Monday,
October 31, 2005

Part VIII

Department of Health and Human Services

Semiannual Regulatory Agenda
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

21 CFR Ch. I

24 CFR Chs. I-V

45 CFR Subtitle A; Subtitle B, Chs. II, III, and XIII

Regulatory Agenda

AGENCY: Office of the Secretary, HHS.

ACTION: Semiannual Regulatory Agenda.

SUMMARY: The Regulatory Flexibility Act of 1980 and Executive Order 12866 require this semi-annual publication inventorying the 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 our 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, D.C. 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 these planned rulemakings. 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.

Dated: September 29, 2005
Ann C. Agnew,
Executive Secretary to the Department.

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<td>0938–AO10</td>
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## Centers for Medicare & Medicaid Services—Completed Actions

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<tr>
<td>1200</td>
<td>Supplier Standards for Home Oxygen, Therapeutic Shoes, and Home Nutrition Therapy (CMS-6010-P)</td>
<td>0938–AJ98</td>
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<td>1201</td>
<td>Evaluation Criteria and Standards for Quality Improvement Program Contracts (CMS-3142-FN)</td>
<td>0938–AN13</td>
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<td>1202</td>
<td>Nondiscrimination In Post-Hospital Referral to Home Health Agencies and Other Entities (CMS-1224-F)</td>
<td>0938–AN19</td>
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<td>1203</td>
<td>Medicare Ambulance Fee Schedule Update (CMS-1492-IFC)</td>
<td>0938–AN24</td>
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<td>1204</td>
<td>Prospective Payment System for Long Term Care Hospitals: Annual Payment Rate Updates and Policy Changes for 2006 (CMS-1483-F)</td>
<td>0938–AN28</td>
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<tr>
<td>1205</td>
<td>Prospective Payment System for Inpatient Rehabilitation Facilities for FY 2006 (CMS-1290-F)</td>
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<td>1206</td>
<td>Development of New Standards for Medigap Policies (CMS-4087-FN)</td>
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<td>1207</td>
<td>Fiscal Year 2006 SCHIP Allocations (CMS-2219-N)</td>
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<td>1208</td>
<td>Changes to the Hospital Inpatient Prospective Payment System and FY 2006 Rates (CMS-1500-F)</td>
<td>0938–AN57</td>
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<td>Special Payment Provisions and Standards for Suppliers of Custom Fabricated Orthotics and Prosthetics (CMS-6012-P)</td>
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<td>Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities—Update for FY 2006 (CMS-1282-F)</td>
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<td>State Children's Health Insurance Program (SCHIP); Redistribution of Unexpended SCHIP Funds From the Appropriation for Fiscal Year (FY) 2002 (CMS-2230-FN)</td>
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<td>Extending Sunset Date for the Interim Final Regulation on Mental Health Parity (CMS-4094-F3)</td>
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<td>Disproportionate Share Hospital Payments—Institutions for Mental Disease (IMDs) (CMS-2062-N2)</td>
<td>0938–AN88</td>
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<td>1214</td>
<td>Hospice Wage Index for FY 2006 (CMS-1286-F)</td>
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<td>Immunization Standard for Long Term Care Facilities (CMS-3198-F)</td>
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<td>Disproportionate Share Hospital Payments — Institutions for Mental Disease (IMDs) (CMS-2209-N)</td>
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<td>1219</td>
<td>Medicare Prescription Drug Discount Card (CMS-4063-F)</td>
<td>0938–AN97</td>
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<td>1220</td>
<td>Inpatient Hospital Deductible and Hospital and Extended Care Services Coinsurance Amounts for Calendar Year 2006 (CMS-8026-N)</td>
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<td>1221</td>
<td>Part A Premiums for Calendar Year 2006 for the Uninsured Aged and for Certain Disabled Individuals Who Have Exhausted Other Entitlement (CMS-8025-N)</td>
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<td>1222</td>
<td>Medicare Part B Monthly Actuarial Rates and Premium Rate Beginning January 1, 2006 (CMS-8027-N)</td>
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## Administration for Children and Families—Proposed Rule Stage

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<tr>
<td>1223</td>
<td>Safeguarding Child Support and Expanded Federal Parent Locator Services (FPLS) Information</td>
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### Administration for Children and Families—Proposed Rule Stage (Continued)

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<td>Developmental Disabilities and Bill of Rights Act</td>
<td>0970–AC07</td>
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<td>1225</td>
<td>Administrative Cost Sharing Under TANF</td>
<td>0970–AC15</td>
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<td>Care and Placement of Unaccompanied Alien Children</td>
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<td>1227</td>
<td>Chafee National Youth in Transition Database</td>
<td>0970–AC21</td>
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<td>1228</td>
<td>Medical Support</td>
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<td>1229</td>
<td>Adoption and Foster Care Analysis and Reporting System</td>
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### Administration for Children and Families—Final Rule Stage

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<td>Administrative Costs for Children in Title IV-E Foster Care</td>
<td>0970–AC14</td>
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<td>1231</td>
<td>Head Start Transportation</td>
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<td>1232</td>
<td>Child Care and Development Fund State Match Provisions</td>
<td>0970–AC18</td>
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<td>1233</td>
<td>Reasonable Quantitative Standard for Review and Adjustment of Child Support Orders</td>
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### Department of Health and Human Services (HHS) Proposed Rule Stage

#### 985. 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 1396u–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 impose 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.

#### 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–AB03

#### 986. 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 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
- **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–AB39
987. SHARED RISK EXCEPTION TO THE SAFE HARBOR PROVISIONS

Priority: Substantive, Nonsignificant
Legal Authority: 42 USC 1302; 42 USC 1320a–7b; 42 USC 1395hh; PL 104–191, sec 216(b)
CFR Citation: 42 CFR 1001
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 for 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.

Timetable:

Action          Date          FR Cite
ANPRM           05/23/97       62 FR 28410
ANPRM Comment   06/09/97       Period End
Interim Final Rule 11/19/99   64 FR 63504
Final Action    03/06/00       

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–AB16

988. 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 rulemaking would seek to expand the existing safe harbor for certain waivers of beneficiary coinsurance and deductible amounts to benefit the policyholders of Medicare SELECT supplemental insurance. Specifically, the amended safe harbor will protect waivers of coinsurance and deductible amounts under part A or part B of the Medicare program owed by beneficiaries covered by a Medicare SELECT policy issued in accordance with section 1882(t)(1) of the Social Security Act, if the waiver is in accordance with a price reduction agreement covering such policyholders between the Medicare SELECT issuer and the provider or supplier offering the waiver.

Timetable:

Action          Date          FR Cite
ANPRM           09/15/03       68 FR 53939
ANPRM Comment   11/14/03       Period End
Final Action    04/06/06       

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

989. 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
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:

Action          Date          FR Cite
ANPRM           04/18/05       70 FR 20224
Final Action    02/06/06       

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Carol Conrad, Department of Health and Human Services, Room 5347, Office of the General Counsel, 330 Independence Avenue SW., Washington, DC 20201 Phone: 202 690–1840

RIN: 0991–AB29
991. 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


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.

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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, Related to 0991–AA91

RIN: 0991–AB38

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

992. CLAIMS 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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Government Levels Affected: None

Agency Contact: Jeffrey S. Davis, Associate General Counsel, Department of Health and Human Services, Office of the Secretary, Office of the General Counsel, Room 5362, HHS Cohen Building, Room 4760, 330 Independence Avenue SW., Washington, DC 20201 Phone: 202 619–0150

RIN: 0991–AB18

993. SALARY OFFSET

Unfunded Mandates: Undetermined

Priority: Substantive, Nonsignificant

Legal Authority: 5 USC 5514; 5 CFR 550

CFR Citation: 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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Government Levels Affected: None

Agency Contact: Jeffrey S. Davis, Associate General Counsel, Department of Health and Human Services, Office of the Secretary, Office of the General Counsel, Room 5362, HHS Cohen Building, Room 4760, 330 Independence Avenue SW., Washington, DC 20201 Phone: 202 619–0150

RIN: 0991–AB19

994. REVISIONS TO THE WAIVER PROVISIONS OF THE OFFICE OF INSPECTOR GENERAL’S (OIG) EXCLUSION AUTHORITIES

Priority: Substantive, Nonsignificant

Legal Authority: PL 108–173, sec 949; PL 105–33, sec 4331; Social Security Act, sec 1128(c)(3)(b)

CFR Citation: 42 CFR 1001

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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Government Levels Affected: None

Agency Contact: Joel Jay Schaer, Regulations Officer, Department of Health and Human Services, Office of the Secretary, Office of the General Counsel, HHS Cohen Building, Room 4760, 330 Independence Avenue SW., Washington, DC 20201 Phone: 202 619–0089

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

RIN: 0991–AB38
## Department of Health and Human Services (HHS) - Long-Term Actions

### Completed Actions

**HHS—OS**  
The Secretary, Office of Inspector General, 330 Independence Avenue SW., Washington, DC 20201  
Phone: 202 619–0089  
RIN: 0991–AB33

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<td>05/09/05</td>
<td>70 FR 24314</td>
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### Regulatory Flexibility Analysis

- **Required:** No
- **Small Entities Affected:** Businesses, Governmental Jurisdictions, Organizations

### Department of Health and Human Services (HHS) - Proposed Rule Stage

#### Substance Abuse and Mental Health Services Administration (SAMHSA)

**996. REQUIREMENTS GOVERNING THE USE OF SECLUSION AND RESTRAINT IN CERTAIN NONMEDICAL COMMUNITY–BASED FACILITIES FOR CHILDREN AND YOUTH**  
**Priority:** Other Significant  
**Legal Authority:** PL 106–310  
**CFR Citation:** Not Yet Determined  
**Legal Deadline:** NPRM, Statutory, April 2001.

**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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### Regulatory Flexibility Analysis

- **Required:** Yes
- **Small Entities Affected:** Businesses

### Government Levels Affected

- Federal, Local, State, Tribal

### Agency Contact

- Paolo Del Vecchio,  
  Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, Room 13–103, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857  
  Phone: 301 443–2619  
  RIN: 0930–AA10

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

#### Substance Abuse and Mental Health Services Administration (SAMHSA)

**997. MANDATORY GUIDELINES FOR THE FEDERAL WORKPLACE DRUG TESTING PROGRAM**  
**Priority:** Other Significant  
**Legal Authority:** PL 100–71; 5 USC 7301

**Legal Deadline:** NPRM, Statutory, December 2003.

**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

### 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, Room 12C–15, 5600 Fishers Lane, Rockville, MD 20857  
  Phone: 301 443–2619
  Fax: 301 443–1450  
  Email: jfaha@samhsa.gov  
  RIN: 0930–AA12
998. 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(h); 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

**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, NIOSH, P.O. Box 18070, 626 Cochrans Mill Road, Pittsburgh, PA 15236

Phone: 412 386–4000

RIN: 0920–AA04

999. 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. These respiratory protective devices are used in emergencies for the protection of miners and workers in other industries.

**Timetable:**

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**Regulatory Flexibility Analysis Required:** Undetermined

**Small Entities Affected:** Businesses

**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, NIOSH, P.O. Box 18070, 626 Cochrans Mill Road, Pittsburgh, PA 15236

Phone: 412 386–4000

RIN: 0920–AA10

1000. CONTROL OF COMMUNICABLE DISEASES, INTERSTATE AND FOREIGN QUARANTINE

**Regulatory Plan:** This entry is Seq. No. 42 in part II of this issue of the Federal Register.

**RIN:** 0920–AA12

1001. • 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


**Timetable:**

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<tr>
<th>Action</th>
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<tr>
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<td>12/00/05</td>
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</table>

**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** None

**Agency Contact:** Larry Elliott, Director, Office of Compensation Analysis and Support, Department of Health and Human Services, Centers for Disease Control and Prevention, NIOSH, R44, 4676 Columbia Pkwy, MS C–46, Cincinnati, OH 45226

Phone: 513 533–6825

RIN: 0920–AA13
1002. 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.

Timetable:

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<tr>
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1003. FOREIGN AND DOMESTIC ESTABLISHMENT REGISTRATION AND LISTING REQUIREMENTS FOR HUMAN DRUGS, INCLUDING DRUGS THAT ARE REGULATED UNDER A BIOLOGICS LICENSE APPLICATION, AND ANIMAL DRUGS

Regulatory Plan: This entry is Seq. No. 43 in part II of this issue of the Federal Register.

