMS–2489–P)

Priority: Other Significant. Major status under 5 USC 801 is undetermined.

Unfunded Mandates: Undetermined
Legal Authority: Not Yet Determined
CFR Citation: Not Yet Determined
Legal Deadline: None
Abstract: The proposed rule would clarify that Federal Financial Participation (FFP) is not available to States on behalf of Medicaid beneficiaries for Medicaid-covered services provided without charge (that is, free care) to individuals receiving the services. Free care means a particular service is available without charge to an individual who receives the service or to any third party on behalf of the individual.

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981. QUALITY STANDARDS FOR GENETIC TESTING (CMS–2121–P)

Priority: Other Significant
Legal Authority: Sec. 353 of Public Health Service Act (42 USC 263a)
CFR Citation: Not Yet Determined
Legal Deadline: None
Abstract: This rule would add to the Clinical Laboratory Improvement Amendment (CLIA) regulations a new specialty of genetic testing that will address recommendations by the Clinical Laboratory Improvement Advisory Committee (CLIAC) and the Secretary’s advisory committee for genetic testing.

Timetable:

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982. MEDICAL IMPROVEMENT ELIGIBILITY GROUP AND DEFINITION OF WORK (CMS–2143–P)

Priority: Other Significant
CFR Citation: 42 CFR 435. 238; 42 CFR 436.232
Legal Deadline: None
Abstract: In order to provide health services to employed individuals whose medical conditions have improved to the point where they are no longer eligible for disability benefits, this proposed rule would provide a definition of “medically determinable severe impairment” under the Ticket to Work and Work Incentives Improvement Act of 1999 (Ticket to Work). Under this definition, States can determine eligibility standards for the Medical Improvement Group authorized under the Ticket to Work law, thereby permitting individuals to retain their Medicaid coverage. Additionally, this proposed rule would give States offering Medicaid buy-in programs for employed individuals with disabilities the option of selecting a minimum work standard for participation.

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983. REVISIONS TO THE PAYMENT POLICIES OF AMBULANCE SERVICES UNDER THE FEE SCHEDULE FOR AMBULANCE SERVICES (CMS–1317–P)

Priority: Substantive, Nonsignificant
Legal Authority: Sections 1834(1), and 1861 (s) (7) of the Social Security Act (the Act).
CFR Citation: 42 CFR 414.610; 42 CFR 414.615
Legal Deadline: None

Abstract: This rule would revise the fee schedule for payment of ambulance services specifically with respect to the definition of Specialty Care Transport (SCT) and the Metropolitan Statistical Area (MSA) geographic breakdown in relation to payment of ambulance services under Medicare. In addition, this proposed rule discusses the conversion factor and the effect of low billers.

Timetable:
Action   Date       FR Cite
NPRM  06/00/06

Regulatory Flexibility Analysis
Required: Undetermined
Small Entities Affected: Businesses
Agency Contact: Anne Elizabeth Tayloe, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop C4–06–28, 7500 Security Boulevard, Baltimore, MD 21244–1850
Phone: 410 786–4546
Email: anne.tayloe@cms.hhs.gov
RIN: 0938–AO10

984. CHANGES TO THE HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEMS AND FY 2007 RATES (CMS–1488–P)

Priority: Economically Significant. Major under 5 USC 801.
Legal Authority: Sec 1886(d) of the Social Security Act; Deficit Reduction Act of 2005, (PL 109–171), sec 5001 and 5003
CFR Citation: 42 CFR 405; 42 CFR 412; 42 CFR 413; 42 CFR 415; 42 CFR 419; 42 CFR 422; 42 CFR 485


Abstract: This rule proposes to revise 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. The Addendum to this proposed rule proposes changes to the amounts and factors used to determine the rates for Medicare hospital inpatient services for operating costs and capital-related costs. These proposed changes would apply to discharges occurring on or after 10/1/06. It also proposes rate-of-increase limits as well as proposed policy changes for hospitals and hospital units excluded from the IPPS that are paid in full or in part on a reasonable cost basis subject to these limits. This rule also incorporates provisions from sections 5001 and 5003 of the Deficit Reduction Act of 2005, which allows for hospital quality improvement and improvement to the Medicare dependent hospital program.

Timetable:
Action   Date       FR Cite
NPRM  04/00/06

Regulatory Flexibility Analysis
Required: Yes
Small Entities Affected: Businesses
Government Levels Affected: Federal
Agency Contact: Tziv Hefter, Director, Division of Acute Care Hospital and Ambulatory Policy Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare Management, Mailstop C4–07–07, 7500 Security Boulevard, Baltimore, MD 21244–1850
Phone: 410 786–4487
Email: tziv.hefter@cms.hhs.gov
RIN: 0938–AO12

985. CHANGES TO THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM AND CALENDAR YEAR 2007 PAYMENT RATES (CMS–1506–P)

Priority: Economically Significant. Major under 5 USC 801.
Legal Authority: BBA; BBRA; BIPA; MMA; Deficit Reduction Act of 2005; (PL 109–171), sec 5103 and 5105
CFR Citation: 42 CFR 419 to 485

Legal Deadline: Final, Statutory, November 1, 2006.

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 and to implement certain related provisions of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003. In addition, the proposed rule describes proposed changes to the amounts and factors used to determine the payment rates for Medicare hospital outpatient services paid under the prospective payment system. These changes would be applicable to services furnished on or after January 1, 2007. In addition, this rule would also propose additions to and deletions from the list of covered procedures for ASCs effective July 1, 2007. Further, this rule would also propose to revise the method by which Medicare sets payment rates for ASC facility services, and the list of covered ASC procedures effective January 1, 2008. This rule would incorporate provisions from the DRA of 2005, which limits payments for procedures in ASCs, and includes a 3-year phase-out of hold harmless for small rural hospitals under the prospective payment system for hospital outpatient department services.

Timetable:
Action   Date       FR Cite
NPRM  07/00/06

Regulatory Flexibility Analysis
Required: Yes
Small Entities Affected: Businesses
Government Levels Affected: Federal
Federalism: This action may have federalism implications as defined in EO 13132.
Agency Contact: Rebecca Kane, Health Insurance Specialist, Center for...
Medicare Management, Hospital & Ambulatory Policy Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Division Group of Outpatient Care, Mailstop C5–01–28, 7500 Security Boulevard, Baltimore, MD 21244–1850 Phone: 410 786–1589 Email: rebecca.kae@cms.hhs.gov

Related RIN: Related to 0938–AO13, Related to 0938–AN23

RIN: 0938–AO15

986. PROSPECTIVE PAYMENT SYSTEM FOR INPATIENT REHABILITATION FACILITIES FOR FY 2007 (CMS–1540–P)

Priority: Economically Significant. Major under 5 USC 801 is undetermined.

Unfunded Mandates: Undetermined

Legal Authority: Section 1866(l) of the Social Security Act; PL 105–33; PL 106–554; PL 106–113;; Deficit Reduction Act of 2005; (PL 109–171), sec 5005

CFR Citation: 42 CFR 412

Legal Deadline: Final, Statutory, August 1, 2006.

Abstract: This proposed rule would update rates for the prospective payment system for inpatient rehabilitation facilities for FY 2007. This rule would also incorporate provisions from section 5055 of the Deficit Reduction Act of 2005, which extends the phase-in of the inpatient rehabilitation facility classification criteria.

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Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Jeremy Silanskis, Health Insurance Specialist, Center for Medicare Services, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop S3–13–15, 7500 Security Boulevard, Baltimore, MD 21244–1850 Phone: 410 786–8533 Email: jeremy.silanskis@cms.hhs.gov

RIN: 0938–AO17

987. OUTPATIENT HOSPITAL SERVICES AND RURAL HEALTH CLINIC SERVICES AMENDMENT (CMS–2213–P)

Priority: Economically Significant. Major under 5 USC 801.

Legal Authority: Section 1102 of the Social Security Act

CFR Citation: 42 CFR 440.20

Legal Deadline: None

Abstract: This rule would amend the definition of outpatient hospital services for the Medicaid program. The purpose of this amendment is to clarify the scope of services available for Federal financial participation (FFP) under the outpatient hospital services benefit category.

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Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses

Government Levels Affected: None

Federalism: Undetermined

Agency Contact: Jeremy Silanskis, Health Insurance Specialist, Center for Medicare Services, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop C5–01–28, 7500 Security Boulevard, Baltimore, MD 21244–1850 Phone: 410 786–1592 Fax: 410 786–8533 Email: jeremy.silanskis@cms.hhs.gov

RIN: 0938–AO17

988. • BEST PRICE REQUIREMENTS FOR AUTHORIZED GENERIC DRUGS (CMS–2238–P)

Priority: Other Significant. Major status under 5 USC 801 is undetermined.

Legal Authority: 42 USC 1395rr; Deficit Reduction Act of 2005, PL 109–171, sec 6001 to 6003

CFR Citation: 42 CFR 447.535


Abstract: This proposed rule would require manufacturers to include best price in the calculation of rebates for authorized generic drugs, when such drugs are transferred or sold to a subsidiary or another unit within a company or to another entity that has been authorized (cross-licensed) to market and/or distribute authorized generic drug products. The proposed rule would define authorized generics as drugs marketed under the brand manufacturer’s new drug application (NDA) and transferred or sold to a subsidiary or another unit within the brand company or to another entity that has been authorized (cross-licensed) to market and/or distribute authorized generic drug products. In addition, the rule would provide guidance to manufacturers regarding the appropriate treatment of authorized generic drugs under the Medicaid Drug Rebate program and would clarify CMS’ policy on the issue.

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Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: State

Agency Contact: Yolanda Lashawn Reese, Health Insurance Specialist, Division of Benefits and Coverage Policy Services, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicaid and State Operations, Mailstop S2–06–15, 7500 Security Boulevard, Baltimore, MD 21244–1850 Phone: 410 786–9898 Fax: 410 786–5882 Email: yolanda.reese@cms.hhs.gov

RIN: 0938–AO20

989. FIVE–YEAR REVIEW OF WORK RELATIVE VALUE UNITS UNDER THE PHYSICIAN FEE SCHEDULE (CMS–1512–PN)

Priority: Economically Significant. Major under 5 USC 801.

Unfunded Mandates: Undetermined

Legal Authority: Social Security Act sec 1848

CFR Citation: Not Yet Determined

Legal Deadline: Final, Statutory, November 1, 2006, Comments to be addressed as part of final physician fee.

Abstract: This notice discusses changes to work relative value units (RVUs) affecting payment for physician services. Comments on this notice will be addressed as part of the final
### 990. REVISIONS TO PAYMENT POLICIES UNDER THE PHYSICIAN FEE SCHEDULE FOR CALENDAR YEAR 2007 (CMS–1321–P)

**Priority:** Economically Significant. Major under 5 USC 801.

**Unfunded Mandates:** Undetermined

**Legal Authority:** Social Security Act, sec 1102; Social Security Act, sec 1871; Deficit Reduction Act of 2005; [PL 109–171], sec 5102, 5104, 5106, 5107, 5112, 5113

**CFR Citation:** 42 CFR 405; 42 CFR 410 to 411; 42 CFR 413 to 414; 42 CFR 426

**Legal Deadline:** Final, Statutory, November 1, 2006.

**Abstract:** This rule would make changes affecting Medicare Part B payment.

**Timetable:**

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**Regulatory Flexibility Analysis Required:** Undetermined

**Government Levels Affected:** Undetermined

**Federalism:** Undetermined

**Agency Contact:** Diane Milstead, Health Insurance Specialist, Center for Medicare and Medicaid Services, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop C4–03–06, 7500 Security Boulevard, Baltimore, MD 21244–1850. Phone: 410 786–3355 Email: diane.milstead@cms.hhs.gov

**Related RIN:** Related to 0938–AN26, Related to 0938–AN05

**RIN:** 0938–AO24

### 991. USE OF REPAYMENT PLANS (CMS–6032–P)

**Priority:** Other Significant

**Legal Authority:** Section 1893(i)(1) of the Social Security Act as amended by sec 935(i)(1) of Medicare Modernization Act (MMA)

**CFR Citation:** 42 CFR 401.601, 42 CFR 401.607

**Legal Deadline:** Final, Statutory, December 9, 2003.

**Abstract:** This proposed rule would modify Medicare regulations to implement a provision of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 pertaining to the use of repayment plans (also known as extended repayment schedules). Under this provision, we propose to grant a provider or a supplier an extended repayment schedule under certain terms and conditions as defined in the statute. The proposed rule would establish criteria and procedures to apply this requirement and to define the concepts of “hardship” and “extreme hardship.”