RIN: 0910–AA49

1004. 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.

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1005. MEDICAL DEVICES; ANESTHESIOLOGY DEVICES; PROPOSED RECLASSIFICATION OF PRESSURE REGULATORS FOR USE WITH MEDICAL OXYGEN

Priority: Substantive, Nonsignificant
Legal Authority: 21 USC 351; 21 USC 352; 21 USC 360c; 21 USC 360i; 21 USC 371
CFR Citation: 21 CFR 868.2700
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 oxygen pressure 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)).

**Timetable:**

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</table>

**Regulatory Flexibility Analysis Required:** Undetermined

**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, Rockville, MD 20850

Phone: 301 827–2971
Fax: 301 594–4765
Email: myh@fda.hhs.gov

**RIN:** 0910–AC30

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**1006. SUBMISSION OF STANDARDIZED ELECTRONIC STUDY DATA FROM CLINICAL STUDIES EVALUATING HUMAN DRUGS AND BIOLOGICS**

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

**RIN:** 0910–AC53

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**1007. MEDICAL GAS CONTAINERS AND CLOSURES; CURRENT GOOD MANUFACTURING PRACTICE REQUIREMENTS**

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

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

**CFR Citation:** 21 CFR 201.161(a); 21 CFR 210.3(b); 21 CFR 211.94

**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.

**Timetable:**

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</table>

**Regulatory Flexibility Analysis Required:** Undetermined

**Government Levels Affected:** None

**Agency Contact:** Elaine H. Tseng, 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
Fax: 301 827–5562
Email: mitchellw@cdr.fda.gov

**RIN:** 0910–AC53

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**1008. 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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**Period End**

Final Action 12/00/06

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

**RIN:** 0910–AC55

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**1009. 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 360i 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.

Timetable:

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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 (HF–7), Rockville, MD 20852

Phone: 301 594–2041
Fax: 301 827–5562
Email: pendletonb@cdr.fda.gov

Related RIN: Previously reported as 0910–AC02

RIN: 0910–AC59

1013. EXPANDED ACCESS TO INVESTIGATIONAL DRUGS FOR TREATMENT USE

Regulatory Plan: This entry is Seq. No. 46 in part II of this issue of the Federal Register.

RIN: 0910–AF13

1014. DISTRIBUTION OF BLOOD DERIVATIVES BY REGISTERED BLOOD ESTABLISHMENTS THAT QUALIFY AS HEALTH CARE ENTITIES; PDMA OF 1987; PDA OF 1992; POLICIES, REQUIREMENTS, AND ADMINISTRATIVE PROCEDURES

Priority: Substantive, Nonsignificant

Legal Authority: 21 USC 371; 21 USC 374

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 rule that published on December 3, 1999, (64 FR 67720), do not allow a registered blood establishment that concurrently distributes 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 to concurrently distribute blood derivatives. The purpose of this proposed rule is to protect consumers who have allergies to the color additives carmine and cochineal extract by requiring label declaration on products under FDA jurisdiction. This action responds to adverse event reports received by FDA and to a citizen petition submitted to FDA.

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</table>

Regulatory Flexibility Analysis Required: Undetermined

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, Suite 3059 (HF–7), Center for Drug Evaluation and Research, 5515 Security Lane, Rockville, MD 20852

Phone: 301 594–2041
Fax: 301–827–5562
Email: rogersc@cdr.fda.gov

RIN: 0910–AF14
1015. REVOCATION OF THE STATUS OF SPECIFIC PRODUCTS; GROUP A STREPTOCOCCUS

Priority: Info./Admin./Other
Legal Authority: 42 USC 262
CFR Citation: 21 CFR 610.19
Legal Deadline: None

Abstract: FDA is issuing 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.

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<td>Direct Final Rule</td>
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Regulatory Flexibility Analysis Required: No

Small Entities Affected: None

Government Levels Affected: None

1016. OBSTETRICAL AND GYNECOLOGICAL DEVICES; DESIGNATION OF SPECIAL CONTROL FOR CONDOMS AND CONDOMS WITH SPERMICIDAL LUBRICANT

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

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.

Timetable:

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Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses

Government Levels Affected: None

1017. 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 201; 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.

Timetable:

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Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses
### 1018. 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 two 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.  
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<td>NPRM (Amendment) (Combinations with Sodium Bicarbonate)</td>
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<td>NPRM (Amendment) (Overindulgence/ Hangover)</td>
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### 1019. 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 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. This action addresses labeling for convenience (small) size OTC drug packages.  
**Timetable:**  
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<td>NPRM (Convenience Sizes)</td>
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### Regulatory Flexibility Analysis

**Required:** Yes  
**Small Entities Affected:** Businesses  

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1020. 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>
<td>NPRM (Emergency First Aid Eyewashes)</td>
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</table>

### Regulatory Flexibility Analysis

**Required:** Yes  
**Small Entities Affected:** Businesses  

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**Government Levels Affected:** None

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**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: rachanow@cdrf.gov

---

**Government Levels Affected:** None  
**Agency Contact:** Paula S. McKeever, Regulatory Policy Analyst, Department of Health and Human Services, Food and Drug Administration, Suite 200N, Center for Biologics Evaluation and Research, 1401 Rockville Pike, Rockville, MD 20852–1448 Phone: 301 827–6210 Fax: 301 827–9434 Email: mckeever@cbcr.fda.gov

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**Related RIN:** Split from 0910–AB26

**RIN:** 0910–AF25
1021. 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. One action addresses 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:

Action | Date | FR Cite
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ANPRM (Sunscreen and Insect Repellent) | 10/00/06 | 69 FR 42288
NPRM (UVA/UVB) | 12/00/05 |

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

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: rachanow@cdr.fda.gov

Related RIN: Split from 0910–AA01

RIN: 0910–AF39

1022. 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 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 phenylpropanolamine, and the other action addresses the ingredient benzocaine.

Timetable:

Action | Date | FR Cite
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NPRM (Phenyl propanolamine) | 12/00/05 |
NPRM (Benzocaine) | 12/00/05 |
Final Action (Phenylpropanolamine) | 10/00/06 |

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

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: rachanow@cdr.fda.gov

Related RIN: Split from 0910–AA01

RIN: 0910–AF45

1023. 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: The Food and Drug Administration (FDA) is proposing to amend its regulations to prohibit the use of certain cattle origin materials in the food or feed of all animals to help 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:

Action | Date | FR Cite
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ANPRM Comment Period End | 07/14/04 | 69 FR 42288
ANPRM Comment Period End | 08/13/04 |
NPRM Comment Period End | 10/06/05 | 70 FR 58569
NPRM Comment Period End | 12/20/05 |
Final Action | 07/00/06 |

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

RIN: 0910–AF46

1024. OVER-THE-COUNTER (OTC) DRUG REVIEW—DANDRUFF, SEBORRHEIC DERMATITIS, AND PSORIASIS PRODUCTS

Priority: Routine and Frequent

Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 360a; 21 USC 371; 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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<th>Action</th>
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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: rachanow@cder.fda.gov

RIN: 0910–AF49

1026. OVER–THE–COUNTER (OTC) DRUG REVIEW—STIMULANT DRUG PRODUCTS

Priority: Routine and Frequent

Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 360a; 21 USC 371; 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 the use of stimulant active ingredients to relieve symptoms associated with a hangover.

Timetable:

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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: rachanow@cder.fda.gov

RIN: 0910–AF53
1029. • 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
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 safety and effectiveness of a new animal drug proposed for indexing.

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1030. • OVER–THE–COUNTER (OTC) DRUG REVIEW—POISON TREATMENT DRUG PRODUCTS

Priority: Routine and Frequent. Major status under 5 USC 801 is undetermined.
Legal Authority: 21 USC 321p; 21 USC 327; 21 USC 328; 21 USC 331; 21 USC 360; 21 USC 371
CFR Citation: 21 CFR 301; 21 CFR 310; 21 CFR 320; 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 the ingredient ipecac.

Timetable:

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Regulatory Flexibility Analysis
Required: Yes
Small Entities Affected: Businesses
Government Levels Affected: None
Agency Contact: Walter Ellenberg, Regulatory Health Project Manager, Center for Drug Evaluation and Research, Department of Health and Human Services, Food and Drug...
1031. • 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.

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Regulatory Flexibility Analysis
Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Walter Ellenberg, Regulatory Health Project Manager, Center for Drug Evaluation and Research, Department of Health and Human Services, Food and Drug Administration, CRP2 RMS214, HFD–560, Rockville, MD 20850 Phone: 301 827–2279 Fax: 301–827–2316 Email: walter.ellenberg@fda.hhs.gov

RIN: 0910–AF69

1032. INVESTIGATIONAL NEW DRUGS: EXPORT REQUIREMENTS FOR UNAPPROVED NEW DRUG PRODUCTS

Priority: Routine and Frequent

Legal Authority: 21 USC 321; 21 USC 381; 21 USC 382; 21 USC 393; 42 USC 241; 42 USC 243; 42 USC 262; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 371

CFR Citation: 21 CFR 312.110

Legal Deadline: None

Abstract: The final rule would amend the regulations on the exportation of unapproved new drug products, including biological products, for investigational use. In general, the rule would provide four different routes for exporting an unapproved new drug product for investigational use. One route would permit exportation, if the drug is the subject of an investigational new drug application (IND) and is being exported for use in the investigation. A second route would permit exportation, without prior Food and Drug Administration (FDA) approval and without an IND, if the product to be exported for use in a clinical investigation and has received marketing authorization in certain developed countries. The third route would permit exportation, without prior FDA approval and without an IND, if the product is to be exported for use in a clinical investigation in certain specified developed countries. The fourth route would permit exportation without an IND, to any country provided that the exporter sends a written certification to FDA at the time the drug is first exported. Drugs exported under any of the first three routes would, however, be subject to certain statutory requirements, such as not conflicting with the foreign country’s laws and not being sold or offered for sale in the United States. Drugs exported under either the second or third routes would be subject to additional statutory requirements, such as being in substantial conformity with the current good manufacturing practices and certain labeling requirements. These provisions would implement changes in FDA’s export authority resulting from the FDA Export Reform and Enhancement Act of 1996 and streamline another mechanism for exporting investigational new drugs while providing safeguards.

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Regulatory Flexibility Analysis
Required: No

Government Levels Affected: None

Agency Contact: Philip L. Chao, Senior Policy Analyst, Department of Health and Human Services, Food and Drug Administration, Room 15–61 (HF–23), Office of Policy and Planning, 5600 Fishers Lane, Room 14C–17, Rockville, MD 20857 Phone: 301 827–0587 Fax: 301 827–4774 Email: philip.chao@fda.hhs.gov

RIN: 0910–AA61

1033. REQUIREMENTS ON CONTENT AND FORMAT OF LABELING FOR HUMAN PRESCRIPTION DRUGS AND BIOLOGICAL PRODUCTS

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

RIN: 0910–AA94

1034. 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: 42 USC 216; 42 USC 241; 42 USC 242a; 42 USC 262; 42 USC 263; 42 USC 263a to 263–n; 42 USC 264; 42 USC 300a; 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
**HHS—FDA**

**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:**

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**Regulatory Flexibility Analysis Required:** Yes

**Small Entities Affected:** Businesses

**Government Levels Affected:** Undetermined

**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–AA97

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**1036. 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 263a; 42 USC 264; 21 USC 372; 21 USC 381; 42 USC 263

**CFR Citation:** 21 CFR 600; 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, Suite 200N (HFM–17), Center for Biologics Evaluation and Research, 5515 Security Lane, Suite 1101 (HFD–7), Rockville, MD 20852–1448

Phone: 301 827–6210
Fax: 301 827–9434
Email: mckeever@cber.fda.gov

**RIN:** 0910–AB34

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**1037. CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKING, OR HOLDING DIETARY INGREDIENTS AND DIETARY SUPPLEMENTS**

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

**RIN:** 0910–AB76
1038. 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: 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 test is positive; and (6) refrigerated storage of shell 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 shell 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 comment 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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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 (HFD–7), Rockville, MD 20852

Phone: 301 594–2041
Fax: 301 827–5562

RIN: 0910–AC07

1039. 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 test is positive; and (6) refrigerated storage of shell 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 shell 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 comment 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.