**Timetable:**

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**Regulatory Flexibility Analysis Required:** No

**Government Levels Affected:** No

**Federalism:** Undetermined

**Agency Contact:** Richard Strauss, Technical Director of Finance Systems & Budget Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Centers for Medicaid and State Operations, Mailstop S3–13–15, 7500 Security Boulevard, Baltimore, MD 21244–1850. Phone: 410 786–2019 Email: richard.strauss@cms.hhs.gov

**RIN:** 0938–AO28

### 992. • REDISTRIBUTION OF UNEXPENDED STATE CHILDREN’S HEALTH INSURANCE PROGRAM (SCHIP) FUNDS FROM THE APPROPRIATION FOR FISCAL YEAR 2004 (CMS–2241–NC)

**Priority:** Other Significant

**Legal Authority:** 42 USC 1397dd(g); 42 USC 1397ee(g); secs 2104(e) & (f) of the Social Security Act

**CFR Citation:** 42 CFR 457.600–630

**Legal Deadline:** None

**Abstract:** This notice announces the procedure for redistribution of States’ unexpended FY 2004 allotments that remained at the end of FY 2004 to those States that fully expended the FY 2004 SCHIP allotment. These redistributed allotments will be available through the end of FY 2007.

**Timetable:**

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**Regulatory Flexibility Analysis Required:** No

**Government Levels Affected:** No

**Federalism:** Undetermined

**Agency Contact:** Thomas A. Noplock, Health Insurance Specialist, Division of Medicare Overpayments, Office of Financial Management, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Financial Services Group, Mailstop C3–15–01, 7500 Security Boulevard, Baltimore, MD 21244–1850. Phone: 410 786–3378 Fax: 410 786–7030 Email: thomas.noplock@cms.hhs.gov

**RIN:** 0938–AO28

### 993. • PROSPECTIVE PAYMENT SYSTEM FOR LONG–TERM CARE HOSPITALS RY 2008: ANNUAL PAYMENT RATE UPDATES (CMS–1529–P)

**Priority:** Economically Significant. Major under 5 USC 801 is undetermined.

**Legal Authority:** PL 106–113 sec 123; PL 106–554 sec 307(b)

**CFR Citation:** 42 CFR 412

**Legal Deadline:** Final, Statutory, Effective 07/01/2007.

**Abstract:** This rule proposes the annual payment rate update for the 2008
prospective payment system for Medicare long-term care hospitals and also presents proposed changes or revisions on LTCH PPS policy for public comment.

**Timetable:**

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**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** Businesses

**Government Levels Affected:** None

**Agency Contact:** Linda McKenna, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244 Phone: 410 786–4537 Email: linda.mckenna@cms.hhs.gov

RIN: 0938–AO30

994. ● HOME HEALTH PROSPECTIVE PAYMENT SYSTEM RATE UPDATE FOR CALENDAR YEAR 2008 (CMS–1541–P)

**Priority:** Economically Significant. Major status under 5 USC 801 is undetermined.

**Legal Authority:** Social Security Act, sec 1895

**CFR Citation:** 42 CFR 493

**Legal Deadline:** Final, Statutory, January 1, 2008, Effective 01/01/08.

**Abstract:** This proposed rule would update the 60-day national episode rate and the national per-visit rate amounts under the Medicare Prospective Payment System for home health agencies, effective 1/1/08. This rule would also propose the first major refinement to the HH PPS since its implementation on 10/1/01.

**Timetable:**

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**Regulatory Flexibility Analysis Required:** Yes

**Small Entities Affected:** Businesses

**Government Levels Affected:** Undetermined

**Agency Contact:** Randy L. Thronset, Technical Advisor; Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop C5–02–03, 7500 Security Boulevard, Baltimore, MD 21244–1850 Phone: 410 786–0131 Email: randy.thronset@cms.hhs.gov

RIN: 0938–AO32

995. ● PROVIDER NOMINATION PROVISION (CMS–1331–P)

**Priority:** Substantive, Nonsignificant. Major status under 5 USC 801 is undetermined.

**Legal Authority:** Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), sec 911(d)(2)(A)

**CFR Citation:** 42 CFR 421.103 to 42 CFR 421.114

**Legal Deadline:** None

**Abstract:** This regulation will allow the provider to utilize an intermediary to process submitted claims and bills. Groups and associations of providers may nominate organizations or agencies to serve as the intermediary for their group. If the provider would like to submit claims to an intermediary outside of the provider’s service area, the provider has the right to nominate this outside intermediary to act on their behalf. CMS must approve these nominations based on a set of standards. If CMS determines an assignment or reassignment of a provider’s intermediary will result in a more effective and efficient administration of the Medicare program, CMS can assign any intermediary to any provider. Effective 9/30/05, the provider nomination provision contained under title XVIII of the Social Security Act, section 1816, will expired. These provisions have been amended by the MMA. Section 911 (d) (2) (A) of the MMA requires the Secretary to enter into new agreements under section 1816 without regard to the provider nomination provisions and contracts under section 1842 of the Social Security Act (42 U.S.C. 1395h, 139u).

**Timetable:**

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**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** Businesses

**Government Levels Affected:** Local

**Agency Contact:** Scott Sturiale, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop S1–14–17, 7500 Security Boulevard, Baltimore, MD 21244–1850 Phone: 410 786–2565 Email: scott.sturiale@cms.hhs.gov

RIN: 0938–AO33

996. ● GYNECOLOGICAL CYTOLOGY PROFICIENCY TESTING REQUIREMENTS FOR LABORATORIES, INDIVIDUALS, AND PROFICIENCY TESTING PROGRAM APPROVALS (CMS–2252–P)

**Priority:** Other Significant

**Legal Authority:** 42 USC 263a, Clinical Laboratory Improvement Amendments of 1988; 42 USC 1395x secs 1861s(15) through 1861s(17)

**CFR Citation:** 42 CFR 493

**Legal Deadline:** None

**Abstract:** This proposed rule would revise certain participation requirements for clinical laboratories offering cytology services and individuals examining gynecological cytology specimens; and CMS-approval requirements for programs offering proficiency testing for gynecological cytology under the Clinical Laboratory Improvement Amendments (CLIA) of 1988 program. Evaluating the competency of each individual who examines gynecologic cytology specimens (pap smears) is required by Federal law and regulations. The cytology community, through professional organizations, is lobbying Congress to request a change in the statute to eliminate proficiency testing of individuals (pathologists and cytotechnologists) who examine pap smears. Failure to publish this rule timely could result in the failure to identify individuals who cannot competently and accurately examine pap smears, or failure to demonstrate a need for continual education. Identifying these individuals is essential in providing quality patient care.

**Timetable:**

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**Regulatory Flexibility Analysis Required:** Undetermined

**Small Entities Affected:** Businesses

**Government Levels Affected:** None

**Federalism:** Undetermined
997. SPECIAL MEDICARE GME AFFILIATIONS FOR A TEACHING HOSPITAL AFFECTED BY A DISASTER (CMS–1531–IFC)

Priority: Other Significant
Legal Authority: sec 1886(h)(d) of the Social Security Act
CFR Citation: Not Yet Determined
Legal Deadline: None

Abstract: This rule will amend the current closed program regulations and Medicare affiliation agreement regulations to ameliorate the disruption in residency training caused by Hurricane Katrina and future emergency situations. Amendments to current closed program and Medicare affiliation agreement regulations will allow hospitals in areas affected by Hurricane Katrina and those hospitals adopting displaced residents, greater flexibility in maintaining Medicare funding during emergency situations. The amended regulations would go into effect during emergency situations as defined by the section 1135 emergency waiver invoked by the Secretary. Without changes to current regulations, adopting hospitals may be financially incapable of accepting displaced residents, home hospitals may have increased difficulty reopening residency training programs, and residents may be unable to continue with their planned residency training.

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Regulatory Flexibility Analysis Required: No
Small Entities Affected: Businesses

Agency Contact: Cheryl B Wiseman, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop, S2–12–25, 7500 Security Boulevard, Baltimore, MD 21244–1850 Phone: 410 786–3340 Email: cheryl.wiseman@cms.hhs.gov
RIN: 0938–AO35

998. STATE CHILDREN’S HEALTH INSURANCE PROGRAM (SCHIP) REDISTRIBUTION OF UNEXPENDED SCHIP FUNDS FROM THE APPROPRIATION FOR FISCAL YEAR 2003 (CMS–2235–NC)

Priority: Other Significant
Legal Authority: 42 USC 1397dd(g); 42 USC 1397ee(g); 2104 (e) & (f) of the Social Security Act, sec 6101 of DRA
CFR Citation: 42 CFR 457.600.630
Legal Deadline: None

Abstract: This notice announces the procedure for redistribution of States, unexpended FY 2003 allotments that remained at the end of FY 2005 to those States that fully expended the FY 2003 SCHIP allotment. It also announces the implementation of the section 6101 of the Deficit Reduction Act of 2006, which provides for additional allotments to eliminate States SCHIP funding shortfalls in FY 2006. These redistributed allotments will be available through the end of FY 2006 (September 30, 2006).

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Regulatory Flexibility Analysis Required: Undetermined
Small Entities Affected: Local
Federalism: Undetermined
Agency Contact: Janet Samen, Acting Director, Division of Technical Payment Policy, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop C5–05–27, 7500 Security Boulevard, Baltimore, MD 21244–1850 Phone: 410 786–9161 Email: janet.samen@cms.hhs.gov
RIN: 0938–AO40

1000. NOTIFICATION PROCEDURES FOR HOSPITAL DISCHARGES (CMS–4105–F)

Priority: Other Significant
Legal Authority: 42 USC 1396ff
CFR Citation: 42 CFR 405; 42 CFR 412; 42 CFR 422; 42 CFR 489
Legal Deadline: Final, Judicial, November 28, 2006, Based on language in settlement agreement.

Abstract: This rule sets forth new requirements for hospital discharge notices under both original Medicare and the Medicare Advantage (MA) program. Notably, this rule requires hospitals to comply with a two-step notice process when discharging hospital inpatients that is similar to the notice requirements applicable to home health agencies (HHAs), skilled nursing facilities (SNFs), and comprehensive outpatient rehabilitation facilities (CORFs).

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| Regulatory Flexibility Analysis | Required: No |
| Small Entities Affected: | No |
| Government Levels Affected: | None |

**Agency Contact:** Eileen Zerhusen, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Department of Health and Human Services, Mailstop S3–23–03, 7500 Security Boulevard, Baltimore, MD 21244 Phone: 410 786–7803 Email: eileen.zerhusen@cms.hhs.gov

**Legal Deadline:** Not Yet Determined

**Legal Authority:** Deficit Reduction Act of 2005; (PL 109–171), sec 6202

**Federalism:** Undetermined

**Government Levels Affected:** Undetermined

### 1001. ● STATE OPTION TO ESTABLISH NON–EMERGENCY MEDICAL TRANSPORTATION PROGRAM (CMS–2234–P)

**Priority:** Other Significant. Major status under 5 USC 801 is undetermined.

**Unfunded Mandates:** Undetermined

**Legal Authority:** Deficit Reduction Act of 2005 (PL 109–171), sec 6083

**Legal Deadline:** Final, Statutory, February 8, 2006.

**Abstract:** Enactment of section 6083 of the Deficit Reduction Act of 2005 (DRA) amends section 1902(a) of the Social Security Act (the Act) by adding a new section 1902(a)(78) that states the authority to establish, under the State plan, a non-emergency medical transportation (NEMT) brokerage program. Such a program may be managed through a contract with a broker(s), as a method of assuring NEMT services for beneficiaries who need access to medical care, but have no other means of transportation. A regulation is needed in order to implement this provision of the DRA.

**Timetable:**

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| Regulatory Flexibility Analysis | Required: Undetermined |
| Government Levels Affected: | Undetermined |

### 1002. ● HIGH RISK POOLS (CMS–2260–P)

**Priority:** Other Significant. Major status under 5 USC 801 is undetermined.

**Unfunded Mandates:** Undetermined

**Legal Authority:** Deficit Reduction Act of 2005; (PL 109–171), sec 6202

**Legal Deadline:** Final, Statutory, March 31, 2006.

**Abstract:** Section 6202 of the Deficit Reduction Act of 2005 extends the funding and authorizes (H.R. 4519) and appropriates for FY 2006 $75 million for grants to help fund existing qualified State high risk pools and $15 million for grants to assist States to create and initially fund qualified high risk pools. The bill also authorizes appropriations of $75 million for each year FY 2007 through 2010. The section 6202 provision amendment to section 2745 establishes: (1) Seed grants to States for the creation and initial operation of a qualified high-risk pool for those States that do not have one, (2) grants to States to reimburse them for a percentage of losses incurred based on a methodology that allocates funding by 40 percent among all states, 30 percent to states based on their number of uninsured residents and 30 percent based on the number of people in State risk pools operating as an existing qualified high-risk pools during specified years and (3) bonus grants for supplemental consumer benefits. A regulation is needed in order to implement this provision of the DRA.