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Regulatory Flexibility Analysis

Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Undetermined

Agency Contact: Louis J. Carson, Deputy Director, Food Safety Initiative, 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: 301 436–2130
Fax: 301 436–2632
Email: louis.carson@cfsan.fda.gov

RIN: 0910–AC14

1040. INSTITUTIONAL REVIEW BOARDS: REGISTRATION REQUIREMENTS

Priority: Info./Admin./Other

Legal Authority: 21 USC 321; 21 USC 346; 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
The final rule amends the sampling plans, test method, and acceptable quality levels in 21 CFR 800.20. As prescribed by this regulation, FDA samples patient examination and surgeons’ gloves and examines them for visual defects and water leaks. Glove lots are considered adulterated if they do not meet specified quality levels. This rule would clarify sampling plans and the scoring of defects, lower acceptance rates for leaking gloves, raise rejection rates for leaking gloves, and add tightened inspection schemes for reexamined glove lots. The rule is intended to facilitate industry compliance and enhance the safety and effectiveness of gloves.

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**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, Rockville, MD 20850

**Phone:**

- 301 827–2971

**Fax:**

- 301 594–4765

**Email:**

- myh@fda.hhs.gov

**RIN:**

- 0910–AC32

**1043. TOLL–FREE NUMBER FOR REPORTING ADVERSE EVENTS ON LABELING FOR HUMAN DRUGS**

**Regulatory Plan:**

- This entry is Seq. No. 49 in part II of this issue of the Federal Register.

**RIN:**

- 0910–AC35

**1044. 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

**Legal Deadline:**


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 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 daily activities.
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, HFS–32, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, College Park, MD 20740
Phone: 301 436–1722
Fax: 301 436–2637
Email: may.nelson@cfssa.fda.gov

RIN: 0910–AC41

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**1045. 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)(ii)(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.

**Timetable:**

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**Regulatory Flexibility Analysis Required:** No

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**1046. 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 360; 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 blood, 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.

**Timetable:**

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**Regulatory Flexibility Analysis Required:** No
Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Brenda R. Friend, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Biologics Evaluation and Research, HFM–17, 1410 Rockville Pike, Suite 200N, Rockville, MD 20852–1448
Phone: 301 827–6210
Fax: 301 827–9434

NPRM Comment

Related RIN: Split from 0910–AB26
RIN: 0910–AF26

1047. 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:

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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
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Email: melissa.scales@cfsan.fda.gov

Related RIN: Split from 0910–AA04
RIN: 0910–AF27

1048. INFANT FORMULA QUALITY FACTORS

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.

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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
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Email: melissa.scales@cfsan.fda.gov

Related RIN: Split from 0910–AA04
RIN: 0910–AF27

1049. 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; 21USC 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 claims for the common cold.

Timetable:

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Regulatory Flexibility Analysis

Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

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: rachanow@cdr.fda.gov

Related RIN: Split from 0910–AA01
RIN: 0910–AF31
1050. 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

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:

Action | Date | FR Cite
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NPRM (Amendment) (Sinusitis Claim) | 08/02/04 | 69 FR 46119
NPRM (Phenylephrine Bitartrate) | 11/02/04 | 69 FR 63482
NPRM (Phenypropanolamine) | 12/00/05 |
Final Action (Amendment) (Sinusitis Claim) | 10/31/05 | 70 FR 58974
Final Action (Phenylpropanolamine) | 10/00/06 |
Final Action (Phenylephrine Bitartrate) | 12/00/05 |

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

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: rachanow@cdr.fda.gov

Related RIN: Split from 0910–AA01
RIN: 0910–AF34

1051. 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

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 laxative drug products.

Timetable:

Action | Date | FR Cite
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Final Action (Laxative Drug Products) | 03/00/06 |
Final Action (Granular Psyllium) | 10/00/06 |

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

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: rachanow@cdr.fda.gov

Related RIN: Split from 0910–AA01
RIN: 0910–AF38

1052. OVER–THE–COUNTER (OTC) DRUG REVIEW—SKIN PROTECTANT 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 358; 21 USC 360; 21 USC 360g to 360s; 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

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 skin protectant products to protect and treat fever blisters and cold sores.

Timetable:

Action | Date | FR Cite
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Final Action (Granular Psyllium) | 10/00/06 |

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

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: rachanow@cdr.fda.gov

Related RIN: Split from 0910–AA01
RIN: 0910–AF42

1053. 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 355; 21 USC 360a; 21 USC 371a; 21 USC 331; 21 USC 358; 21 USC 360; 21 USC 360g to 360s; 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. This action addresses labeling warning statements for products containing nonoxynol 9.

Timetable:

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Regulatory Flexibility Analysis
Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Gerald M. Rachenow, 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
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Email: rachenow@cder.fda.gov

Related RIN: Split from 0910–AA01
RIN: 0910–AF44

1055. 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
Phone: 301 436–1486
Fax: 301 436–2632
Email: rebecca.buckner@cfsan.fda.gov

RIN: 0910–AF48

1054. 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, effective immediately, to prohibit the use of certain cattle material, to address the potential risk of bovine spongiform encephalopathy (BSE), in human food, including dietary supplements, and cosmetics. Prohibited cattle materials include specified risk materials, small intestine of all cattle, material from nonambulatory disabled cattle, material from cattle not inspected and passed for human consumption, and mechanically separated (MS) (Beef). Specified risk materials are the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia of cattle 30 months and older; and the tonsils and distal ileum of the small intestine of all cattle. Prohibited cattle materials do not include tallow that contains no more than 0.15 percent hexane-insoluble impurities and tallow derivatives. This action minimizes human exposure to materials that scientific studies have demonstrated are highly likely to contain the BSE agent in cattle infected with the disease. Scientists believe that the human disease variant Creutzfeldt-Jakob disease (vCJD) is likely caused by the consumption of products contaminated with the agent that causes BSE. After reviewing comments received to the interim final rule, FDA intends to issue a final rule.

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Regulatory Flexibility Analysis
Required: No

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Rebecca Buckner, Consumer Safety Officer, 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: rachenow@cder.fda.gov

Related RIN: Split from 0910–AA01
RIN: 0910–AF44

1056. OVER–THE–COUNTER (OTC) DRUG REVIEW—ANTACID PRODUCTS

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 371; 21 USC 371a; 21 USC 331
On December 13, 1985, the Food and Drug Administration (FDA) proposed to amend the biologics regulations in response to the report and recommendations of the Panel on Review of Bacterial Vaccines and Toxoids (the Panel). The Panel reviewed the safety, efficacy, and labeling of bacterial vaccines and toxoids with standards of potency, bacterial antitoxins, and immune globulins. After reviewing the Panel’s report and comments on the proposal, FDA published a final rule and final order on January 5, 2004 (69 FR 255). On October 27, 2004, the United States District Court for the District of Columbia vacated the January 5, 2004, final rule and final order. On December 29, 2004 (69 FR 78280), FDA published a withdrawal of the January 5, 2004, final rule and final order. Concurrently with the withdrawal of the final rule and final order, FDA published again a proposed rule and proposed order (December 2004 proposal) (69 FR 78281) to provide notice and to give interested persons an opportunity to comment. FDA is proposing to amend the biologics regulations in response to the report and recommendations of the Panel and in consideration of comments submitted to the Division of Dockets Management. FDA intends to classify these products as Category I (safe, effective, and not misbranded), Category II (unsafe, ineffective, or misbranded), or Category III (off the market pending completion of studies permitting a determination of effectiveness).

The December 2004 proposal included a proposed order for Anthrax Vaccine Absorbed. The final order Anthrax Vaccine Absorbed will be published separately in the same issue of the Federal Register as the final rule and final order for the other products included in the December 2004 proposal.

**1058. BIOLOGICAL PRODUCTS; BACTERIAL VACCINES AND TOXOIDS; IMPLEMENTATION OF EFFICACY REVIEW**

**Priority:** Substantive, Nonsignificant

**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 to 360d; 21 USC 360h; 21 USC 360i; 21 USC 360j; 21 USC 360gg to 360ss; 21 USC 371; 21 USC 372; 21 USC 374; 21 USC 379e; 21 USC 381; 42 USC 216; 42 USC 241; 42 USC 262; 42 USC 263; 42 USC 263a; 42 USC 264

**CFR Citation:** 21 CFR 201.59; 21 CFR 610.21

**Legal Deadline:** None

**Abstract:** On December 13, 1985, the Food and Drug Administration (FDA) proposed to amend the biologics regulations and proposed to classify the bacterial vaccines and toxoids on the basis of findings and recommendations of the Panel on Review of Bacterial Vaccines and Toxoids (the Panel). The Panel reviewed the safety, efficacy, and labeling of bacterial vaccines and toxoids with standards of potency, bacterial antitoxins, and immune globulins. After reviewing the Panel’s report and comments on the proposal, FDA published a final rule and final order on January 5, 2004 (69 FR 255). On October 27, 2004, the United States District Court for the District of Columbia vacated the January 5, 2004, final rule and final order. On December 29, 2004 (69 FR 78280), FDA published a withdrawal of the January 5, 2004, final rule and final order. Concurrently with the withdrawal of the final rule and final order, FDA published again a proposed rule and proposed order (December 2004 proposal) (69 FR 78281) to provide notice and to give interested persons an opportunity to comment. FDA is proposing to amend the biologics regulations in response to the report and recommendations of the Panel and in consideration of comments submitted to the Division of Dockets Management. FDA intends to classify these products as Category I (safe, effective, and not misbranded), Category II (unsafe, ineffective, or misbranded), or Category III (off the market pending completion of studies permitting a determination of effectiveness).

The December 2004 proposal included a proposed order for Anthrax Vaccine Absorbed. The final order Anthrax Vaccine Absorbed will be published separately in the same issue of the Federal Register as the final rule and final order for the other products included in the December 2004 proposal.

**CFR Citation:** 21 CFR 201.59; 21 CFR 610.21

**Legal Deadline:** None

**Abstract:** On December 13, 1985, the Food and Drug Administration (FDA) proposed to amend the biologics regulations and proposed to classify the bacterial vaccines and toxoids on the basis of findings and recommendations of the Panel on Review of Bacterial Vaccines and Toxoids (the Panel). The Panel reviewed the safety, efficacy, and labeling of bacterial vaccines and toxoids with standards of potency, bacterial antitoxins, and immune globulins. After reviewing the Panel’s report and comments on the proposal, FDA published a final rule and final order on January 5, 2004 (69 FR 255). On October 27, 2004, the United States District Court for the District of Columbia vacated the January 5, 2004, final rule and final order. On December 29, 2004 (69 FR 78280), FDA published a withdrawal of the January 5, 2004, final rule and final order. Concurrently with the withdrawal of the final rule and final order, FDA published again a proposed rule and proposed order (December 2004 proposal) (69 FR 78281) to provide notice and to give interested persons an opportunity to comment. FDA is proposing to amend the biologics regulations in response to the report and recommendations of the Panel and in consideration of comments submitted to the Division of Dockets Management. FDA intends to classify these products as Category I (safe, effective, and not misbranded), Category II (unsafe, ineffective, or misbranded), or Category III (off the market pending completion of studies permitting a determination of effectiveness).

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**CFR Citation:** 21 CFR 201.59; 21 CFR 610.21

**Legal Deadline:** None

**Abstract:** On December 13, 1985, the Food and Drug Administration (FDA) proposed to amend the biologics regulations and proposed to classify the bacterial vaccines and toxoids on the basis of findings and recommendations of the Panel on Review of Bacterial Vaccines and Toxoids (the Panel). The Panel reviewed the safety, efficacy, and labeling of bacterial vaccines and toxoids with standards of potency, bacterial antitoxins, and immune globulins. After reviewing the Panel’s report and comments on the proposal, FDA published a final rule and final order on January 5, 2004 (69 FR 255). On October 27, 2004, the United States District Court for the District of Columbia vacated the January 5, 2004, final rule and final order. On December 29, 2004 (69 FR 78280), FDA published a withdrawal of the January 5, 2004, final rule and final order. Concurrently with the withdrawal of the final rule and final order, FDA published again a proposed rule and proposed order (December 2004 proposal) (69 FR 78281) to provide notice and to give interested persons an opportunity to comment. FDA is proposing to amend the biologics regulations in response to the report and recommendations of the Panel and in consideration of comments submitted to the Division of Dockets Management. FDA intends to classify these products as Category I (safe, effective, and not misbranded), Category II (unsafe, ineffective, or misbranded), or Category III (off the market pending completion of studies permitting a determination of effectiveness).