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| Regulatory Flexibility Analysis | Required: Undetermined |
| Government Levels Affected: | Undetermined |

### 1003. ● COST SHARING OPTIONS (CMS–2244–P)

**Priority:** Other Significant. Major status under 5 USC 801 is undetermined.

**Unfunded Mandates:** Undetermined

**Legal Authority:** Deficit Reduction Act of 2005, PL 109–171

**CFR Citation:** Not Yet Determined

**Legal Deadline:** Final, Statutory, March 31, 2006, sec 6041 & 6042.

**Abstract:** This rule would incorporate sections 6041, 6042, and 6043 of the Deficit Reduction Act of 2005 (DRA), which provides State Medicaid agencies with increased flexibility to implement premium and cost sharing requirements for certain Medicaid recipients. This authority is in addition to the current authority States already had under section 1916 of the Social Security Act to implement premiums and cost sharing. Sections 6041, 6042, and 6043 of the DRA provide States with additional State plan flexibility to implement alternative premiums for certain recipients and to implement alternative cost sharing for certain medical services, particularly non-preferred drugs and non-emergency care furnished in a hospital emergency department.

**Timetable:**

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| Regulatory Flexibility Analysis | Required: Undetermined |
| Government Levels Affected: | Undetermined |

**Federalism:** Undetermined

**Agency Contact:** Jean Sheil, Director, Family and Children’s Health Programs Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop S2–01–16, 7500 Security Boulevard, Baltimore, MD 21244 Phone: 410 786–5647 Email: jean.sheil@cms.hhs.gov

**RIN:** 0938–AO45

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**RIN:** 0938–AO46
### 1004. • BENCHMARK BENEFIT PACKAGE (CMS–2232–P)

**Priority:** Other Significant. Major status under 5 USC 801 is undetermined.

**Unfunded Mandates:** Undetermined

**Legal Authority:** Deficit Reduction Act of 2005; sec 6044

**CFR Citation:** Not Yet Determined

**Legal Deadline:** Final, Statutory, March 31, 2006.

**Abstract:** Enactment of section 6044 of the Deficit Reduction Act of 2005 (DRA) responds to State requests for additional flexibility by providing States with new options. For non-disabled, non-elderly persons who are eligible for Medicaid, the DRA allows States to follow the lead established by SCHIP and provide more flexible benefit packages that are more comparable to those in the private sector. Benchmark coverage is one four types of coverage: Blue Cross/Blue Shield standard FEHBP coverage; State employee coverage; coverage of the largest commercial HMO in the states; and Secretary approved coverage. Children under age 19 enrolled in a benchmark plan will continue to receive EPSDT benefits through wrap-around coverage. A regulation is needed in order to implement this provision of the DRA.

**Timetable:**

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**Regulatory Flexibility Analysis Required:** Undetermined

**Government Levels Affected:** Undetermined

**Federalism:** Undetermined

**Agency Contact:** Jean Sheil, Director, Family and Children’s Health Programs Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, MailStop S2–01–16, 7500 Security Boulevard, Baltimore, MD 21244–1850

Phone: 410 786–5647
Fax: 410 786–8534
Email: jean.sheil@cms.hhs.gov

RIN: 0938–AO47

### 1005. • IMPROVED ENFORCEMENT OF DOCUMENTATION REQUIREMENTS (CMS–2257–P)

**Priority:** Other Significant. Major status under 5 USC 801 is undetermined.

**Unfunded Mandates:** Undetermined

**Legal Authority:** Deficit Reduction Act of 2005 (PL 109–171), sec 6036

**CFR Citation:** Not Yet Determined

**Legal Deadline:** Final, Statutory, July 1, 2006.

**Abstract:** Enactment of section 6036 of the Deficit Reduction Act of 2005 (DRA) requires that, effective July 1, 2006, all new applicants for Medicaid must, in addition to declaring that they are a citizen or national of the U.S. or an alien in a satisfactory immigration status, if claiming to be a citizen or national submit to the State evidence of citizenship. Since 1987, aliens claiming to be in a satisfactory immigration status have had to provide evidence of the claimed status and have that status verified with the Department of Homeland Security (previously the Immigration and Naturalization Service). A regulation is needed in order to implement this provision of the DRA.

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**Regulatory Flexibility Analysis Required:** Undetermined

**Government Levels Affected:** Undetermined

**Federalism:** Undetermined

**Agency Contact:** Jean Sheil, Director, Family and Children’s Health Programs Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, MailStop S2–01–16, 7500 Security Boulevard, Baltimore, MD 21244–1850

Phone: 410 786–5647
Fax: 410 786–8534
Email: jean.sheil@cms.hhs.gov

RIN: 0938–AO48

### 1006. • SELF–DIRECTED PERSONAL ASSISTANCE SERVICES STATE PLAN OPTION (CMS–2229–P)

**Priority:** Other Significant

**Legal Authority:** Deficit Reduction Act of 2005; (PL 109–171), sec 6087

**CFR Citation:** Not Yet Determined

**Legal Deadline:** Final, Statutory, January 1, 2007.

**Abstract:** The regulation is in support of the Deficit Reduction Act. Section 6087 allows a State to offer self-directed personal assistance services as a State Plan option and is intended to offer guidance to States on implementing the statutory provision.

**Timetable:**

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**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** Federal, State

**Agency Contact:** Theresa Pratt, Director, Division of Integrated Health Systems, Disabled and Elderly Health Programs Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop S2–14–26, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786–9499
Email: theresa.pratt@cms.hhs.gov

RIN: 0938–AO51

**Agency Contact:** Jean Sheil, Director, Family and Children’s Health Programs Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Centers for Medicaid States Operations, Mailstop S2–01–16, 7500 Security Boulevard, Baltimore, MD 21244–1850

Phone: 410 786–5957
Fax: 410 786–8534
Email: jean.sheil@cms.hhs.gov

RIN: 0938–AO52
1007. REQUIREMENTS FOR PROVIDERS AND SUPPLIERS TO ESTABLISH AND MAINTAIN MEDICARE ENROLLMENT (CMS–6002–F)

Priority: Other Significant
Legal Authority: 42 USC 1302; 42 USC 1395hh
CFR Citation: 42 CFR 424
Legal Deadline: Final, Statutory, April 25, 2006, MMA Sec 902.
Abstract: This final rule requires that all providers and suppliers (other than physicians who have elected to “opt-out” of the Medicare program) complete an enrollment form and submit specific information to CMS. This rule will require that all providers and suppliers periodically update and certify the accuracy of their enrollment information to receive and maintain billing privileges in the Medicare program. In addition, this final rule will implement provisions in the Medicare statute that require CMS to ensure that all Medicare providers and suppliers are qualified to provide the appropriate health care services. These statutory provisions include requirements meant to protect beneficiaries and the Medicare Trust Funds by preventing unqualified, fraudulent, or excluded providers and suppliers from providing items or services to Medicare beneficiaries or billing the Medicare program or its beneficiaries.

Timetable:
Action Date FR Cite
NPRM 11/16/00 65 FR 69416
Interim Final Rule With 08/00/06 Comment
Regulatory Flexibility Analysis Required: No
Small Entities Affected: Businesses
Government Levels Affected: None
Agency Contact: Thomas Shenk, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Division of Benefits & Coverage Policy, Mailstop S2–14–26, 7500 Security Boulevard, Baltimore, MD 21244 Phone: 410 786–3295 Email: thomas.shenk@cms.hhs.gov
RIN: 0938–AJ96

1008. HOSPITAL CONDITIONS OF PARTICIPATION: LABORATORY SERVICES (CMS–3014–IFC) (SECTION 610 REVIEW)

Priority: Substantive, Nonsignificant
Legal Authority: 42 USC 1302; 42 USC 1395hh
CFR Citation: 42 CFR 482
Legal Deadline: None
Abstract: This interim final rule with comment period requires hospitals that transfuse blood and blood products to prepare and follow written procedures for appropriate action when it is determined that blood and blood products the hospital received and transfused are at increased risk for transmitting hepatitis C virus (HCV); quarantine prior collections from a donor who is at increased risk for transmitting HCV infection; notify transfusion recipients, as appropriate, of the need for HCV testing and counseling; and maintain records for at least 10 years.

Timetable:
Action Date FR Cite
NPRM 11/16/00 65 FR 69416
Interim Final Rule With 08/00/06 Comment
Regulatory Flexibility Analysis Required: No
Small Entities Affected: Businesses
Government Levels Affected: None
Agency Contact: Mary Collins, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Clinical Standards Group, Mailstop S3–02–01, 7500 Security Boulevard, Baltimore, MD 21244 Phone: 410 786–3189 Email: mary.collins@cms.hhs.gov
RIN: 0938–AJ29

1009. USE OF RESTRAINTS AND SECLUSION IN RESIDENTIAL TREATMENT FACILITIES PROVIDING INPATIENT PSYCHIATRIC SERVICES TO INDIVIDUALS UNDER AGE 21 (CMS–2065–F)

Priority: Other Significant
Legal Authority: 42 USC 1302; 42 USC 1396d
CFR Citation: 42 CFR 441, 42 CFR 442, and 42 CFR 483
Legal Deadline: None
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.

Timetable:
Action Date FR Cite
Interim Final Rule 01/22/01 66 FR 7148
60–Day Delay of Effective Date To 03/21/01 66 FR 15800
Interim Final Rule Comment Period End
Interim Final Rule Effective
Interim Final Rule Amendment with Clarification
Interim Final Rule Comment Period End
Final Action 10/00/06

Regulatory Flexibility Analysis Required: No
Small Entities Affected: Businesses
Government Levels Affected: None
Agency Contact: Michael Collett, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of Financial Management, Program Integrity Group, Division of Provider/Supplier Enrollment, N3–22–17, 7500 Security Boulevard, Baltimore, MD 21244 Phone: 410 786–6121
RIN: 0938–AH73

1010. PHYSICIANS’ REFERRALS TO HEALTH CARE ENTITIES WITH WHICH THEY HAVE FINANCIAL RELATIONSHIPS (CMS–1810–F)

Priority: Other Significant
Legal Authority: 42 USC 1877
CFR Citation: 42 CFR 411; 42 CFR 424
Abstract: This final rule incorporates into regulation certain statutory provisions that preclude payment for services under Medicare if a physician makes a referral to a facility in which he or she has a financial interest. It addresses comments from the January 9, 1998, proposed rule concerning the ownership, investment, and compensation exceptions. It also
addresses comments from the January 4, 2001, final rule with comment period.

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Regulatory Flexibility Analysis
Required: Yes
Small Entities Affected: Businesses, Organizations
Government Levels Affected: None
Agency Contact: Linda P. Howard, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare Management, Chronic Care Policy Group, Mailstop C4–25–02, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–5255
Email: linda.howard@cms.hhs.gov
RIN: 0938–AK67

1011. ENHANCED DSH TREATMENT FOR CERTAIN HOSPITALS (CMS–2198–F)
Priority: Other Significant
Legal Authority: Section 1923(a)(2)(D) of the Social Security Act
CFR Citation: 42 CFR 447; 42 CFR 455
Legal Deadline: Final, Statutory, December 8, 2003, Sec 1001(d) of MMA.
Abstract: This rule implements section 1001(d) of the Medicare Prescription Drug Improvement, and Modernization Act of 2003 which requires States to report additional information about their disproportionate share hospital (DSH) programs in their annual report. This section also requires States to independently audit and submit these certified audits annually to the Secretary.