The December 2004 proposal included a proposed order for Anthrax Vaccine Absorbed. The final order Anthrax Vaccine Absorbed will be published separately in the same issue of the Federal Register as the final rule and final order for the other products included in the December 2004 proposal.

**CFR Citation:** 21 CFR 201.59; 21 CFR 610.21

**Legal Deadline:** None

**Abstract:** On December 13, 1985, the Food and Drug Administration (FDA) proposed to amend the biologics regulations and proposed to classify the bacterial vaccines and toxoids on the basis of findings and recommendations of the Panel on Review of Bacterial Vaccines and Toxoids (the Panel). The Panel reviewed the safety, efficacy, and labeling of bacterial vaccines and toxoids with standards of potency, bacterial antitoxins, and immune globulins. After reviewing the Panel’s report and comments on the proposal, FDA published a final rule and final order on January 5, 2004 (69 FR 255). On October 27, 2004, the United States District Court for the District of Columbia vacated the January 5, 2004, final rule and final order. On December 29, 2004 (69 FR 78280), FDA published a withdrawal of the January 5, 2004, final rule and final order. Concurrently with the withdrawal of the final rule and final order, FDA published again a proposed rule and proposed order (December 2004 proposal) (69 FR 78281) to provide notice and to give interested persons an opportunity to comment. FDA is proposing to amend the biologics regulations in response to the report and recommendations of the Panel and in consideration of comments submitted to the Division of Dockets Management. FDA intends to classify these products as Category I (safe, effective, and not misbranded), Category II (unsafe, ineffective, or misbranded), or Category III (off the market pending completion of studies permitting a determination of effectiveness).

The December 2004 proposal included a proposed order for Anthrax Vaccine Absorbed. The final order Anthrax Vaccine Absorbed will be published separately in the same issue of the Federal Register as the final rule and final order for the other products included in the December 2004 proposal.
1059. 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 314.96(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.

Timetable:

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<td>68 FR 61640</td>
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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, HFD-7. Center for Drug Evaluation and Research, 5515 Security Lane, Suite 1101, Rockville, MD 20857

Phone: 301 594–2041

Fax: 301 827–5562

RIN: 0910–AC23

1060. 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 343; 21 USC 371

CFR Citation: 21 CFR 101

Legal Deadline: None

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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Regulatory Flexibility Analysis

Required: Undetermined

Government Levels Affected: Federal

Agency Contact: Julie Moss, Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, HFS–830, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, College Park, MD 20740

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Fax: 301 436–2639

Email: julie.moss@fda.gov

Related RIN: Related to 0910–AB66

RIN: 0910–AC50

1061. 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

Legal Deadline: None

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 67402). 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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**Regulatory Flexibility Analysis**

**Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** Undetermined

**Agency Contact:** Ritu Nalubola, Staff Fellow, Department of Health and Human Services, Food and Drug Administration, HFS–820, Center for Food Safety and Applied Nutrition, Harvey Wiley Building, 5100 Paint Branch Parkway, College Park, MD 20740

Phone: 301 436–2371
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Email: ritu.nalubola@cfsan.fda.gov

**Related RIN:** Related to 0583–AC72

**RIN:** 0910–AC54

### 1062. 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.

**Timetable:**

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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: mullerh@cdr.fda.gov

**RIN:** 0910–AF08

### 1063. 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.

**Timetable:**

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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.cranecf.fda.gov

**RIN:** 0910–AF09
1064. 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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Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: Undetermined
Agency Contact: Jill Kevala, Chemist, Department of Health and Human Services, Food and Drug Administration, HFS–830, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, College Park, MD 20740
Phone: 301 436–1450
Fax: 301 436–2636
Email: jkevala@cfsan.fda.gov

RIN: 0910–AF22

1065. 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 changes to the agency’s nutrition labeling regulations on serving size and comments on allowance of truthful, nonmisleading, and useful approaches for promoting consumption of smaller portion sizes.

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Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: Undetermined
Agency Contact: Jill Kevala, Chemist, Department of Health and Human Services, Food and Drug Administration, HFS–830, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, College Park, MD 20740
Phone: 301 436–1450
Fax: 301 436–2636
Email: jkevala@cfsan.fda.gov

RIN: 0910–AF22

Small Entities Affected: Businesses

1066. 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 combination products containing an oral bronchodilator.

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Regulatory Flexibility Analysis Required: Yes

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: rachanow@cdr.fda.gov

RIN: Split from 0910–AA01
RIN: 0910–AF32

Government Levels Affected: None

1067. 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. This action addresses combination products containing an oral bronchodilator.

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Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

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
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Email: rachanow@cdr.fda.gov

RIN: Split from 0910–AA01
RIN: 0910–AF32

Government Levels Affected: None
**1068. 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.

**Timetable:**

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**Regulatory Flexibility Analysis Required:** Yes

**Small Entities Affected:** Businesses

**Government Levels Affected:** None

**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: rachanow@cdr.fda.gov

**Related RIN:** Split from 0910–AA01

**RIN:** 0910–AF35

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**1071. 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 501; 21 USC 502; 21 USC 505; 21 USC 512; 21 USC 516; 21 USC 519; 21 USC 701; 21 USC 704; 21 USC 801; 42 USC 351; 42 USC 361


**Legal Deadline:** None

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

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Regulatory Flexibility Analysis Required: No

Small Entities Affected: None

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: 301 827–0891

Fax: 301 827–4774

Email: eric.flamm@fda.hhs.gov

Related RIN: Merged with 0910–AF55

RIN: 0910–AF54

1074. • 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

Legal Authority: 21 USC 321; 21 USC 341; 21 USC 343; 21 USC 348; 21 USC 371; 21 USC 379

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

Legal Deadline: None

Abstract: Part 131 (21 CFR Part 131) describes regulations for standards of identity for milk and milk products. Part 133 (21 CFR Part 133) describes regulations for standards of identity for cheese and cheese products. The 1996 final rule (61 FR 58991) removed standards of identity for sweetened condensed skim milk, lowfat dry milk, evaporated skim milk, lowfat milk, acidified lowfat milk, skim (nonfat) milk, cultured skim (nonfat) milk, sour half-and-half, acidified sour half-and-half, and lowfat cottage cheese. The final rule amended the standard of identity for dry cream by removing the reference to the lowfat milk standard. The regulation also amended the nutrient content claims regulations for fat, fatty acids, and cholesterol (part 101.62) to provide for “skim” as a synonym for “nonfat” when used in labeling milk products. The purpose of this review is to determine whether the regulations in parts 131 and 133 should be continued without change, or whether they 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 regulations in parts 131 and 133; (2) the nature of complaints or comments received concerning the regulations in parts 131 and 133; (3) the complexity of the regulations in parts 131 and 133; (4) the extent to which the regulations in parts 131 and 133 overlap, duplicate, or conflict with other Federal, State, or governmental rules; and (5) the degree to which technology, economic conditions, or other factors have changed for the products still subject to the food standard regulations in parts 131 and 133.

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. The combined effect of the two reviews will be to determine if it is possible to redesign milk and cheese food standards of identity in ways that will maintain or increase the effectiveness of food labeling in providing useful information to consumers, and, at the same time, reduce compliance and other costs associated with the regulations.

**Timetable:**

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**Regulatory Flexibility Analysis**

Required: No

**Government Levels Affected:**

Undetermined

**Federalism:**

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@cfsan.fda.gov

**RIN:** 0910–AF64

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**1075. OVER–THE–COUNTER (OTC) ANALGESIC DRUG PRODUCTS**

**Priority:** Routine and Frequent

**CFR Citation:** 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 the ingredient phenazopyridine.

**Timetable:**

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**Regulatory Flexibility Analysis**

Required: Yes

**Small Entities Affected:** Businesses

**Government Levels Affected:** None

**Agency Contact:** Walter Ellenberg, Regulatory Health Project Manager, Center for Drug Evaluation and Research, Department of Health and Human Services, Food and Drug Administration, CRP2 RMS214, HFD–560, Rockville, MD 20850
Phone: 301 827–2279
Fax: 301–827–2316
Email: walter.ellenberg@fda.hhs.gov

**RIN:** 0910–AF70

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

**Food and Drug Administration (FDA)**

**1076. REQUIREMENTS PERTAINING TO SAMPLING SERVICES AND PRIVATE LABORATORIES USED IN CONNECTION WITH IMPORTED FOOD**

**Priority:** Routine and Frequent

**CFR Citation:** 21 CFR 59

**Completed:**

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**Regulatory Flexibility Analysis**

Required: Yes

**Small Entities Affected:** Businesses

**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–AB96

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**1077. AMENDMENTS TO THE PERFORMANCE STANDARD FOR DIAGNOSTIC X–RAY SYSTEMS AND THEIR MAJOR COMPONENTS**

**Priority:** Economically Significant

**CFR Citation:** 21 CFR 1020.30; 21 CFR 1020.31; 21 CFR 1020.32; 21 CFR 1020.33

**Completed:**

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**Regulatory Flexibility Analysis**

Required: Yes

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**1078. REGISTRATION OF FOOD AND ANIMAL FEED FACILITIES**

**Priority:** Other Significant

**CFR Citation:** 21 CFR 1; 21 CFR 20

**Completed:**

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**Regulatory Flexibility Analysis**

Required: No
Small Entities Affected: Businesses
Government Levels Affected: None
Agency Contact: Catherine Copp
Phone: 301 436–1589
Fax: 301 436–2637
Email: catherine.copp@cfpan.fda.gov
RIN: 0910–AC40

1079. QUALITY STANDARD REGULATION ESTABLISHING AN ALLOWABLE LEVEL FOR ARSENIC IN BOTTLED WATER
Priority: Other Significant
CFR Citation: 21 CFR 165.110(b)
Completed: Final Rule 06/09/05 70 FR 33694
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: Henry Kim
Phone: 301 436–2023
Fax: 301 436–2651
Email: hkim@cfpan.fda.gov
RIN: 0910–AF10

1080. 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:
Action Date FR Cite
NPRM 09/01/98 63 FR 46538
Second NPRM 12/00/05

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–AC44

Department of Health and Human Services (HHS)
Health Resources and Services Administration (HRSA)

1081. NATIONAL PRACTITIONER DATA BANK FOR ADVERSE INFORMATION ON PHYSICIAN AND OTHER HEALTH CARE PRACTITIONERS: REPORTING ADVERSE AND NEGATIVE ACTIONS
Priority: Substantive, Nonsignificant
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:
Action Date FR Cite
NPRM 10/00/05

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

1082. 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

**Government Levels Affected:** None

**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

RIN: 0906–AA62

### 1083. 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, 300a–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 Health Service Act, 42 U.S.C. section 300a-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 would 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: gevansr@hrsa.gov

RIN: 0906–AA68

### 1084. HEALTHY TOMORROW’S PARTNERSHIP FOR CHILDREN (HTPC) PROGRAM

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

**Legal Authority:** Social Security Act, title V, sec 501(a)(2); 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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1085. INTERIM FINAL RULE FOR THE 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 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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<td>68 FR 51492</td>
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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–AA60

1086. SMALLPOX VACCINE INJURY COMPENSATION PROGRAM: ADMINISTRATIVE IMPLEMENTATION

Priority: Other Significant. 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 provide benefits to certain persons harmed as a result of receiving smallpox covered countermeasures, including the smallpox vaccine, or as a result of contracting vaccinia through accidental exposure to certain persons. The Secretary may also provide death benefits to certain survivors of people who died as a direct result of these injuries.

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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

1087. 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.

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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
### 1088. REVISION TO 42 CFR SUBPART D—PUBLIC HEALTH SERVICE (PHS) GRANT APPEALS PROCEDURE

| Abstract | The Health Resources and Services Administration (HRSA), an operating division under the U.S. Department of Health and Human Services, is proposing to no longer require its grantees to appeal certain adverse agency decisions to an “informal” appeals board (as outlined in 42 CFR part 50, subpart D—Public Health Service Grant Appeals Procedure) before exercising the right to appeal to the Departmental Appeals Board. In doing so, HRSA will join other PHS agencies (Substance Abuse and Mental Health Services Administration and the Indian Health Service) which no longer require the use of an informal appeal procedure. |

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### 1089. NATIONAL PRACTITIONER DATA BANK FOR ADVERSE INFORMATION ON PHYSICIANS AND OTHER HEALTH CARE PRACTITIONERS: MEDICAL MALPRACTICE PAYMENTS REPORTING REQUIREMENTS

| 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. |

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### 1090. OPERATION OF THE ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK (OPTN)

| 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:

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1091. 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

Government Levels Affected: None

Agency Contact: Jerry Moore, NIH Regulations Officer, Department of Health and Human Services, National Institutes of Health, Room 601 MSC 7669, 6011 Executive Boulevard, Rockville, MD 20852

Phone: 301 496–4606
Fax: 301 402–0169
Email: jm40z@nih.gov

RIN: 0925–AA47

1092. • GRANTS FOR RESEARCH PROJECTS — 42 CFR PART 52—NPRM

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, Room 601 MSC 7669, 6011 Executive Boulevard, Rockville, MD 20852

Phone: 301 496–4606
Fax: 301 402–0169
Email: jm40z@nih.gov

RIN: 0925–AA42

1093. • NATIONAL INSTITUTES OF HEALTH LOAN REPAYMENT PROGRAMS

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 216 42 USC 288–5a; 42 USC 287c–33 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 (LPR) authorities. This action will include rescinding the current regulations at 42 CFR 66a and at 42 CFR 68c in lieu of the new consolidated set of LRP regulations. This action will also include withdrawing the previously announced planned actions concerning NIH LRP authorities.

Timetable:

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Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

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@hq.ihs.gov

RIN: 0917–AA07

1094. • 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 Project 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 project director to one single individual when that more accurately reflects the management needs of a research project.

Timetable:

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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, Room 601 MSC 7669, 6011 Executive Boulevard, Rockville, MD 20852

Phone: 301 496–4606
Fax: 301 402–0169
HHS—NIH

1095. MINORITY BIOMEDICAL RESEARCH SUPPORT PROGRAM

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

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 program.

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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, Room 601 MSC 7669, 6011 Executive Boulevard, Rockville, MD 20852

Phone: 301 496–4606
Fax: 301 402–0169
Email: jm40z@nih.gov

RIN: 0925–AA44

1096. NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES HAZARDOUS SUBSTANCES BASIC RESEARCH AND TRAINING GRANTS

Priority: Substantive, Nonsignificant

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

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.

Timetable:

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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, Room 601 MSC 7669, 6011 Executive Boulevard, Rockville, MD 20852

Phone: 301 496–4606
Fax: 301 402–0169
Email: jm40z@nih.gov

RIN: 0925–AA46

1097. 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.

Timetable:

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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, Room 601 MSC 7669, 6011 Executive Boulevard, Rockville, MD 20852

Phone: 301 496–4606
Fax: 301 402–0169
Email: jm40z@nih.gov

RIN: 0925–AA28

1098. STANDARDS FOR A NATIONAL CHIMPANZEE SANCTUARY SYSTEM

Priority: Other Significant

Legal Authority: 42 USC 287a–3a

CFR Citation: 42 CFR 9


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.

Timetable:

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Regulatory Flexibility Analysis Required: No

Small Entities Affected: No
Federal Register / Vol. 70, No. 209 / Monday, October 31, 2005 / Unified Agenda

HHS—NIH

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<td>Regulations Officer, Department of Health and Human Services, National Institutes of Health, Room 601 MSC 7669, 6011 Executive Boulevard, Rockville, MD 20852</td>
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<td>Fax: 301 402–0169</td>
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<tr>
<td>Email: <a href="mailto:jm40z@nih.gov">jm40z@nih.gov</a></td>
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Department of Health and Human Services (HHS)

National Institutes of Health (NIH)

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| **1100. NATIONAL INSTITUTES OF HEALTH LOAN REPAYMENT PROGRAM FOR RESEARCH GENERALLY** |
| Priority: Substantive, Nonsignificant |
| CFR Citation: 42 CFR 68d |
| Completed: Withdrawn 08/05/05 |
| Regulatory Flexibility Analysis Required: No |
| Government Levels Affected: None |
| Agency Contact: Jerry Moore |
| Phone: 301 496–4606 |
| Fax: 301 402–0169 |
| Email: jm40z@nih.gov |
| RIN: 0925–AA10 |

| **1101. NATIONAL INSTITUTES OF HEALTH AIDS RESEARCH LOAN REPAYMENT PROGRAM** |
| Priority: Substantive, Nonsignificant |
| CFR Citation: 42 CFR 68 |
| Completed: Withdrawn 08/05/05 |
| Regulatory Flexibility Analysis Required: No |
| Small Entities Affected: No |
| Government Levels Affected: None |
| Agency Contact: Jerry Moore |
| Phone: 301 496–4606 |
| Fax: 301 402–0169 |
| Email: jm40z@nih.gov |
| RIN: 0925–AA32 |

| **1102. NATIONAL INSTITUTES OF HEALTH EXTRAMURAL LOAN REPAYMENT PROGRAM FOR CLINICAL RESEARCHERS** |
| Priority: Substantive, Nonsignificant |
| CFR Citation: 42 CFR 68g |
| Completed: Withdrawn 10/20/05 |
| Regulatory Flexibility Analysis Required: No |
| Small Entities Affected: No |
| Government Levels Affected: None |
| Agency Contact: Jerry Moore |
| Phone: 301 496–4606 |
| Fax: 301 402–0169 |
| Email: jm40z@nih.gov |
| RIN: 0925–AA33 |

| **1103. NATIONAL INSTITUTES OF HEALTH PEDIATRIC RESEARCH LOAN REPAYMENT PROGRAM** |
| Priority: Substantive, Nonsignificant |
| CFR Citation: 42 CFR 68e |
| Completed: Withdrawn 10/20/05 |
| Regulatory Flexibility Analysis Required: No |
| Small Entities Affected: No |
| Government Levels Affected: None |
| Agency Contact: Jerry Moore |
| Phone: 301 496–4606 |
| Fax: 301 402–0169 |
| Email: jm40z@nih.gov |
| RIN: 0925–AA34 |

| **1104. NATIONAL INSTITUTES OF HEALTH LOAN REPAYMENT PROGRAM FOR HEALTH DISPARITIES RESEARCH** |
| Priority: Substantive, Nonsignificant |
| CFR Citation: 42 CFR 68f |
| Completed: Withdrawn 10/20/05 |
| Regulatory Flexibility Analysis Required: No |
| Small Entities Affected: No |
| Government Levels Affected: None |
| Agency Contact: Jerry Moore |
| Phone: 301 496–4606 |
| Fax: 301 402–0169 |
| Email: jm40z@nih.gov |
| RIN: 0925–AA35 |

| **1105. NATIONAL INSTITUTES OF HEALTH CLINICAL RESEARCH LOAN REPAYMENT PROGRAM FOR INDIVIDUALS FROM DISADVANTAGED BACKGROUNDS** |
| Priority: Substantive, Nonsignificant |
| CFR Citation: 42 CFR 68a |
| Completed: Withdrawn 10/20/05 |
| Regulatory Flexibility Analysis Required: No |
| Small Entities Affected: No |
| Government Levels Affected: None |
| Agency Contact: Jerry Moore |
| Phone: 301 496–4606 |
| Fax: 301 402–0169 |
| Email: jm40z@nih.gov |
| RIN: 0925–AA36 |
### HHS—NIH

**Phone:** 301 496–4606  
**Fax:** 301 402–0169  
**Email:** jm40z@nih.gov  
**RIN:** 0925–AA36

#### 1106. NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT CONTRACEPTION AND INFERTILITY RESEARCH LOAN REPAYMENT PROGRAM

**Priority:** Substantive, Nonsignificant  
**CFR Citation:** 42 CFR 68c  
**Completed:**

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**Regulatory Flexibility Analysis**  
**Required:** No  
**Small Entities Affected:** No  
**Government Levels Affected:** None  
**Agency Contact:** Jerry Moore  
**Phone:** 301 496–4606  
**Fax:** 301 402–0169  
**Email:** jm40z@nih.gov  
**RIN:** 0925–AA41

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

**Office of Public Health and Science (OPHS)**

### Prerule Stage

#### 1107. 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.

**Timetable:**

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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,**  
**Suite 200, The Tower Building,**  
**1101 Wootten Parkway,**  
**Rockville, MD 20852**  
**Phone:** 240 453–6900  
**Fax:** 301 402–2071  
**RIN:** 0940–AA11

### Final Rule Stage

#### 1108. 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 section 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.

**Timetable:**

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**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, Suite 750, 1101 Wooten Parkway, Rockville, MD 20852  
**Phone:** 240 453–8200
1109. 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 system. 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.

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, Suite 200, The Tower Building, 1101 Wooten Parkway, Rockville, MD 20852
Phone: 240 453–6900
Fax: 301 402–2071
RIN: 0940–AA06

1110. FEDERAL POLICY FOR THE PROTECTION OF HUMAN SUBJECTS TECHNICAL AMENDMENT

Priority: Substantive, Nonsignificant
Legal Authority: 5 USC 301; 42 USC 289; 42 USC 300v–1(b)
CFR Citation: 45 CFR 46
Legal Deadline: None

Abstract: This final rule amends the Department of Health and Human Services (HHS) regulations for the protection of human subjects by changing all references to the Office for Protection from Research Risks (OPRR) to the Office for Human Research Protections (OHRP) and revising the footnote at the end of 45 CFR 46.101(i) by deleting the references to research involving fetuses, pregnant women, or human in vitro fertilization and subpart B of 45 CFR part 46. This technical amendment is being made in conjunction with the other federal departments and agencies that have promulgated the Federal Policy for the Protection of Human Subjects.

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Michael A. Carome, MD, Department of Health and Human Services, Office of Public Health and Science, Suite 200, The Tower Building, 1101 Wooten Parkway, Rockville, MD 20852
Phone: 240 453–6900
Fax: 301 402–2071
RIN: 0940–AA10
### HHS—OPHS

#### Long-Term Actions

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

**Agency Contact:** Michael A. Carome  
MD, Department of Health and Human Services, Office of Public Health and Science, Suite 200, The Tower  
Building, 1101 Wootton Parkway, Rockville, MD 20852  
Phone: 240 453–6900  
Fax: 301 402–2071  
RIN: 0940–AA08

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**Completed Actions**

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

**Office of Public Health and Science (OPHS)**

1112. PUBLIC HEALTH SERVICE POLICIES ON RESEARCH MISCONDUCT

- **Priority:** Other Significant
- **CFR Citation:** 42 CFR 93

**Completed:**

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**Regulatory Flexibility Analysis**
- **Required:** No
- **Small Entities Affected:** No

**Government Levels Affected:** None

**Agency Contact:** Chris Pascal  
Phone: 240 453–8200  
Fax: 301 443–5351  
Related RIN: Related to 0940–AA01  
RIN: 0940–AA04

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**Prerule Stage**

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

**Centers for Medicare & Medicaid Services (CMS)**

1113. INNOVATIONS IN FEE–FOR–SERVICE PAYMENT SYSTEMS TO IMPROVE QUALITY AND OUTCOMES (CMS–1298–ANPR)

- **Regulatory Plan:** This entry is Seq. No. 50 in part II of this issue of the *Federal Register.*
- **RIN:** 0938–AN91

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**Proposed Rule Stage**

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

**Centers for Medicare & Medicaid Services (CMS)**

1114. 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 the Administration’s 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:** No
- **Small Entities Affected:** Businesses, Organizations
- **Government Levels Affected:** None

**Agency Contact:** Scott Cooper, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Clinical Standards Group, Mailstop S3–05–14, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786–9465  
Email: scott.cooper@cms.hhs.gov  
Mercedes Benitez–McCray, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Clinical Standards Group, Mailstop S3–05–14, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786–5716  
Email: mercedes.benitezmccra@cms.hhs.gov  
RIN: 0938–AG81

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1115. STANDARD UNIQUE NATIONAL HEALTH PLAN IDENTIFIER (CMS–6017–P)

- **Priority:** Other Significant. Major under 5 USC 801.
- **Unfunded Mandates:** This action may affect State, local or tribal governments.
- **Legal Authority:** 42 USC 1320d to 1320d–8
would incorporate provisions from section 936 of the Medicare Modernization Act.