Timetable:

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<tr>
<th>Action</th>
<th>Date</th>
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Regulatory Flexibility Analysis
Required: No

Small Entities Affected: None
Government Levels Affected: State
Agency Contact: James Frizzera, Director, National Institutional Payment Policy Center for Medicaid and State Operations, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop S3–13–15, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–3263
Email: james.frizzera@cms.hhs.gov
RIN: 0938–AN09

1012. NONDISCRIMINATION IN HEALTH COVERAGE IN THE GROUP MARKET (CMS–4081–F)
Priority: Substantive, Nonsignificant. Major status under 5 USC 801 is undetermined.
Legal Authority: 42 USC 300gg
CFR Citation: 45 CFR 146.121
Abstract: This final rule governs the provisions prohibiting discrimination based on a health factor for group health plans and issuers of health insurance coverage offered in connection with a group health plan. The rules contained in this document implement changes made to the Internal Revenue Code of 1986 (Code), the Employee Retirement Income Security Act of 1974, and the Public Health Service Act enacted as part of the Health Insurance Portability and Accountability Act of 1996. It also addresses comments we received on the Bonafide Wellness Plan proposed rule.

Timetable:

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Regulatory Flexibility Analysis
Required: No
Small Entities Affected: Businesses, Governmental Jurisdictions

Government Levels Affected: Local, State
Agency Contact: David Mlawsky, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Beneficiary Choices, Medicare Plan Policy Group, S3–16–26, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–6851
Email: david.mlawsky@cms.hhs.gov
Related RIN: Previously reported as 0938–AK19
RIN: 0938–AN29

1013. HOSPITAL CONDITIONS OF PARTICIPATION: PATIENTS’ RIGHTS (CMS–3018–F)
Priority: Other Significant. Major status under 5 USC 801 is undetermined.
Legal Authority: 42 USC 1395x; 42 USC 1396d; 42 USC 1395bb
CFR Citation: 42 CFR 482
Abstract: This final rule sets forth standards for the use of restraints and seclusion in Medicare- and Medicaid-participating hospitals as part of the Patients’ Rights Condition of Participation (CoP) and finalizes other patients’ rights afforded by that CoP. It finalizes six standards that ensure minimum protections of each patient’s physical and emotional health and safety. These standards address each patient’s right to: Notification of his or her rights; the exercise of his or her rights in regard to his or her care; privacy and safety; confidentiality of patient records; freedom from restraints used in the provision of acute medical and surgical care unless clinically necessary; and freedom from seclusion and restraint for behavior management unless clinically necessary.

Timetable:

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Regulatory Flexibility Analysis
Required: No
Small Entities Affected: None
Government Levels Affected: None
Agency Contact: Patricia Chmielewski, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Beneficiary Choices, Medicare Plan Policy Group, S3–16–26, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–6851
Email: david.mlawsky@cms.hhs.gov
Related RIN: Previously reported as 0938–AK19
RIN: 0938–AN29
1014. NATIONAL PLAN AND PROVIDER ENUMERATION SYSTEM (NPPES) DATA DISSEMINATION (CMS–6060–NC)

Priority: Other Significant. Major status under 5 USC 801 is undetermined.
Legal Authority: HIPAA of 1996, secs 1117 to 1179 of the Social Security Act (42 USC 1329d to 1320d–8); NPI final rule (01/23/2004); NPS System of Records (07/28/1998)
CFR Citation: 45 CFR 163
Legal Deadline: None

Abstract: The National Provider Identifier final rule, published January 23, 2004, stated that CMS would publish a follow-up notice to describe the data dissemination processes and any applicable charges for data. This notice with comment period describes the data that would be available from the National Plan and Provider Enumeration System (NPPES), in compliance with the provisions of the Privacy Act, the Freedom of Information Act, the Electronic Freedom of Information Act (FOIA) Amendments of 1996, and other applicable regulations and authorities, and must be consistent with the National Provider System of Records Notice published on July 28, 1998. The notice describes the data dissemination strategy, processes, and any applicable charges for data.

Timetable:

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Regulatory Flexibility Analysis Required: No
Small Entities Affected: No
Government Levels Affected: None
Agency Contact: Helen Dietrick, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of Financial Management, Program Integrity Group, Mailstop C3–02–16, 7500 Security Boulevard, Baltimore, MD 21244 Phone: 410 786–7448 Email: helen.dietrick@cms.hhs.gov
RIN: 0938–AN71

1015. PAYMENT ERROR RATE MEASUREMENT (PERM) PROGRAM (CMS–6026–IFC2)

Priority: Other Significant
Legal Authority: Improper Payment Information Act of 2002
CFR Citation: 42 CFR 431; 42 CFR 457
Legal Deadline: Final, Statutory, October 1, 2005.

Abstract: This interim final rule sets forth the State requirements to provide information to us for purposes of estimating improper payments in Medicaid and SCHIP. The Improper Payments Information Act of 2002 (IPIA) requires heads of Federal agencies to annually estimate and report to the Congress these estimates of improper payments for the programs they oversee and submit a report on actions the Agency is taking to reduce erroneous payments. This interim final rule responds to the public comments on the October 5, 2005 interim final rule and sets forth State requirements for submitting claims and policies to the Federal contractor for purposes of conducting FFS and managed care reviews. This interim final rule also solicits comments on the State requirements for conducting eligibility reviews and estimating payment error rates due to errors in eligibility determinations.

Timetable:

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Regulatory Flexibility Analysis Required: No
Government Levels Affected: State
Agency Contact: Christine Jones, Division Director, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of Financial Management, Mailstop C3–02–16, 7500 Security Boulevard, Baltimore, MD 21244 Phone: 410 786–3722 Email: christine.jones@cms.hhs.gov
Related RIN: Related to 0938–AM86
RIN: 0938–AN77

1016. INPATIENT PSYCHIATIC FACILITY PROSPECTIVE PAYMENT SYSTEM—UPDATE FOR FY 2006 (CMS–1306–F)
Priority: Economically Significant. Major under 5 USC 801.
Legal Authority: PL 106–113, sec 124 BBRA
CFR Citation: 42 CFR 412
Legal Deadline: Final, Statutory, July 1, 2006.

Abstract: This rule will update the Prospective Payment Rate for Medicare Inpatient Psychiatric Facilities for discharges occurring during the rate year beginning 7/1/06 to 6/30/07. This rule will update and revise the market basket and the use of new market area definitions.

Timetable:

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Regulatory Flexibility Analysis Required: Undetermined
Small Entities Affected: Businesses, Governmental Jurisdictions
Government Levels Affected: Local
Agency Contact: Janet Samen, Acting Director, Division of Technical Payment Policy, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop C5–05–27, 7500 Security Boulevard, Baltimore, MD 21244 Phone: 410 786–9161 Email: janet.samen@cms.hhs.gov
RIN: 0938–AN82

1017. PROGRAM FOR ALL–INCLUSIVE CARE FOR THE ELDERLY (PACE): PROGRAM REVISIONS (CMS–1201–F)
Priority: Other Significant
Legal Authority: PL 108–173, sec 902 of MMA; BIPA, sec 903
CFR Citation: 42 CFR 460

Abstract: This rule finalizes two interim final rules with comment periods. The November 24, 1999 rule established requirements for Programs of All-inclusive Care for the Elderly (PACE) under the Medicare and Medicaid programs and the October 1, 2002 rule implemented section 903 of BIPA. These are pre-paid, capitated
programs for beneficiaries who meet special eligibility requirements and who elect to enroll.

**Timetable:**

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**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** Businesses, Governmental Jurisdictions, Organizations

**Government Levels Affected:** Federal, Local, State, Tribal

**Agency Contact:** Janet Harris, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare Management, Chronic Care Policy Group, Mailstop CS–05–27, 7500 Security Boulevard, Baltimore, MD 21244–1850

Phone: 410 786–3137

Email: janet.harris@cms.hhs.gov

**Related RIN:** Previously reported as 0938–AL59

**RIN:** 0938–AN83

---

### 1018. PROSPECTIVE PAYMENT SYSTEM FOR LONG-TERM CARE HOSPITALS RY 2007: ANNUAL PAYMENT RATE UPDATES (CMS–1485–F)

**Priority:** Economically Significant. Major under 5 USC 801.

**Legal Authority:** sec 123 PL 106–113; sec 307(b), PL 106–554

**CFR Citation:** 42 CFR 412

**Legal Deadline:** Final, Statutory, Effective July 1, 2006.

**Abstract:** This rule proposes the annual payment rate update for the RY 2007 prospective payment system for Medicare long-term care hospitals and also presents proposed changes or revisions in LTCH PPS policy for public comment.

**Timetable:**

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<th>Action</th>
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**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** Businesses

**Government Levels Affected:** None

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### 1019. PART A PREMIUMS FOR CALENDAR YEAR 2007 FOR THE UNINSURED AGED AND FOR CERTAIN DISABLED INDIVIDUALS WHO HAVE EXHAUSTED OTHER ENTITLEMENT (CMS–8028–N)

**Priority:** Other Significant

**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 1818 A(d)(2)

**CFR Citation:** None

**Legal Deadline:** Final, Statutory, September 30, 2006.

**Abstract:** This notice announces the hospital insurance premium for calendar year 2007 under Medicare’s Hospital Insurance program (Medicare Part A) for the uninsured aged and for certain disabled individuals who have exhausted other entitlement.

**Timetable:**

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**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** None

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### 1020. INPATIENT HOSPITAL DEDUCTIBLE AND HOSPITAL AND EXTENDED CARE SERVICES COINSURANCE AMOUNTS FOR CALENDAR YEAR 2007 (CMS–8029–N)

**Priority:** Other Significant

**Legal Authority:** 42 USC 1395e–2(b)(2); Social Security Act, sec 1813 (b)(2)

**CFR Citation:** None

**Legal Deadline:** Final, Statutory, September 15, 2006.

**Abstract:** This notice announces the inpatient hospital deductible and the hospital and extended care services coinsurance amounts for services furnished in calendar year 2007 under Medicare’s Hospital Insurance program (Medicare Part A). The Medicare statute specifies the formulae used to determine these amounts.

**Timetable:**

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**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** None

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### 1021. FISCAL YEAR 2007 SCHIP ALLOTMENTS (CMS–2251–N)

**Priority:** Other Significant

**Legal Authority:** Title XXI of the Social Security Act, sec 2104

**CFR Citation:** 42 CFR 457

**Legal Deadline:** Final, Statutory, September 30, 2006.

**Abstract:** This notice sets forth the final State Children’s Health Insurance Program (SCHIP) allotments of Federal funding available to each State, the District of Columbia, and each U.S. Territory and Commonwealth for fiscal year 2007.
Phone: 410 786–2019
Email: richard.strauss@cms.hhs.gov

Small Entities Affected: No

Government Levels Affected: State

Agency Contact: Richard Strauss, Technical Director, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicaid State Operations, Mailstop S3–13–15, 7500 Security Boulevard, Baltimore, MD 21244–1850

Phone: 410 786–2019
Email: richard.strauss@cms.hhs.gov

RIN: 0938–AO21

1022. PART B MONTHLY ACTUARIAL RATES AND PREMIUM RATE BEGINNING JANUARY 1, 2007 (CMS–8030–N)

Priority: Other Significant

Legal Authority: 42 USC 1395r; Social Security Act, sec 1839; MMA, sec 629; MMA, sec 811; Deficit Reduction Act of 2005, PL 109–171, sec 5111

CFR Citation: None


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 2007. It also announces the monthly Part B premium to be paid by all enrollees, and the Part B deductible, during 2007. This notice will also incorporate provisions from section 5111 of the Deficit Reduction Act of 2005, which affects implementation of income income-related change in part B premium subsidy.

Timetable:

Action Date FR Cite
Final Notice 08/00/06

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Suzanne Codespote, Deputy Director, Medicare and Medicaid Cost Estimates Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of the Actuary, Mailstop N3–26–00, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–7737
Email: suzanne.codespote@cms.hhs.gov

RIN: 0938–AO23

1023. PROSPECTIVE PAYMENT SYSTEM AND CONSOLIDATED BILLING FOR SKILLED NURSING FACILITIES—UPDATE FOR FY 2007 (CMS–1530–N)

Priority: Economically Significant. Major under 5 USC 801.

Legal Authority: Social Security Act, sec 1888(e)

CFR Citation: 42 CFR 424

Legal Deadline: Other, Statutory, July 31, 2006, Notice must be published before 08/01/2006.

Abstract: This notice updates the payment rates used under the SNF PPS beginning 10/1/06.

Timetable:

Action Date FR Cite
Final Action 07/00/06

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Agency Contact: Bill Ullman, Health Insurance Specialist, Division of Institutional Post Acute Care, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Chronic Care Policy Group, Mailstop C5–08–27, 7500 Security Boulevard, Baltimore, MD 21244–1850
Phone: 410 786–5667
Email: bill.ullman@cms.hhs.gov

RIN: 0938–AO24

1024. HOSPICE WAGE INDEX FOR FY 2007 (CMS–1535–N)

Priority: Other Significant

Legal Authority: 1814(i) (1) of the Act; 1814(i) (2)

CFR Citation: 42 CFR 418

Legal Deadline: Final, Statutory, September 1, 2006.