**Timetable:**

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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, 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: 410 786–7448

Email: michael.collett@cms.hhs.gov

RIN: 0938–AH87

### 1117. 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 1395h

**CFR Citation:** 42 CFR 405.874

**Legal Deadline:** None

**Abstract:** This proposed rule would 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.

**Timetable:**

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**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** Businesses

**Government Levels Affected:** State

**Agency Contact:** Carla McGregor, Health Insurance Specialist, Survey and
1119. REVISIONS TO CONDITIONS FOR COVERAGE FOR AMBULATORY SURGICAL CENTERS (CMS–3887–P)

Priority: Other Significant. Major under 5 USC 801.

Unfunded Mandates: Undetermined

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: 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–AL26

1120. MODIFICATIONS TO ELECTRONIC TRANSACTIONS AND CODE SETS (CMS–0009–P)

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

Legal Authority: Sec 1171 to 1179 of the Social Security Act

CFR Citation: 42 CFR 162.1002; 42 CFR 162.1802

Legal Deadline: None

Abstract: This proposed rule would revise some of the electronic transactions and code set standards mandated by the Health Insurance Portability and Accountability Act of 1996.

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Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses, Governmental Jurisdictions, Organizations

Government Levels Affected: Federal, Local, State, Tribal

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

Agency Contact: Gladys C. Wheeler, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of E–Health Standards and Services, Mail Stop S2–24–18, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786–0273

Email: gladys.wheeler@cms.hhs.gov

RIN: 0938–AM50

1121. REQUIREMENTS FOR LONG–TERM CARE FACILITIES: HOSPICE SERVICES (CMS–3140–P)

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

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Regulatory Flexibility Analysis Required: Yes

1122. COMPETITIVE ACQUISITION FOR CERTAIN DURABLE MEDICAL EQUIPMENT (DME), PROSTHETICS, ORTHOTICS, AND SUPPLIES AND RESIDUAL ISSUES (CMS–1270–P)

Priority: Economically Significant. Major under 5 USC 801.

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.

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Regulatory Flexibility Analysis Required: Yes
Small Entities Affected: Businesses, Governmental Jurisdictions, Organizations

Government Levels Affected: Federal, Local, State, Tribal

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

Energy Effects: Statement of Energy Effects planned as required by Executive Order 13211.

Agency Contact: Gladys Wheeler, Health Insurance Specialist, Office of E–Health Standards and Services, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop S2–26–17, 7500 Security Boulevard, Baltimore, MD 21244–1850
Phone: 410 786–0273
Email: gladys.wheeler@cms.hhs.gov

RIN: 0938–AN25

1124. PAYMENT FOR CLINICAL LABORATORY TESTS (CMS–1494–P)

Priority: Substantive, Nonsignificant
Legal Authority: Sec 1833(h)(2) of the MMA; Sec 416 of the MMA; PL 108–173
CFR Citation: Not Yet Determined

Abstract: The Medicare Modernization Act of 2003 (MMA), requires codification of the payment basis for determining Medicare payments for new clinical laboratory tests under the clinical laboratory fee schedule. Also, section 416 of the MMA eliminates the application of the clinical laboratory fee schedule for hospital outpatient laboratory testing by a hospital with fewer than 50 beds in a qualified rural area for cost reporting periods beginning during the two-year period beginning on July 1, 2004. Section 1833(h) of the Social Security Act mandates payment for outpatient clinical laboratory tests under a clinical laboratory fee schedule.

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

Agency Contact: Anita Greenberg, Health Insurance Specialist, Center for Medicare Management, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop C4–07–07, 7500 Security Boulevard, Baltimore, MD 21244 Phone: 410 786–4601 Email: anita.greenberg@cms.hhs.gov

RIN: 0938–AN26

1125. TERMINATION OF NON–RANDOM PREPAYMENT MEDICAL REVIEW (CMS–6022–F)

Priority: Other Significant
Legal Authority: Sec 934 of the MMA
CFR Citation: Not Yet Determined

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, 2004. This rule provides guidelines for terminating a provider of services or supplier from non-random payment review.

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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, Mailstop S3–02–01, 7500 Security Boulevard, Baltimore, MD 21244 Phone: 410 786–7861 Email: marie.casey2@cms.hhs.gov

RIN: 0938–AN42

1126. LIMITATION ON RECOUPMENT OF OVERPAYMENTS (CMS–6025–P)

Priority: Other Significant. Major under 5 USC 801 is undetermined.
Legal Authority: Section 935 of the MMA
CFR Citation: None

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 prohibit recoupment where a provider or supplier has appealed an overpayment determination until the reconsideration-level appeal is decided.

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Regulatory Flexibility Analysis Required: No
1128. PHYSICIANS’ REFERRALS TO HEALTH CARE ENTITIES WITH WHICH THEY HAVE FINANCIAL RELATIONSHIPS; EXCEPTIONS FOR CERTAIN ELECTRONIC PRESCRIBING AND ELECTRONIC HEALTH RECORDS ARRANGEMENTS (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).

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Regulatory Flexibility Analysis Required: No

Small Entities Affected: No
Government Levels Affected: None

Agency Contact: Linda Howard, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C5–13–08, 7500 Security Boulevard, Baltimore, MD 21244–1850
Phone: 410 786–5255
Email: linda.howard@cms.hhs.gov

RIN: 0938–AN69

1129. NATIONAL PLAN AND PROVIDER ENUMERATION SYSTEM (NPPES) DATA DISSEMINATION (CMS–6060–PN)

Priority: Other Significant. Major status under 5 USC 801 is undetermined.
Legal Authority: HIPAA of 1996, secs 1171 to 1179 of the Social Security Act (42 USC 1320d 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 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 would describe the data dissemination strategy, processes, and any applicable charges for data.

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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

1130. CHANGES TO THE DISCLOSURE OF INFORMATION REQUIREMENTS FOR QUALITY IMPROVEMENT ORGANIZATIONS (CMS–3156–P)

Priority: Other Significant. Major status under 5 USC 801 is undetermined.
Legal Authority: sec 1154 to 1160 of the Social Security Act
CFR Citation: Not Yet Determined
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.

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

Agency Contact: Maria L. Hammel, 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: 410 786–1775
Email: maria.hammel@cms.hhs.gov

RIN: 0938–AN73
1131. 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

CFR Citation: 42 CFR 484

Legal Deadline: Final, None, January 1, 2007, effective date.

Abstract: The proposed rule would set 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.

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Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Randy Thronset, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C5–07–28, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786–0131
Email: rthronset@cms.hhs.gov

RIN: 0938–AN76

1132. 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: On July 16, 2004, GAO published a report on Federal fire safety standards and procedures in nursing facilities. The GAO Report recommended that CMS explore requiring sprinkler systems in all nursing facilities. This proposed rule would implement this regulation. We propose to require sprinkler systems in all long-term care facilities and solicit public comment regarding an appropriate and feasible phase-in period for this regulation.

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Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses, Governmental Jurisdictions

Government Levels Affected: Local

Federalism: Undetermined

Agency Contact: Paul Olenick, 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: 410 786–4533
Email: paul.olenick@cms.hhs.gov

RIN: 0938–AO06

Janet Samen, Chronic Care Management and the Chronic Care Policy Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop C5–05–07, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–9161
Email: janet.samen@cms.hhs.gov

RIN: 0938–AN82

1133. INPATIENT PSYCHIATRIC FACILITY PROSPECTIVE PAYMENT SYSTEM—UPDATE FOR 2006 (CMS–1306–P)

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

Legal Authority: PL 106–113, sec 124 BBRA

CFR Citation: 42 CFR 412.400, subpart N

Legal Deadline: None

Abstract: This rule would update the Inpatient Psychiatric Facility Prospective Payment System for 2006. This rule would update and revise the market basket and the use of new market area definitions.

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Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Judith Richter, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–2590
Email: jrichter@cms.hhs.gov

RIN: 0938–AN79

1134. PROSPECTIVE PAYMENT SYSTEM FOR LONG-TERM CARE HOSPITALS FY 2007: ANNUAL PAYMENT RATE UPDATES (CMS–1485–P)

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

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

CFR Citation: 42 CFR 412

Legal Deadline: Final, Statutory, May 1, 2005, To be effective July 1, 2005.

Abstract: This rule proposes the payment rate update for the 2007 prospective payment system for Medicare long-term care hospitals. The new rates will be based on cost reports from the first LTC PPS rate year. (The proposed and final rules must be published by 5/1/06 to be effective 7/1/06.)

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Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Judith Richter, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–2590
Email: jrichter@cms.hhs.gov

RIN: 0938–AN82

1135. 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
### 1136.● CHANGES TO THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM AND CALENDAR YEAR 2007 PAYMENT RATES (CMS–1506–P)

**Priority:** Substantive, Nonsignificant

**Legal Authority:** BBA; BBRA; BIPA; MMA

**CFR Citation:** 42 CFR 419 and 485

**Legal Deadline:** Final, None, 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 ongoing experience with this system and to implement certain related provisions of the Medicare 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.

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### Regulatory Flexibility Analysis

**Required:** Yes

**Small Entities Affected:** Businesses

**Government Levels Affected:** Federal

**Federalism:** Undetermined

**Agency Contact:** Joan H. Sanow, Deputy Director, Division of Outpatient Care, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare Management, Mailstop C4–03–18, 7500 Security Boulevard, Baltimore, MD 21244–1850

Phone: 410 786–9739
Fax: 410 786–4940
Email: joan.sanow@cms.hhs.gov

RIN: 0938–AO13

### 1137.● CHANGES TO THE HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEMS AND FY 2007 RATES (CMS–1488–P)

**Regulatory Plan:** This entry is Seq. No. 52 in part II of this issue of the Federal Register.

**RIN:** 0938–AO11

#### Timetable:

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### Regulatory Flexibility Analysis

**Required:** Undetermined

**Small Entities Affected:** None

**Government Levels Affected:** Federal

**Agency Contact:** Anne Elizabeth Tayloe, Health Insurance Specialist, Department of Health and Human Services, Mailstop C4–06–28, 7500 Security Boulevard, Baltimore, MD 21244–1850

Phone: 410 786–4546
Email: anne.tayloe@cms.hhs.gov

RIN: 0938–AO11

### 1138.● REVISED PAYMENT SYSTEM FOR SERVICES FURNISHED IN AMBULATORY SURGICAL CENTERS (ASCs) EFFECTIVE JANUARY 1, 2008 (CMS–1517–P)

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

**Unfunded Mandates:** Undetermined

**Legal Authority:** 42 CFR 416, Social Security Act 1832(2)(F) and 1833(i), as amended by section 626 of the Medicare Modernization Act

**CFR Citation:** 42 FR 416

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

**Abstract:** This rule, proposes to revise the method by which Medicare sets payment rates for ASC facility services, and will propose new payment rates for ASC services in accordance with that methodology. (Effective January 1, 2008).

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### Regulatory Flexibility Analysis

**Required:** Yes

**Small Entities Affected:** Businesses

**Government Levels Affected:** Federal

**Agency Contact:** Ellen W. Blackwell, Disability & Elderly Health Programs Group, Department of Health and Human Services, Mailstop C4–03–26, 7500 Security Boulevard, Baltimore, MD 21244–1850

Phone: 410 786–4498
Fax: 410 786–3262
Email: ellen.blackwell@cms.hhs.gov

RIN: 0938–AO07

### 1139.● REVISIONS TO PAYMENT OF AMBULANCE SERVICES UNDER MEDICARE (CMS–1317–P)

**Priority:** Substantive, Nonsignificant

**Legal Authority:** Section 1834(1) of the Social Security Act (the Act).

**CFR Citation:** 42 CFR 414.605; 42 CFR 412.64; 42 CFR 410.40

**Legal Deadline:** None

**Abstract:** This rule would increase States’ accountability for Federal Financial participation (FFP) provided for certain services furnished without charge to (but not limited to) the following groups: children residing in various foster care settings; juvenile offenders residing in detention, correctional, or shelter facilities; and others. The rule would clarify circumstances under which Federal financial participation (FFP) will or will not be made available to States on behalf of Medicaid beneficiaries in instances where the services are provided free of charge to all users in the community. The regulation would specify the criteria for determining when a service is free.