Abstract: This notice announces the annual update to the hospice wage index for FY 2007. The wage index is used to reflect local differences in wage levels. The hospice wage index methodology and values are based on recommendations of a negotiated rulemaking advisory committee and were originally published on 8/8/97.

Timetable:

Action Date FR Cite
Final Action 08/00/06

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Terri Deutsch, Health Insurance Specialist, Division of Community Post Acute Care, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Chronic Care Policy Group, Mailstop C5–06–27, 7500 Security Boulevard, Baltimore, MD 21244–1850
Phone: 410 786–9462
Email: terri.deutsch@cms.hhs.gov

RIN: 0938–AO26

1025. STATE ALLOTMENTS FOR PAYMENT OF MEDICARE PART B PREMIUMS FOR QUALIFYING INDIVIDUALS: FISCAL YEAR 2006 (CMS–2231–IFC)

Priority: Other Significant

Legal Authority: QI, TMA, and Abstinence Programs Extension and Hurricane Katrina Unemployment Relief Act of 2005, sec 101

CFR Citation: 42 CFR 433.10


Abstract: On August 26, 2005 CMS published in the FR an interim final rule for determining the revised FY 2005 allotments, CMS–2210–IFC. When CMS published this in the FR, we did not reference the allotments for fiscal years after FY 2005, since the funding for the program ended with FY 2005. However, on October 20, 2005, Pub. L. 109-91 was enacted; section 101 of that law extended the QI program to FY 2006 and FY 2007. In particular, section 101 extended the qualifying individual program through September 30, 2007 with no change in funding; that is, under this legislation, $400 million per fiscal year is appropriated for each of FY 2006 and FY 2007. We are publishing this rule as an IFC
because of the need to notify individual States of the limitations on Federal funds for their Medicaid expenditures for payment of Medicare Part B premiums for QIs. Some States have experienced deficits in their current allotments that have caused them to deny benefits to eligible applicants, while other States project a surplus in their allotments. This rule permits redistribution of funds and will allow all eligible applicants to receive QI benefits during this calendar year.

### Timetable:

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<td>Agency Contact:</td>
<td>Richard Strauss, Department of Health and Human Services, Centers for Medicare &amp; Medicaid Services, C5–22–25, 7500 Security Blvd, Baltimore, MD 21244 Phone: 410 786–2019 Email: <a href="mailto:richard.strauss@cms.hhs.gov">richard.strauss@cms.hhs.gov</a></td>
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1026. • STATE HEALTH INSURANCE ASSISTANCE PROGRAM (SHIP) (CMS–4005–F)

**Priority:** Other Significant

**Legal Authority:** sec 4360 of OBRA 1990 (PL 101–508)

**CFR Citation:** 42 CFR 403

**Legal Deadline:** Final, Statutory, December 8, 2006, MMA Section 902.

**Abstract:** This rule adopts as final the provisions in the interim final regulation that published June 1, 2000, which explain the terms and conditions that apply to State grants for counseling and assistance to Medicare beneficiaries, and makes several minor technical clarifications.

### Timetable:

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1027. • FEE SCHEDULE FOR PAYMENT OF AMBULANCE SERVICES—UPDATE FOR CY 2007 (CMS–1532–N)

**Priority:** Economically Significant. Major under 5 USC 801.

**Legal Authority:** Sec 1834(1) of the Social Security Act

**CFR Citation:** 42 CFR 410

**Legal Deadline:** Final, Statutory, Effective 01/01/2007.

**Abstract:** This notice updates the fee schedule for ambulance services under the Medicare program, implementing section 1834(1) of the Social Security Act (effective 1/1/07).

### Timetable:

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<tr>
<td>Agency Contact:</td>
<td>Anne Tayloe, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare &amp; Medicaid Services, Mailstop C4–07–07, 7500 Security Boulevard, Baltimore, MD 21244–1850 Phone: 410 786–4546 Email: <a href="mailto:ann.tayloe@cms.hhs.gov">ann.tayloe@cms.hhs.gov</a></td>
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**Priority:** Info./Admin./Other

**Legal Authority:** 42 USC 1395

**CFR Citation:** 42 CFR 423

**Legal Deadline:** None

**Abstract:** This notice permits the use of Version 8.1 of the NCPDP SCRIPT standard for e-prescribing transactions. Use of the standard is voluntary at this time. Version 5.0 of the NCPDP SCRIPT was adopted as an e-prescribing foundation standard 11/7/05. Voluntary use of Version 8.1 will be pilot tested with other available e-prescribing standards during the 2006 e-prescribing pilot project.

### Timetable:

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Federalism: This action may have federalism implications as defined in EO 13132.
Agency Contact: David Mlawsky, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C5–16–16, 7500 Security Boulevard, Baltimore, MD 21244 Phone: 410 786–6851 Email: david.mlawsky@cms.hhs.gov

**Related RIN:** Related to 0938–AI17

**RIN:** 0938–AO43

**1030. • TARGETED CASE MANAGEMENT (CMS–2237–IFC)**

**Priority:** Other Significant. Major status under 5 USC 801 is undetermined.

**Unfunded Mandates:** Undetermined

**Legal Authority:** Deficit Reduction Act of 2005; (PL 109–171), sec 6052

**CFR Citation:** Not Yet Determined

**Legal Deadline:** Final, Statutory, January 1, 2006.

**Abstract:** This regulation is required by the Deficit Reduction Act. Section 6052 clarifies what is reimbursable under the Medicare case management and targeted case management benefit and is intended to offer guidance to States on implementing the statutory provision.

**Timetable:**

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**Regulatory Flexibility Analysis Required:** Undetermined

**Government Levels Affected:** Undetermined

**Federalism:** Undetermined

Agency Contact: Theresa Pratt, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244 Phone: 410 786–9499 Email: theresa.pratt@cms.hhs.gov

**RIN:** 0938–AO50

**1031. • HOME AND COMMUNITY–BASED SERVICES (HCBS) STATE PLAN OPTION (CMS–2249–IFC)**

**Priority:** Other Significant. Major status under 5 USC 801 is undetermined.

**Unfunded Mandates:** Undetermined

**Legal Authority:** Deficit Reduction Act of 2005; (PL 109–171), sec 6086

**CFR Citation:** Not Yet Determined

**Legal Deadline:** Final, Statutory, January 1, 2007.

**Abstract:** The regulation would offer guidance to States on implementing the statutory provisions of sec 6086 of the Deficit Reduction Act

**Timetable:**

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**Regulatory Flexibility Analysis Required:** Undetermined

**Government Levels Affected:** Undetermined

**Federalism:** Undetermined

Agency Contact: Theresa Pratt, Director, Division of Integrated Health Systems, Disabled and Elderly Health Programs Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop S2–14–26, 7500 Security Boulevard, Baltimore, MD 21244 Phone: 410 786–9499 Email: theresa.pratt@cms.hhs.gov

**RIN:** 0938–AO53

**1032. END STAGE RENAL DISEASE (ESRD) CONDITIONS FOR COVERAGE (CMS–3818–F) (SECTION 610 REVIEW)**

**Priority:** Other Significant

**Legal Authority:** 42 USC 1395rr et al

**CFR Citation:** 42 CFR 410, 42 CFR 411, 42 CFR 412, 42 CFR 414, 42 CFR 415, 42 CFR 416, 42 CFR 417, 42 CFR 418, and 42 CFR 419

**Legal Deadline:** Final, Statutory, February 4, 2008, MMA sec. 902.

**Abstract:** This final rule revises the requirements that end stage renal disease (ESRD) facilities must meet to be certified under the Medicare program.

**Timetable:**

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**Regulatory Flexibility Analysis Required:** Yes

**Small Entities Affected:** Businesses

**Government Levels Affected:** None

Agency Contact: Teresa Casey, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Clinical Standards Group, S3–02–01, 7500 Security Boulevard, Baltimore, MD 21244 Phone: 410 786–7215 Email: mary.casey@cms.hhs.gov

Rebecca Donnay, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Clinical Standards Group, Mailstop S3–02–01, 7500 Security Boulevard, Baltimore, MD 21244 Phone: 410 786–1428 Email: rebecca.donnay@cms.hhs.gov

**RIN:** 0938–AG82

**1033. HOSPITAL CONDITIONS OF PARTICIPATION: REQUIREMENTS FOR APPROVAL AND REAPPROVAL OF TRANSPLANT CENTERS TO PERFORM ORGAN TRANSPLANTS (CMS–3835–F)**

**Priority:** Other Significant

**Legal Authority:** 42 USC 1302; 42 USC 1395hh

**CFR Citation:** 42 CFR 405, ; 42 CFR 482, and 42 CFR 488

**Legal Deadline:** Final, Statutory, February 4, 2008, MMA sec. 902.

**Abstract:** This rule establishes conditions of participation for Medicare-covered transplant centers.

**Timetable:**

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**Regulatory Flexibility Analysis Required:** No
**Small Entities Affected:** Businesses, Organizations

**Government Levels Affected:** None

**Agency Contact:** Eva Fung, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Clinical Standards Group, Mailstop S3–02–01, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786–7539
Email: eva.fung@cms.hhs.gov

**RIN:** 0938–AH17

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### 1034. HOSPICE CARE CONDITIONS OF PARTICIPATION (CMS–3844–F)

**Priority:** Other Significant

**Legal Authority:** 42 USC 1302; 42 USC 1395hh

**CFR Citation:** 42 CFR 418

**Legal Deadline:** Final, Statutory, May 27, 2008, MMA sec. 902.

**Abstract:** This final rule is a regulatory reform initiative that revises existing conditions of participation that hospices must meet to participate in the Medicare and Medicaid programs. The requirements focus on the actual care delivered to patients and patients’ families by hospices and the results of that care, reflect an interdisciplinary view of patient care, and allow hospices greater flexibility in meeting quality standards. 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.

**Timetable:**

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**Regulatory Flexibility Analysis Required:** Undetermined

**Small Entities Affected:** Businesses, Organizations

**Government Levels Affected:** None

**Agency Contact:** Danielle Shearer, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Clinical Standards Group, Mailstop S3–02–01, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786–6617
Email: danielle.shearer@cms.hhs.gov

**RIN:** 0938–AH27

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### 1035. ELECTRONIC CLAIMS ATTACHMENTS STANDARDS

**Priority:** Economically Significant.

**Legal Authority:** 42 USC 1320d–2(a)(2)(B)

**CFR Citation:** 45 CFR 162

**Legal Deadline:** Final, Statutory, February 21, 1999.

**Abstract:** This rule finalizes an electronic standard for health care claims attachments. The standard is required by the Health Insurance Portability and Accountability Act of 1996. It will be used to transmit clinical or administrative data, in addition to the data contained in the claims standard, to help establish medical necessity or policy compliance for coverage and payment.

**Timetable:**

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**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** Businesses

**Government Levels Affected:** Federal, Local, State, Tribal

**Federalism:** This action may have federalism implications as defined in EO 13132.

**Agency Contact:** Danielle Shearer, Health Insurance Specialist, Office of E–Health Standards and Services, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Clinical Standards Group, Mailstop S3–02–01, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786–6597 Email: danielle.shearer@cms.hhs.gov

**RIN:** 0938–AH27

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### 1036. ORGAN PROCUREMENT ORGANIZATION CONDITIONS FOR COVERAGE AND RECERTIFICATION

**Priority:** Economically Significant.

**Legal Authority:** 42 USC 1302 et al

**CFR Citation:** 42 CFR 413; 42 CFR 441; 42 CFR 486; 42 CFR 498

**Legal Deadline:** Final, Statutory, February 4, 2008, MMA sec 902.

**Abstract:** This rule establishes conditions for coverage for organ procurement organizations (OPOs) to be certified by the Secretary to receive payment from Medicare and Medicaid for organ procurement costs, and to be designated by the Secretary for a specific geographic service area. The Organ Procurement Organization Certification Act of 2000 requires CMS to increase the certification cycle for OPOs from two years to four years and to promulgate new performance standards for OPOs.

**Timetable:**

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**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** Businesses

**Government Levels Affected:** None

**Agency Contact:** Tzvi Hefter, Director, Division of Acute Care Hospital and Ambulatory Policy Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Centers for Medicare and Medicaid Services, Mailstop C4–07–07, 7500 Security Boulevard, Baltimore, MD 21244–1850

Phone: 410 786–4487 Email: tzvi.hefter@cms.hhs.gov

**RIN:** 0938–AK62

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### 1037. PROVIDER REIMBURSEMENT DETERMINATIONS AND APPEALS

**Priority:** Substantive, Nonsignificant

**Legal Authority:** Sec 1878 of the Social Security Act

**CFR Citation:** 42 CFR 405

Abstract: This final rule redefines, clarifies, and updates the guidelines and procedures for Provider Reimbursement Review Board appeals, based on recent court decisions.

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Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses, Organizations

Government Levels Affected: Federal, Local, State

Federalism: This action may have federalism implications as defined in EO 13132.

Agency Contact: Morton Marcus, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C4–25–02, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–4477
Email: morton.marcus@cms.hhs.gov
RIN: 0938–AL54

1038. HEALTH COVERAGE PORTABILITY: TOLLING CERTAIN TIME PERIODS AND INTERACTIONS WITH FAMILY AND MEDICAL LEAVE ACT (CMS–2158–F)

Priority: Other Significant

Legal Authority: 42 USC 300gg; PL 104–191

CFR Citation: 45 CFR 146.113; 45 CFR 146.115; 45 CFR 146.117; 45 CFR 146.120; 45 CFR 146.145

Legal Deadline: None

Abstract: This final rule will clarify certain portability requirements for group health plans and issuers of health insurance coverage offered in connection with a group health plan. It also implements changes made to the Internal Revenue Code, the Employee Retirement Income Security Act, and the Public Health Service Act enacted as part of the Health Insurance Portability and Accountability Act of 1996.

Timetable:

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Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses, Organizations

Government Levels Affected: Federal, Local, State

Federalism: This action may have federalism implications as defined in EO 13132.

Agency Contact: David Mlawsky, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Beneficiary Choices, Medicare Plan Policy Group, Mailstop S3–16–26, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–6851
Email: david.mlawsky@cms.hhs.gov
RIN: 0938–AL88

1040. HOSPITAL CONDITIONS OF PARTICIPATION: REQUIREMENTS FOR HISTORY AND PHYSICAL EXAMINATIONS; AUTHENTICATION OF VERBAL ORDERS; SECURING MEDICATIONS; AND POST–ANESTHESIA EVALUATIONS (CMS–3122–F)

Priority: Other Significant

Legal Authority: 42 USC 1395x; 42 USC 1396d; 42 USC 1395bb

CFR Citation: 42 CFR 482


Abstract: This rule will reduce the burden on hospitals and allow hospitals to conform to current standards of practice. Hospitals must meet these final requirements to participate in Medicare and Medicaid programs. They must establish and maintain policies and procedures that will ensure their hospital will meet these requirements by using standard practices for history and physical examinations, securing medications, authenticating verbal orders, and completing post-anesthesia evaluations.

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Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Organizations

Government Levels Affected: None

Additional Information: Decreases burden for hospitals and clinicians.

Agency Contact: Patricia Chmielewski, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Clinical Standards and Quality Group, Mailstop S3–02–01, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–6899
Email: patricia.chmielewski@cms.hhs.gov
RIN: 0938–AM88
1041. REVISED CIVIL MONEY PENALTIES, ASSESSMENTS, EXCLUSIONS, AND RELATED APPEALS PROCEDURES (CMS–6146–F)

Priority: Substantive, Nonsignificant. Major status under 5 USC 801 is undetermined.

Unfunded Mandates: Undetermined

Legal Authority: Not Yet Determined

CFR Citation: 42 CFR 802


Abstract: This final rule proposes revisions to the CMS civil money penalty authorities. These proposed revisions are intended to add the specific exclusion sanction authorities as established in the procedures for imposing civil money penalties, assessments, and exclusions for certain violations of the Medicare and Medicaid programs. This rule also finalizes an August 4, 2005, rule that outlines the process for health care providers to follow if they wish CMS reimbursement for Medicare.

Timetable:

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Regulatory Flexibility Analysis

Required: Undetermined

Government Levels Affected: Undetermined

Agency Contact: Joel Cohen, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of Financial Management, C3–04–06, 7500 Security Boulevard, Baltimore, MD 21244–1850

Phone: 410 786–3349

Email: misty.whitaker@cms.hhs.gov

RIN: 0938–AN10

1042. PRIOR DETERMINATION PROCESS FOR CERTAIN ITEMS AND SERVICES (CMS–6024–F)

Priority: Other Significant

Legal Authority: Sec 938 of the Medicare Modernization Act of 2003

CFR Citation: 42 CFR 410

Legal Deadline: Final, Statutory, June 8, 2005.

Abstract: Section 938 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 requires the Secretary to establish a process for Medicare contractors to provide eligible participating physicians and Medicare Part A and B beneficiaries with a determination of coverage relating to medical necessity for certain physicians’ services before the services are furnished. This rule is intended to afford the physician and beneficiary the opportunity to know the financial liability for a service before expenses are incurred. This final rule establishes reasonable limits on physicians’ services for which a prior determination of coverage may be requested and discusses generally our plans for establishing the procedures by which those determinations may be obtained.

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Regulatory Flexibility Analysis

Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Misty D. Whitaker, Health Insurance Specialist, Office of Financial Management, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Program Integrity Group, Office of Financial Management, Mail Stop C3–02–16, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786–3087

Email: misty.whitaker@cms.hhs.gov

RIN: 0938–AN27

1043. MEDICARE SECONDARY PAYER AMENDMENTS (CMS–6272–F)

Priority: Substantive, Nonsignificant. Major status under 5 USC 801 is undetermined.

Legal Authority: Sec 301 of the Medicare Modernization Act of 2003

CFR Citation: 42 CFR 411; 42 CFR 489


Abstract: This final rule implements amendments to the Medicare Secondary Payer (MSP) provisions under Title III of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). The MMA amendments clarify the MSP provisions regarding the obligations of primary plans and primary payers, the nature of the insurance arrangements subject to the MSP rules, the circumstances under which Medicare may make conditional payments, and the obligations of primary payers to reimburse Medicare.

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Regulatory Flexibility Analysis

Required: No

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Marie Casey, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of Financial Management, C3–02–14, 7500 Security Boulevard, Baltimore, MD 21244–1850

Phone: 410 786–0970

Fax: 410 786–7030

Email: marie.casey@hhs.gov

RIN: 0938–AN27

1044. RANDOM PREPAYMENT REVIEW (CMS–6022–F)

Priority: Other Significant

Legal Authority: Sec 934 of the MMA

CFR Citation: 42 CFR 421


Abstract: This rule implements the statutory requirements regarding the termination of non-random prepayment review under section 934 of the Medicare Modernization Act beginning December 8, 2003. This rule provides guidelines for terminating a provider of services or supplier from non-random payment review.

Timetable:

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Regulatory Flexibility Analysis

Required: No

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Suzanne Ripley, Health Insurance Specialist, Centers for Medicare Services Office, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop C3–14–16, 7500 Security Boulevard, Baltimore, MD 21244–1850

Phone: 410 786–0970

Fax: 410 786–7030

Email: suzanne.ripley@cms.hhs.gov

RIN: 0938–AN27
of Financial Management, Mailstop S3–02–01, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786–7861  
Email: marie.casey2@cms.hhs.gov  
RIN: 0938–AN31

1045. FIRE SAFETY REQUIREMENTS FOR CERTAIN HEALTH CARE FACILITIES; ALCOHOL–BASED HAND SANITIZER AMENDMENT (CMS–3145–F)  
Priority: Other Significant  
Legal Authority: Not Yet Determined  
CFR Citation: 42 CFR 403; 42 CFR 416; 42 CFR 418; 42 CFR 460; 42 CFR 482 to 42 CFR 483; 42 CFR 485  
Abstract: This final rule amends the fire safety standards for religious nonmedical health care institutions, hospices, programs of all-inclusive care for the elderly, hospitals, long-term care facilities, intermediate care facilities for the mentally retarded, and critical access hospitals that participate in Medicare and Medicaid. The rule adopts a change made to the 2000 edition of the Life Safety Code (LSC) published by the National Fire Protection Association (NFPA). The LSC change allows facilities to place alcohol-based hand rub dispensers in exit corridors under certain conditions. Additionally, this rule includes a requirement for placement of battery-operated smoke alarms in resident rooms in non-sprinkled SNFs.

Timetable:  
Action Date  
Interim Final Rule With Comment 03/25/05 70 FR 15229  
Final Action 03/25/05 70 FR 15229  
Regulatory Flexibility Analysis Required: Yes  
Small Entities Affected: Businesses  
Government Levels Affected: None  
Agency Contact: Edmund E. Kasaitis, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop C4–01–26, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786–7861  
Email: edmund.kasaitis@cms.hhs.gov  
RIN: 0938–AN36

1046. MEDICARE PART B COMPETITIVE ACQUISITION OF OUTPATIENT DRUGS AND BIOLOGICALS (CMS–1325–F)  
Priority: Other Significant  
Legal Authority: MMA of 2003, sec. 303(d)  
CFR Citation: 42 CFR 414  
Legal Deadline: Final, Statutory, July 1, 2006.  
Abstract: Section 303(d) of the Medicare Modernization Act requires the implementation of a competitive bidding program for Medicare Part B drugs not paid on a cost or prospective payment system basis. Beginning July 1, 2006, physicians will be given a choice between purchasing these drugs and being paid by Medicare under the average sales price (ASP) system, or obtaining these drugs from vendors selected in a competitive bidding process. If the physician elects to obtain drugs from a competitive vendor, the vendor will bill Medicare for the drug.

Timetable:  
Action Date  
NPRM 03/04/05 70 FR 10745  
Interim Final Rule 07/06/05 70 FR 39022  
Final Action 07/06/05 70 FR 39022  
Regulatory Flexibility Analysis Required: Yes  
Small Entities Affected: None  
Government Levels Affected: None  
Agency Contact: Danielle Shearer, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop S3–02–01, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786–6617  
Email: danielle.shearer@cms.hhs.gov  
RIN: 0938–AN36

1047. PHYSICIANS’ REFERRALS TO HEALTH CARE ENTITIES WITH WHICH THEY HAVE FINANCIAL RELATIONSHIPS; E–PRESCRIBING EXCEPTIONS (CMS–1303–F)  
Priority: Other Significant  
Legal Authority: 1827(b)(4)–(b)(5); 1860D–4(e)(6); 1860D–42(e)(8)(B)

CFR Citation: 42 CFR 411.357  
Abstract: This rule proposes an exception to the physician self-referral prohibition for certain nonmonetary remuneration related to electronic prescribing (section 1860D–4 of the Medicare Modernization Act).

Timetable:  
Action Date  
NPRM 07/17/05 70 FR 5255  
Final Action 07/17/05 70 FR 5255  
Regulatory Flexibility Analysis Required: No
Small Entities Affected: Businesses
Government Levels Affected: None
Agency Contact: Gary D. Williams, Health Insurance Specialist, Centers for Medicare & Medicaid Services, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of Financial Management, Mailstop C3–02–16, 7500 Security Boulevard, Baltimore, MD 21244–1850
Phone: 410 786–6433
Email: gary.williams4@cms.hhs.gov

1049. HEALTH CARE INFRASTRUCTURE IMPROVEMENT PROGRAM; LOAN PROGRAM FOR QUALIFYING HOSPITALS ENGAGED IN CANCER–RELATED HEALTH CARE (CMS–1287–F)
Priority: Economically Significant. Major under 5 USC 801.
Legal Authority: PL 108–173 sec 1016
CFR Citation: 42 CFR 505
Abstract: This rule will establish a loan program to improve certain hospital infrastructure, including capital improvement. To receive assistance, the applicant will be required to: 1) Engage in cancer research; and 2) be designated by the National Cancer Institute (NCI) as a cancer center or by the State as the official cancer institute. This rule will also establish the conditions under which these loans may be forgiven. No later than 4 years after enactment, the Secretary must submit a report to the Congress summarizing the financial performance of the projects that have received assistance under the loan program.