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### Regulatory Flexibility Analysis

**Required:** Undetermined

**Small Entities Affected:** Governmental Jurisdictions

**Agency Contact:** Anne Elizabeth Tayloe, Health Insurance Specialist, Department of Health and Human Services, Mailstop C4–06–28, 7500 Security Boulevard, Baltimore, MD 21244–1850

Phone: 410 786–4546
Email: anne.tayloe@cms.hhs.gov

RIN: 0938–AO11

### CFR Citation

42 CFR 419 and 416, Social Security Act 1832(2)(F) and 1833(i), as amended by section 626 of the Medicare Modernization Act

**Legal Authority:** BBA; BBRA; BIPA; MMA

**CFR Citation:** 42 CFR 419 and 485

**Legal Deadline:** Final, None, November 1, 2006.
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.kane@cms.hhs.gov
RIN: 0938–AO15

### 1140. ● 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 106–534; PL 106–113

**CFR Citation:** 42 CFR 412

**Legal Deadline:** Final, None, August 1, 2006.

**Abstract:** This proposed rule would update rates for the prospective payment system for inpatient rehabilitation facilities for FY 2007. (Effective October 1, 2006).

**Timetable:**

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**Regulatory Flexibility Analysis Required:** Undetermined

**Small Entities Affected:** Businesses

**Government Levels Affected:** None

**Federalism:** Undetermined

**Agency Contact:** Jeremy Silanski, Health Insurance Specialist, Center for Medicaid Services, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Division Group of State Operations, 7500 Security Boulevard, Baltimore, MD 21244–1850
Phone: 410 786–1592
Fax: 410 786–8533
Email: jeremy.silanski@cms.hhs.gov
RIN: 0938–AO17

### 1141. ● 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 Medicare 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.

**Timetable:**

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<tr>
<td>NPRM</td>
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**Regulatory Flexibility Analysis Required:** Undetermined

**Small Entities Affected:** Businesses

**Government Levels Affected:** None

**Federalism:** Undetermined

**Agency Contact:** Robert Kuhl, Division Director of Center for Medicaid and Medicare, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop C5–06–24, 7500 Security Boulevard, Baltimore, MD 21244–1850
Phone: 410 786–4597
Email: bkuhl@cms.hhs.gov
RIN: 0938–AO16

### 1142. ● 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:** Other, Statutory, April 2006

**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 physician fee schedule rule required to be published by 11/01/06.

**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, 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
RIN: 0938–AO22

### 1143. ● 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

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

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

**Abstract:** This rule would make several changes affecting Medicare Part B payment. (The statute requires the final rule be published by 11/01/06.)

**Timetable:**

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Medicaid Services, Mailstop C4–03–06, 7500 Security Boulevard, Baltimore, MD 21244–1850
Phone: 410 786–3355
Email: diane.milstead@cms.hhs.gov
RIN: 0938–AO24

1144. 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 401.607, 42 CFR 401.601

Abstract: This rule would implement a provision of section 935 of the MMA and adds a new subsection to section 1893 (42 U.S.C. 1395ddd) of the Social Security Act. The provision, “Use of Repayment Plans,” requires CMS to enter into a repayment plan with a provider or supplier when repaying a Medicare overpayment would be a hardship for the provider or supplier absent specific exceptions. The rule would establish criteria and procedures to apply this requirement to include the concepts of extreme hardship and the discretionary right to accelerate upon default.

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Regulatory Flexibility Analysis
Required: No
Small Entities Affected: No

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–AO27

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

1145. REQUIREMENTS FOR ESTABLISHING AND MAINTAINING MEDICARE BILLING PRIVILEGES (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 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.

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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
Email: mary.collins@cms.hhs.gov
RIN: 0938–AH73

1146. 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.

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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
1147. MEDICARE HOSPICE CARE AMENDMENTS (CMS–1022–F)

Priority: Substantive, Nonsignificant

Legal Authority: PL 105–33, sec 1961(dd); PL 105–33, sec 1814(i); PL 105–33, sec 4441 to 4444; PL 105–33, sec 4448; PL 106–113, sec 131; PL 106–554, sec 321; PL 106–554, sec 322; PL 105–33, sec 4449

CFR Citation: 42 CFR 414

Legal Deadline: Final, Statutory, November 22, 2005, MMA 902.

Abstract: This final rule revises certain regulations governing coverage and payments for hospice care under the Medicare program as required by the Balanced Budget Act of 1997.

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Regulatory Flexibility Analysis

Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Linda Smith, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Chronic Care Policy Group, Mailstop C5–02–24, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786–5650

Related RIN: Previously reported as 0938–AH73

RIN: 0938–AJ36

1148. USE OF RESTRAINT 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; 42 CFR 483

Legal Deadline: None

Abstract: This 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.

1149. ORGAN PROCUREMENT ORGANIZATION CONDITIONS FOR COVERAGE (CMS–3064–IFR)

(SECTION 610 REVIEW)

Regulatory Plan: This entry is Seq. No. 53 in part II of this issue of the Federal Register.

RIN: 0938–AK81

1150. PAYMENT FOR RESPIRATORY ASSIST DEVICES WITH BI–LEVEL CAPABILITY AND A BACK–UP RATE (CMS–1167–F)

Priority: Other Significant

Legal Authority: 42 USC 1395(m)(3)

CFR Citation: 42 CFR 414.222(a)(1)

Legal Deadline: Final, Statutory, August 22, 2006, MMA, section 902.

Abstract: This final rule clarifies that respiratory assist devices with bi-level capability and a back-up rate must be classified as capped rental durable medical equipment (DME) in accordance with section 1834(a)(3) of the Social Security Act (42 U.S.C. 1395(m)(3)).

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Regulatory Flexibility Analysis

Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Joel Kaiser, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare Management, Chronic Care Policy Group, Mailstop C5–07–26, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786–4499

Email: joel.kaiser@cms.hhs.gov

Related RIN: Related to 0938–AL27

RIN: 0938–AN02

1151. ENHANCED DSH TREATMENT FOR CERTAIN HOSPITALS (CMS–2198–F)

Priority: Other Significant

Legal Authority: Section 1923(i) of the Social Security Act

CFR Citation: Not Yet Determined

Legal Deadline: None

Abstract: This rule implements section 1001(d) of the Medicare Modernization Act which requires States to report additional information about their disproportionate share hospital (DSH) programs to their annual report. This section also requires States to independently audit and submit these certified audits annually to the Secretary (effective December 8, 2003).

Timetable:

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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

1152. UPDATE OF THE LIST OF COVERED PROCEDURES FOR AMBULATORY SURGICAL CENTERS FOR 2005 (CMS–1478–IFC)
Priority: Other Significant
Legal Authority: Not Yet Determined
CFR Citation: None
Legal Deadline: Final, Statutory, July 1, 2005.
Abstract: This final rule updates the list of Medicare-covered ASC procedures.

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<td>69 FR 69178</td>
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<td>05/04/05</td>
<td>70 FR 23690</td>
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Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: None

Agency Contact: Dana Burley, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare Management, Hospital and Ambulatory Policy Group, Mailstop C4–05–17, 7500 Security Boulevard, Baltimore, MD 21244.
Phone: 410 786–4547
Email: dana.burley@cms.hhs.gov

RIN: 0938–AN23

1154. HOME HEALTH PROSPECTIVE PAYMENT SYSTEM RATE UPDATE FOR CALENDAR YEAR 2006 (CMS–1301–F)
Priority: Economically Significant. Major under 5 USC 801.
Legal Authority: Sec 1895 of the Social Security Act
CFR Citation: 42 CFR 484
Legal Deadline: Final, Statutory, November 1, 2005.
Abstract: This final rule updates the 60-day national episode rates and the national per-visit amounts under the Medicare prospective payment system for home health agencies.

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Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Federal

Agency Contact: Jeremy Silanskis, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Centers for Medicaid Services Office, Mail Stop S3–13–15, 7500 Security Boulevard, Baltimore, MD 21244–1850.
Phone: 410 786–1592
Fax: 410 786–8533
Email: jeremy.silanskis@cms.hhs.gov

RIN: 0938–AN27

1156. ALL PROVIDER BAD DEBT PAYMENT (CMS–1126–F)
Priority: Other Significant
Legal Authority: SSA, sec 1834
CFR Citation: 42 CFR 412; 42 CFR 413; 42 CFR 1902
Abstract: This final rule will achieve a consistent bad debt reimbursement policy for all providers currently eligible to receive payments from Medicare for bad debt. It implements a court settlement agreement and removes the cap on End Stage Renal Disease (ESRD) bad debt reimbursement, which limits payment of allowable bad debts to the facility’s unrecovered costs.

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Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: Federal

Agency Contact: Katie Walker, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center of Medicare Management, Mailstop C6–03–03, 7500 Security Boulevard, Baltimore, MD 21244.
Phone: 410 786–7278
Email: katie.walker@cms.hhs.gov
Related RIN: Related to 0938–AK02
RIN: 0938–AN75

1157. PAYMENT ERROR RATE MEASUREMENT (PERM) PROGRAM (CMS–6026–F)
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 rule requires States to estimate improper payments in the Medicare program and the State Children’s Health Insurance Program. The State level estimates will be used to produce estimates of improper payments for both Medicaid and SCHIP at the national level. These national level estimates will enable us to comply with the Improper Payments Information Act of 2002. The intended effect of this regulation is for States to produce estimates of improper payments for their Medicaid and SCHIP programs and identify existing and emerging vulnerabilities that can be effectively targeted for corrective actions by the States.

Timetable:

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<td>10/05/05</td>
<td>70 FR 58260</td>
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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, Mail stop 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

1158. REVISIONS TO PAYMENT POLICIES UNDER THE PHYSICIAN FEE SCHEDULE FOR CALENDAR YEAR 2006 (CMS–1502–FC)

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

RIN: 0938–AN84

1159. FEE SCHEDULE FOR PAYMENT OF AMBULANCE SERVICES — UPDATE FOR CY 2006 (CMS–1294–N)

Priority: Economically Significant. Major under 5 USC 801.

Unfunded Mandates: Undetermined

Legal Authority: Sec 1834(1) of the Social Security Act

CFR Citation: 42 CFR 410

Legal Deadline: None

Abstract: This notice updates the fee schedule for ambulance services under the Medicare program, implementing section 1834(1) of the Social Security Act. (effective January 1, 2006)

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Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Anne Tayloe, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicaid and State Operations, Mailstop C4–07–07, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786–4546

Email: anne.tayloe@cms.hhs.gov

RIN: 0938–AN99

1160. STATE ALLOTMENTS FOR PAYMENT OF MEDICARE PART B PREMIUMS FOR QUALIFYING INDIVIDUALS (CMS–2210–F)

Priority: Other Significant

Legal Authority: Section 4732 of the Balanced Budget Act of 1997 (PL 105–33)

CFR Citation: Not Yet Determined

Legal Deadline: None

Abstract: Section 4732 of the Balanced Budget Act amended the Social Security Act to provide for certain low income Medicare Beneficiaries (also known as Qualified Individuals, or QIs) for whom Medicaid payment can be made for Medicare Part B premiums. Section 1933(c) of the Act limits the total amount of Federal funds available for payment of Part B premiums each fiscal year and specifies the formula to be used to determine an allotment for each State from this total amount. States must limit the number of QIs so that the amount of assistance provided during the fiscal year is approximately equal to the allotment for that year. For FY 2005 some States have experienced a deficit in their allotments which has necessitated denial of benefits to applicants after a certain date, while other States project that they will not utilize their full allotments. To fully utilize the authorized funding and to prevent denial of benefits to eligible applicants, the FY 2005 funds will be reallocated based on current data available from States. This interim final rule with comment period announces the reallocation of funds available to States for FY 2005 and describes the methodology used to determine each State’s allotment.