Timetable:

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Regulatory Flexibility Analysis
Required: Undetermined

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Melinda Jones, Health Insurance Specialist, Quality Measurement & Health Assessment Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop S3–02–01, 7500 Security Boulevard, Baltimore, MD 21244–1850
Phone: 410 786–7069
Email: melinda.jones@cms.hhs.gov

Tzvi Hefter, Director of the Division of Acute Care, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop C4–01–17, 7500 Security Boulevard, Baltimore, MD 21244–1850
Phone: 410 786–4487
Email: tzvi.hefter@cms.hhs.gov

Related RIN: Related to 0938–AI09
RIN: 0938–AN72

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

1051. STANDARD UNIQUE NATIONAL HEALTH PLAN IDENTIFIER (CMS–6017–P)
Priority: Other Significant. Major under 5 USC 801.
CFR Citation: 45 CFR 160; 45 CFR 162
Completed:

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Regulatory Flexibility Analysis
Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: State

Federalism: This action may have federalism implications as defined in EO 13132.

Agency Contact: Helen Dietrick
Phone: 410 786–7448
RIN: 0938–AH87

1052. MEDICARE OUTCOME AND ASSESSMENT INFORMATION SET (OASIS) DATA REPORTING REQUIREMENTS (CMS–3006–F)
Priority: Other Significant
CFR Citation: 42 CFR 484.11; 42 CFR 484.20; 42 CFR 488.68
Completed:

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Regulatory Flexibility Analysis
Required: No

Small Entities Affected: Businesses

Government Levels Affected: Local, State, Tribal

Agency Contact: Rebecca Donnay
Phone: 410 786–1428
Email: rebecca.donnay@cms.hhs.gov
RIN: 0938–AJ10
### 1053. HOSPICE CARE AMENDMENTS (CMS–1022–F)

**Priority:** Other Significant  
**CFR Citation:** 42 CFR 418

**Completed:**

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**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** Businesses  
**Government Levels Affected:** None  
**Agency Contact:** Linda Smith  
Phone: 410 786–5650

**Related RIN:** Previously reported as 0938–AH73  
**RIN:** 0938–AJ36

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### 1054. ELECTRONIC MEDICARE CLAIMS SUBMISSION (CMS–0008–F)

**Priority:** Other Significant  
**CFR Citation:** None

**Completed:**

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**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** No  
**Government Levels Affected:** None  
**Agency Contact:** Stewart Streimer  
Phone: 410 786–9318  
Email: stewart.streimer@cms.hhs.gov

**RIN:** 0938–AM22

---

### 1055. REQUIREMENTS FOR LONG–TERM CARE FACILITIES; NURSING SERVICES; POSTING OF NURSE STAFFING INFORMATION (CMS–3121–F)

**Priority:** Other Significant  
**CFR Citation:** 42 CFR 483

**Completed:**

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**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** No  
**Government Levels Affected:** None  
**Agency Contact:** Anita Panicker  
Phone: 410 786–5646  
Fax: 410 786–8532  
Email: anita.panicker@cms.hhs.gov

**RIN:** 0938–AM55

---

### 1056. CONDITIONS FOR COVERAGE FOR PAYMENT OF POWER MOBILITY DEVICES, INCLUDINGPOWERED WHEELCHAIRS AND POWER–OPERATED VEHICLES (CMS–3017–F)

**Priority:** Economically Significant. Major under 5 USC 801.

**CFR Citation:** 42 CFR 410.38

**Completed:**

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**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** No  
**Government Levels Affected:** None  
**Agency Contact:** Karen Daily  
Phone: 410 786–0189  
Email: karen.daily@cms.hhs.gov

**RIN:** 0938–AM74

---

### 1057. PAYMENT FOR RESPIRATORY ASSIST DEVICES WITH BI–LEVEL CAPABILITY AND A BACK–UP RATE (CMS–1167–F)

**Priority:** Other Significant  
**CFR Citation:** 42 CFR 414.222(a)(1)

**Completed:**

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**Regulatory Flexibility Analysis Required:** Yes

**Small Entities Affected:** Businesses  
**Government Levels Affected:** None  
**Agency Contact:** Joel Kaiser  
Phone: 410 786–4499  
Email: joel.kaiser@cms.hhs.gov

**Related RIN:** Related to 0938–AL27  
**RIN:** 0938–AN02

---

### 1058. UPDATE OF THE LIST OF COVERED PROCEDURES FOR AMBULATORY SURGICAL CENTERS FOR 2005 (CMS–1478–F)

**Priority:** Other Significant  
**CFR Citation:** None

**Completed:**

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**Regulatory Flexibility Analysis Required:** Yes

**Small Entities Affected:** No  
**Government Levels Affected:** Local, State  
**Agency Contact:** David Mlawsky  
Phone: 410 786–6851  
Email: david.mlawsky@cms.hhs.gov

**RIN:** 0938–AN35

---

### 1059. PAYMENT FOR CLINICAL LABORATORY TESTS (CMS–1494–P)

**Priority:** Substantive, Nonsignificant

**CFR Citation:** None

**Completed:**

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**Regulatory Flexibility Analysis Required:** Yes

**Small Entities Affected:** Businesses  
**Government Levels Affected:** None  
**Agency Contact:** Anita Greenberg  
Phone: 410 786–4601  
Email: anita.greenberg@cms.hhs.gov

**Related RIN:** Merged with 0938–AO24  
**RIN:** 0938–AN26

---

### 1060. FEDERAL ENFORCEMENT IN GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS (CMS–4091–F)

**Priority:** Other Significant

**CFR Citation:** 45 CFR 150.101 to 150.465

**Completed:**

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**Regulatory Flexibility Analysis Required:** Yes

**Small Entities Affected:** Businesses  
**Government Levels Affected:** Local, State  
**Agency Contact:** David Mlawsky  
Phone: 410 786–6851  
Email: david.mlawsky@cms.hhs.gov

**RIN:** 0938–AN35

---

### 1061. HOME HEALTH PROSPECTIVE PAYMENT SYSTEM RATE UPDATE FOR CALENDAR YEAR 2006 (CMS–1301–F)

**Priority:** Economically Significant. Major under 5 USC 801.

**CFR Citation:** 42 CFR 484

**Completed:**

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**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** No  
**Government Levels Affected:** None  
**Agency Contact:** Dana Burley  
Phone: 410 786–4547  
Email: dana.burley@cms.hhs.gov

**Related RIN:** Merged with 0938–AO15  
**RIN:** 0938–AN23
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**Agency Contact:**
Randy Thronset  
Phone: 410 786–0131  
Email: randy.thronset@cms.hhs.gov

**RIN:** 0938–AN44

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<tr>
<th>1062. CHANGES TO THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM AND CALENDAR YEAR 2006 PAYMENT RATES (CMS–1501–FC)</th>
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**Regulatory Flexibility Analysis Required:** Yes

**Small Entities Affected:** Businesses

**Government Levels Affected:** Federal

**Agency Contact:** Rebecca Kane  
Phone: 410 786–1589  
Email: rebecca.kane@cms.hhs.gov

**RIN:** 0938–AN46

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<th>1063. REVISED CIVIL MONEY PENALTIES, ASSESSMENTS, EXCLUSIONS, AND RELATED APPEALS PROCEDURES (CMS–6019–F)</th>
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**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** Federal

**Agency Contact:** Joel Cohen  
Phone: 410 786–3349  
Email: joel.cohen@cms.hhs.gov

**Related RIN:** Merged with 0938–AN48

**RIN:** 0938–AN46

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<th>1065. GROUP MARKET HEALTH INSURANCE REFORM: GUARANTEED AVAILABILITY, GUARANTEED RENEWABILITY, DISCLOSURES TO SMALL EMPLOYERS (CMS–4102–F)</th>
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**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** Federal

**Agency Contact:** Gladys Wheeler  
Phone: 410 786–0273  
Email: gladys.wheeler@cms.hhs.gov

**RIN:** 0938–AN49

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<th>1066. INDIVIDUAL MARKET HEALTH INSURANCE REFORM: PORTABILITY FROM GROUP TO INDIVIDUAL COVERAGE; FEDERAL RULES FOR ACCESS IN THE INDIVIDUAL MARKET; STATE ALTERNATIVE MECHANISMS TO FEDERAL RULES (CMS–4103–F)</th>
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**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** Federal

**Agency Contact:** David R. Mlawsky  
Phone: 877 267–2323  
Email: david.mlawsky@cms.hhs.gov

**Related RIN:** Related to 0938–AI08

**RIN:** 0938–AN61

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<th>1067. ALL PROVIDER BAD DEBT PAYMENT (CMS–1126–F)</th>
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**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** Businesses

**Government Levels Affected:** Federal

**Agency Contact:** Jill Keplinger  
Phone: 410 786–4550  
Email: jill.keplinger@cms.hhs.gov

**Related RIN:** Related to 0938–AK02

**RIN:** 0938–AN75

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<th>1068. APPLICATION OF INHERENT REASONABLENESS TO ALL MEDICARE PART B SERVICES (OTHER THAN PHYSICIAN SERVICES) (CMS–1908–F)</th>
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**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** Businesses

**Government Levels Affected:** Federal

**Agency Contact:** Bill Long  
Phone: 410 786–5655  
Email: bill.long@cms.hhs.gov

**Related RIN:** 0938–AN81

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<th>1069. REVISIONS TO PAYMENT POLICIES UNDER THE PHYSICIAN FEE SCHEDULE FOR CALENDAR YEAR 2006 (CMS–1502–FC)</th>
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#### Regulatory Flexibility Analysis
- Required: Yes
- Small Entities Affected: Businesses, Organizations
- Government Levels Affected: Federal
- Agency Contact: Diane Milstead
  - Phone: 410 786–3355
- Related RIN: Related to 0938–AN04
- RIN: 0938–AN84

**1070. ELECTRONIC SUBMISSION OF COST REPORTS (CMS–1199–F)**

- **Priority:** Substantive, Nonsignificant
- **CFR Citation:** None
- **Completed:**
  - Reason: Withdrawn
  - Date: 02/10/06
- **Regulatory Flexibility Analysis**
  - Required: No
  - Small Entities Affected: Businesses
  - Government Levels Affected: None
  - Agency Contact: Darryl E. Simms
    - Phone: 410 786–4524
    - Email: darryl.simms@cms.hhs.gov
  - Related RIN: Related to 0938–AL51
  - RIN: 0938–AN87

**1071. LOAN FORGIVENESS CRITERIA FOR THE HEALTH CARE INFRASTRUCTURE LOAN PROGRAM (CMS–1320–F)**

- **Priority:** Other Significant
- **CFR Citation:** 42 CFR 505
- **Completed:**
  - Reason: Withdrawn
  - Date: 02/08/06
- **Regulatory Flexibility Analysis**
  - Required: No
  - Small Entities Affected: Businesses
  - Government Levels Affected: None
  - Agency Contact: Tzvi Hefter
    - Phone: 410 786–4487
    - Email: tzvi.hefter@cms.hhs.gov
  - Related RIN: Merged with 0938–AO03
  - RIN: 0938–AN93

**1072. FEE SCHEDULE FOR PAYMENT OF AMBULANCE SERVICES—UPDATE FOR CY 2006 (CMS–1294–N)**

- **Priority:** Economically Significant.
- **CFR Citation:** 42 CFR 410
- **Completed:**
  - Reason: Notice
  - Date: 11/25/05
  - FR Cite: 70 FR 71163
- **Regulatory Flexibility Analysis**
  - Required: No
  - Small Entities Affected: No
  - Government Levels Affected: Federal
  - Agency Contact: Anne Tayloe
    - Phone: 410 786–4546
    - Email: anne.tayloe@cms.hhs.gov
  - Related RIN: Related to 0938–AN99
  - RIN: 0938–AN93

**1073. STATE ALLOTMENTS FOR PAYMENT OF MEDICARE PART B PREMIUMS FOR QUALIFYING INDIVIDUALS (CMS–2210–F)**

- **Priority:** Other Significant
- **CFR Citation:** None
- **Completed:**
  - Reason: Comment Period End
  - Date: 10/25/05
  - Withdrawn: 02/08/06
- **Regulatory Flexibility Analysis**
  - Required: No
  - Small Entities Affected: No
  - Government Levels Affected: State
  - Agency Contact: Richard Strauss
    - Phone: 410 786–2019
    - Email: richard.strauss@cms.hhs.gov
  - Related RIN: Related to 0938–AO31
  - RIN: 0938–AO04

**1074. FEDERAL GOVERNMENT’S ADOPTION OF TWENTY (20) HEALTHCARE MESSAGING AND VOCABULARY STANDARDS RECOMMENDED BY THE CONSOLIDATED HEALTH INFORMATICS INITIATIVE (CMS–0015–N)**

- **Priority:** Other Significant
- **CFR Citation:** 42 CFR 403
- **Completed:**
  - Reason: Notice
  - Date: 12/23/05
  - FR Cite: 70 FR 76287
- **Regulatory Flexibility Analysis**
  - Required: No
  - Small Entities Affected: Organizations
  - Government Levels Affected: Federal
  - Agency Contact: Cheryl Ford
    - Phone: 410 786–7415
    - Email: cheryl.ford@cms.hhs.gov
  - Related RIN: Merged with 0938–AO15
  - RIN: 0938–AO13

**1075. REVISED PAYMENT SYSTEM FOR SERVICES FURNISHED IN AMBULATORY SURGICAL CENTERS (ASCS) EFFECTIVE JANUARY 1, 2008 (CMS–1517–P)**

- **Priority:** Economically Significant.
- **CFR Citation:** 42 CFR 416
- **Completed:**
  - Reason: Withdrawn
  - Date: 02/10/06
- **Regulatory Flexibility Analysis**
  - Required: Yes
  - Small Entities Affected: Organizations
  - Government Levels Affected: Federal
  - Agency Contact: Joan H. Sanow
    - Phone: 410 786–9739
    - Fax: 410 786–4490
    - Email: joan.sanow@cms.hhs.gov
  - Related RIN: Merged with 0938–AO15
  - RIN: 0938–AO13

**1076. FIRE SAFETY REQUIREMENTS FOR RELIGIOUS NON–MEDICAL HEALTH CARE INSTITUTIONS: CORRECTION TO ADD WRITTEN FIRE CONTROL PLANS & MAINTENANCE OF DOCUMENTATION (CMS–3183–IFC)**

- **Priority:** Other Significant
- **CFR Citation:** 42 CFR 403
- **Completed:**
  - Reason: Withdrawn
  - Date: 02/08/06
- **Regulatory Flexibility Analysis**
  - Required: No
  - Small Entities Affected: Businesses
  - Government Levels Affected: None
  - Agency Contact: Janice A. Graham
    - Phone: 410 786–8020
    - Fax: 410 786–2532
    - Email: janice.graham@cms.hhs.gov
  - Related RIN: Related to 0938–AM90
  - RIN: 0938–AO14
Department of Health and Human Services (HHS)
Administration for Children and Families (ACF)

1077. DEVELOPMENTAL DISABILITIES AND BILL OF RIGHTS ACT

Priority: Substantive, Nonsignificant
Legal Authority: PL 106–402; 42 USC 15001 et seq
CFR Citation: 45 CFR 1385 to 1388
Abstract: A notice of proposed rulemaking to amend current regulations and to implement changes made by the Developmental Disabilities Assistance and Bill of Rights Act of 2000.

Timetable:

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Regulatory Flexibility Analysis Required: No
Small Entities Affected: Governmental Jurisdictions, Organizations

Government Levels Affected: Local, State

Agency Contact: Grant Collins, Deputy Director, Office of Family Assistance, Department of Health and Human Services, Administration for Children and Families, 5th Floor East, 370 L’Enfant Promenade SW., Washington, DC 20447
Phone: 202 401–6953
Email: gcollins@acf.hhs.gov
RIN: 0970–AC15

1079. CARE AND PLACEMENT OF UNACCOMPANIED ALIEN CHILDREN

Priority: Other Significant
Legal Authority: 6 USC 279
CFR Citation: 45 CFR 410
Legal Deadline: None
Abstract: This rule concerns the placement of unaccompanied alien children in appropriate facilities and homes, the services provided for the children while they are in the care of the Office of Refugee Resettlement (ORR) and the criteria for release of these children from Federal custody to sponsors. The rule also implements ORR’s role in Flores class-action settlement agreement.

Timetable:

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Regulatory Flexibility Analysis Required: No
Small Entities Affected: No

Government Levels Affected: Federal

Agency Contact: Elsbeth Wyatt, Program Specialist, Department of Health and Human Services, Administration for Children and Families, 370 L’Enfant Promenade SW., Washington, DC 20447
Phone: 202 690–5841
RIN: 0970–AC07

1078. ADMINISTRATIVE COST SHARING UNDER TANF

Priority: Substantive, Nonsignificant
Legal Authority: 42 USC 1302
CFR Citation: 45 CFR 263; 45 CFR 263.14
Legal Deadline: None
Abstract: This proposed rule will require States (including the District of Columbia) and territories to use the “benefiting” cost allocation methodology in allocating the common administrative costs of determining eligibility in the Temporary Assistance for Needy Families (TANF) program, the Medicaid program, and the Food Stamp programs.

Timetable:

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Regulatory Flexibility Analysis Required: No
Small Entities Affected: No

Government Levels Affected: Federal

Agency Contact: Maureen Dunn, Department of Health and Human Services, Administration for Children and Families, 370 L’Enfant Promenade SW, Washington, DC 20447
Phone: 202 401–5523
Email: mdunn@acf.hhs.gov
RIN: 0970–AC20

1080. CHAFEE NATIONAL YOUTH IN TRANSITION DATABASE

Priority: Other Significant
Legal Authority: 42 USC 677
CFR Citation: 45 CFR 1356
Legal Deadline: None
Abstract: This rule would require States to collect and report data on youth who are receiving independent living services and the outcomes of certain youth who are in foster care or who age-out of foster care.

Timetable:

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<th>Action</th>
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<tr>
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Regulatory Flexibility Analysis Required: No
Small Entities Affected: Governmental Jurisdictions

Government Levels Affected: Local, State

Agency Contact: Elizabeth C. Matheson, Director, Policy and Planning Division, Department of Health and Human Services, Administration for Children and Families, Office of Child Support Enforcement, 370 L’Enfant Promenade SW, Washington, DC 20447
Phone: 202 401–9386
Email: bmatheson@acf.hhs.gov
RIN: 0970–AC22
### 1082. ADOPTION AND FOSTER CARE ANALYSIS AND REPORTING SYSTEM

**Priority:** Substantive, Nonsignificant  
**Legal Authority:** 42 USC 679  
**CFR Citation:** 45 CFR 1355  
**Legal Deadline:** None  

**Abstract:** This NPRM amends the Adoption and Foster Care Analysis and Reporting System (AFCARS) regulations at 45 CFR 1355.40 and the appendices to part 1355 to modify the requirements for States to collect and report data to ACF on children in foster care and in subsidized adoption or guardianship arrangements with the State. The rule also implements the AFCARS penalty requirements of the Adoption Promotion Act of 2003 (Pub. L. 108-145).

**Timetable:**

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**Regulatory Flexibility Analysis**  
**Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** State

**Agency Contact:** Kathleen McHugh, Director, Division of Policy, Children’s Bureau, ACYF/ACF/HHS, Department of Health and Human Services, Administration for Children and Families, 370 L’Enfant Promenade SW, Washington, DC 20447  
**Phone:** 202 401–5789  
**Fax:** 202 205–8221  
**Email:** kmchugh@acf.hhs.gov  

**RIN:** 0970–AC23

### 1083. CHILD SUPPORT PROVISIONS OF THE DEFICIT REDUCTION ACT

**Priority:** Substantive, Nonsignificant  
**Legal Authority:** 42 USC 1302  
**CFR Citation:** Not Yet Determined  
**Legal Deadline:** None

**Abstract:** The proposed rule would implement provisions of the Deficit Reduction Act of 2005 related to review and adjustment of child support orders, Federal financial participation in the program, and fees for program services.

**Timetable:**

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**Regulatory Flexibility Analysis**  
**Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** Federal, Local, State, Tribal

**Agency Contact:** Elizabeth C. Matheson, Director, Policy and Planning Division, Department of Health and Human Services, Administration for Children and Families, Office of Child Support Enforcement, 370 L’Enfant Promenade SW, Washington, DC 20447  
**Phone:** 202 401–9386  
**Email:** bmatheson@acf.hhs.gov  

**RIN:** 0970–AC24

### 1084. PRIVATIZING FUNCTIONS

**Priority:** Substantive, Nonsignificant  
**Legal Authority:** 42 USC 1302  
**CFR Citation:** 45 CFR 1355 to 1356  
**Legal Deadline:** None

**Abstract:** Proposed rule would address States’ ability to delegate decision-making authority to private agencies performing administration functions and the availability of funding for training funds under the Foster Care program.

**Timetable:**

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<th>Action</th>
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**Regulatory Flexibility Analysis**  
**Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** None

**Agency Contact:** Craig Turner, Department of Health and Human Services, Administration for Children and Families, P.O. Box 1182, Washington, DC 20013  
**Phone:** 202 205–8236  
**Email:** cturner@acf.hhs.gov  

**RIN:** 0970–AC26

### 1085. HEAD START TRANSPORTATION

**Priority:** Substantive, Nonsignificant  
**Legal Authority:** 42 USC 9801 et seq  
**CFR Citation:** 45 CFR 1310  
**Legal Deadline:** None

**Abstract:** This proposed rule will address waiver for Head Start grantees from certain transportation requirements related to child safety restraint systems and bus monitors.

**Timetable:**

<table>
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<th>Action</th>
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**Regulatory Flexibility Analysis**  
**Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** None

**Agency Contact:** Craig Turner, Department of Health and Human Services, Administration for Children and Families, P.O. Box 1182, Washington, DC 20013  
**Phone:** 202 205–8236  
**Email:** cturner@acf.hhs.gov  

**RIN:** 0970–AC25

### 1086. SAFEGUARDING CHILD SUPPORT AND EXPANDED FEDERAL PARENT LOCATOR SERVICES (FPLS) INFORMATION

**Priority:** Other Significant  
**Legal Authority:** 42 USC 652 to 654A; 42 USC 663; 42 USC 1302  
**CFR Citation:** 45 CFR 303.3; 45 CFR 303.21; 45 CFR 303.70  
**Legal Deadline:** None

**Abstract:** The Personal Responsibility and Work Opportunity Reconciliation Act of 1996 made far-reaching amendments to title IV-D of the Social Security Act, which governs the child support enforcement program. The Balanced Budget Act of 1997, the Adoption and Safe Families Act of 1997, and the Child Support Performance and Incentive Act of 1998 further amended title IV-D. A significant result of this legislation is
an expansion in the scope of information available to State IV-D child support enforcement agencies. The legislation has rendered obsolete or inconsistent several regulations at 45 CFR chapter III, Office of Child Support Enforcement, including the regulations on the Federal Parent Locator Service, the State Parent Locator Services, the offset of Federal payments for purposes of collecting child support, and the safeguarding of information. This regulation would update various sections in 45 CFR chapter III to reflect the statutory changes.

### Timetable:

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### Regulatory Flexibility Analysis

Required: No

Government Levels Affected: Local, State

Agency Contact: Karen Tvrdt, Policy Director, Child Care Bureau, Department of Health and Human Services, Administration for Children and Families, 330 C Street SW, Room 2046, Washington, DC 20447

Phone: 202 401–5130

Email: ktvrdt@acf.hhs.gov

RIN: 0970–AC19

1089. TANF WORK PROVISIONS OF THE DEFICIT REDUCTION ACT

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1302

CFR Citation: Not Yet Determined


Abstract: Interim final rule will be issued to address new work requirements associated with the Deficit Reduction Act of 2005, including what counts as work activities, reporting and verifying hours of work and who should be included in the work participation rate.

### Timetable:

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<th>Action</th>
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### Regulatory Flexibility Analysis

Required: No

Government Levels Affected: No

Small Entities Affected: No

### Final Rule Stage

Department of Health and Human Services (HHS)
Administration for Children and Families (ACF)

1090. ADMINISTRATIVE COSTS FOR CHILDREN IN TITLE IV–E FOSTER CARE

Priority: Other Significant

CFR Citation: 45 CFR 1356.60(c)

Completed:

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### Regulatory Flexibility Analysis

Required: No

Small Entities Affected: No

Government Levels Affected: State
**Agency Contact:** Kathleen McHugh  
Phone: 202 401–5789  
Fax: 202 205–8221  
Email: kmchugh@acf.hhs.gov  
**RIN:** 0970–AC14

1091. HEAD START TRANSPORTATION  
**Priority:** Other Significant. Major status under 5 USC 801 is undetermined.  
**CFR Citation:** 45 CFR 1310  
**Completed:**  
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**Regulatory Flexibility Analysis Required:** No  
**Government Levels Affected:** None  
**Agency Contact:** Windy Hill  
Phone: 202 205–8573  
Email: whill@acf.hhs.gov  
**RIN:** 0970–AC16  
[FR Doc. 06–2942 Filed 04–21–06; 8:45 am]  
BILLING CODE 4150–24–S