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<td>70 FR 50214</td>
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<td>Comment Period End</td>
<td>10/25/05</td>
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Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: State

Agency Contact: Richard Strauss, Technical Director Finance Systems & Budget Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare State Operations, Mailstop S3–13–15, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786–2019

Email: richard.strauss@cms.hhs.gov

RIN: 0938–AL004

1161. 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

Legal Authority: Not Yet Determined

CFR Citation: None

Legal Deadline: None

Abstract: This notice identifies the 20 messaging and vocabulary standards adopted for use by the Federal government health information technology systems. The first set of 5 standards were adopted on 3/21/03, and the second set of 15 standards were adopted on 5/6/04, which completed the initial portfolio of the Consolidated Health Informatics initiative.

Timetable:

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### 1162. 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

**Legal Authority:** 42 USC.1395hh; 42 USC 1302

**CFR Citation:** 42 CFR 403

**Abstract:** On January 10, 2003, CMS issued a final rule amending the fire safety standards for religious non-medical 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. This final rule adopted, with certain exceptions, the 2000 edition of the Life Safety Code (LSC) published by the National Fire Protection Assoc. (NFPA). On August 11, 2004, the final Inpatient PPS rule was published. The LSC provisions in the August rule were meant to clarify the effective date of the roller latch prohibition. The clarifying regulatory language was accidentally deleted. These requirements will be restored by this regulation.

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**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** Federal

**Agency Contact:** Alicia Bradford, Office of HIPAA Standards, Director, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mailstop C5–25–04, Baltimore, MD 21244–1850

Phone: 410 786–4160

Email: clare.mcfarland@cms.hhs.gov

RIN: 0938–AO05

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### 1163. 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. Major under 5 USC 801.

**Legal Authority:** 42 USC 1395i–2(d)(2); Social Security Act, Section 1818(d)(2); Social Security Act, section 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.

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**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** None

**Agency Contact:** Clare McFarland, Division Director, Medicare and Medicaid Cost Estimates Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of Actuary, Mailstop N3–26–00, 7500 Security Boulevard, Baltimore, MD 21244–1850

Phone: 410 786–6390

Email: clare.mcfarland@cms.hhs.gov

RIN: 0938–AO14

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### 1164. INPATIENT HOSPITAL DEDUCTIBLE AND HOSPITAL AND EXTENDED CARE SERVICES COINSURANCE AMOUNTS FOR CALENDAR YEAR 2007 (CMS–8029–N)

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

**Legal Authority:** 42 USC 1395e–2(b)(2); Social Security Act, section 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:** No

**Government Levels Affected:** None

**Agency Contact:** Clare McFarland, Division Director, Medicare and Medicaid Cost Estimates Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of Actuary, Mailstop N3–26–00, 7500 Security Boulevard, Baltimore, MD 21244–1850

Phone: 410 786–6390

Email: clare.mcfarland@cms.hhs.gov

RIN: 0938–AO19

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### 1165. 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 allotments of Federal funding available to each State, the District of Columbia, and each U.S. Territory and Commonwealth for fiscal year 2007.

**Timetable:**

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**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** None

**Agency Contact:** Clare McFarland, Division 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 21244–1850

Phone: 410 786–6390

Email: clare.mcfarland@cms.hhs.gov

RIN: 0938–AO18
1166. • 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, section 1839; MMA, section 629; MMA, section 811
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.
Timetable:

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

1167. • 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 30, 2005, Notice must be published before August 1, 2006.
Abstract: This notice updates the payment rates used under the SNF PPS beginning 10/1/06.
Timetable:

Agency Contact: Richard Strauss, Technical Director, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of Actuary, Mailstop N3–26–00, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–7737
Email: richard.strauss@cms.hhs.gov
RIN: 0938–AO21

1168. • HOSPICE WAGE INDEX FOR FY 2007 (CMS–1535–N)

Priority: Other Significant
Legal Authority: 1824 (i)(2)(D) of the Act; 1814 (i)(1)(A); 1814 (i)(C)(ii)
CFR Citation: 42 CFR 418.306 (c)
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:

Agency Contact: Terri Deutsch, Health Insurance Specialist, Division of Community Post Acute Care, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Hospital and Ambulatory Policy Group, Mailstop C5–08–18, 7500 Security Boulevard, Baltimore, MD 21244–1850
Phone: 410 786–9462
Email: terri.deutsch@cms.hhs.gov
RIN: 0938–AO26

Abstract: This final rule revises the requirements that end stage renal disease (ESRD) facilities must meet to be certified under the Medicare program.
### 1170. Hospital Conditions of Participation: Requirements for Approval and Re-Approval of Transplant Centers to Perform Organ Transplants (CMS–3835–F)

- **Priority:** Other Significant
- **Legal Authority:** 42 USC 1302; 42 USC 1395hh
- **CFR Citation:** 42 USC 405; 42 USC 482; 42 USC 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

### 1171. Hospice Care—Conditions of Participation (CMS–3844–F) (Section 610 Review)

- **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 would revise existing conditions of participation that hospices must meet to participate in the Medicare and Medicaid programs. The proposed 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, allow hospices greater flexibility in meeting quality standards, and eliminate unnecessary procedural requirements.

**Timetable:**

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**Regulatory Flexibility Analysis**
- **Required:** Undetermined

**Small Entities Affected:** Businesses, Organizations

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

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

**Agency Contact:** 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

### 1172. Medicare Outcome and Assessment Information Set (OASIS) Data Reporting Requirements (CMS–3006–F)

- **Priority:** Other Significant
- **Legal Authority:** 42 USC 1302; 42 USC 1395(hh)
- **CFR Citation:** 42 CFR 484.11; 42 CFR 484.20; 42 CFR 488.68


**Abstract:** This final rule requires home health agencies to electronically report OASIS data as a condition of participation in the Medicare program.

**Timetable:**

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**Regulatory Flexibility Analysis**
- **Required:** Undetermined

**Small Entities Affected:** Businesses

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

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

**Agency Contact:** 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–AJ10

### 1173. Standards for Electronic Health Care Claim Attachments (CMS–0050–P)

- **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 claims
1174. 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  
**Legal Deadline:** Final, Statutory, March 26, 2007, MMA sec. 902.  

**Abstract:** This final rule redefines, clarifies, and updates the guidelines and procedures for Provider Reimbursement Review Board appeals, based on recent court decisions.

**Timetable:**

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**Agency Contact:**  
Lorraine Doo, Health Insurance Specialist, Office of E–Health Standards and Services, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop S–25–17, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786–6597  
Email: lorraine.doo@cms.hhs.gov  
RIN: 0938–AK62

1175. PROVIDER REIMBURSEMENT DETERMINATIONS AND APPEALS (CMS–1727–F)

**Priority:** Substantive, Nonsignificant  
**Legal Authority:** Sec 1878 of the Social Security Act  
**CFR Citation:** 42 CFR 405  
**Legal Deadline:** Final, Statutory, June 25, 2007, MMA sec. 902.  

**Abstract:** This final rule redefines, clarifies, and updates the guidelines and procedures for Provider Reimbursement Review Board appeals, based on recent court decisions.

**Timetable:**

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**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

1176. HEALTH COVERAGE PORTABILITY: TOLLING CERTAIN TIME PERIODS AND INTERACTIONS WITH FAMILY AND MEDICAL LEAVE ACT (CMS–2158–F)

**Priority:** Other Significant  
**Legal Authority:** 24 USC 1999  
**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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**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: david.mlawsky@cms.hhs.gov  
RIN: 0938–AL88

1177. ELECTRONIC MEDICARE CLAIMS SUBMISSION (CMS–0008–F)

**Priority:** Other Significant  
**Legal Authority:** PL 107–105  
**CFR Citation:** Not Yet Determined  
**Legal Deadline:** Final, Statutory, December 8, 2006, MMA sec. 902.
**Abstract:** This final rule implements the requirements for electronic submission of Medicare claims, submitted on or after October 16, 2003. In addition, this rule also implements the conditions upon which a waiver could be granted for these requirements.

**Timetable:**

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**Regulatory Flexibility Analysis**

**Required:** Yes

**Government Levels Affected:** Federal

**Agency Contact:** Stewart Streimer, Director, Provider Billing Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C4–10–07, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786–9318

Email: stewart.streimer@cms.hhs.gov

**RIN:** 0938–AM22

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**1179. REVISIONS TO THE APPEALS PROCESS FOR INITIAL CLAIM DETERMINATIONS (CMS–4064–F)**

**Priority:** Economically Significant

**Legal Authority:** Sec 521 of BIPA

**CFR Citation:** 42 CFR 401 and 405

**Legal Deadline:** Final, Statutory, June 30, 2008, MMA sec. 902.

**Abstract:** This final rule will revise the Medicare appeals process by adding five levels of review. It will remove the distinction between the processing of initial determinations and appeals under part A and part B required by section 521 of Benefits Improvement and Protection Act of 2000 (BIPA).

**Regulatory Flexibility Analysis**

**Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** Federal

**Agency Contact:** Karen Daily, Health Insurance Specialist Coverage & Analysis Group, Department of Health and Human Services, Centers for Medicare and Medicaid Services, Mailstop C1–09–06, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786–0189

Email: karen.daily@cms.hhs.gov

**RIN:** 0938–AM74

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**1180. CONDITIONS FOR COVERAGE OF POWER MOBILITY DEVICES, INCLUDING POWERED WHEELCHAIRS AND POWER–OPERATED VEHICLES SCOOTER (CMS–3017–F)**

**Priority:** Economically Significant

**Legal Authority:** Sec 1102 of the Social Security Act; Sec 1871 of the Social Security Act; 42 USC 1302; 42 USC 1359 hh

**CFR Citation:** 42 CFR 410.38

**Legal Deadline:** Final, Statutory, August 26, 2008, MMA sec. 902.

**Abstract:** This rule will make the requirements to purchase power operated vehicles, functioning as wheelchairs, less stringent. It expands who can order a Powered Operated Vehicle. It also requires a face-to-face examination of the beneficiary before ordering a device.

**Regulatory Flexibility Analysis**

**Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** None

**Agency Contact:** Karen Daily, Health Insurance Specialist Coverage & Analysis Group, Department of Health and Human Services, Centers for Medicare and Medicaid Services, Mailstop C1–09–06, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786–0189

Email: karen.daily@cms.hhs.gov

**RIN:** 0938–AM74

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**1181. 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 1395dd; 42 USC 1395bb

**CFR Citation:** 42 CFR 482

**Legal Deadline:** Final, Statutory, March 25, 2008, MMA sec. 902.
1182. 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 402

**Legal Deadline:** Final, Statutory, August 23, 2007, MMA sec. 902.

**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.

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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–AN10

1184. NONDISCRIMINATION IN HEALTH COVERAGE AND WELLNESS PLANS 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

**Legal Deadline:** Final, Statutory, December 8, 2006, MMA sec. 902.

**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 (CMS-2078-P).

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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: dmlawsky@cms.hhs.gov

**RIN:** 0938–AN29
1185. 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.

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Regulatory Flexibility Analysis

Required: No

Small Entities Affected: No

Government Levels Affected: Local, State

Agency Contact: David Mlawsky, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of Clinical Standards and Quality, Mailstop S3–05–27, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786–6851

Email: david.mlawsky@cms.hhs.gov

RIN: 0938–AN35

1186. HOSPITAL CONDITIONS OF PARTICIPATION: FEDERAL ENFORCEMENT IN GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS (CMS–4091–F)

Priority: Other Significant

Legal Authority: 42 USC 300gg–22; 42 USC 300gg–31

CFR Citation: 45 CFR 150.101 to 150.465

Legal Deadline: None

Abstract: This rule finalizes, without any substantive changes, an interim final regulation (HCFA–2019–IFC) that sets forth the process by which CMS enforces the HIPAA title I requirements with regard to State and local governmental group health plans. It also finalizes the process by which CMS assumes direct enforcement responsibility in a State with regard to group and individual market health insurance issues.

Timetable:

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Regulatory Flexibility Analysis

Required: No

Small Entities Affected: No

Government Levels Affected: None

Additional Information: Providers requesting publication of this regulation.

Agency Contact: Danielle Shearer, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of Clinical Standards and Quality, Mailstop S3–02–01, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786–6617

Email: danielle.shearer@cms.hhs.gov

RIN: 0938–AN36

1187. 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; 42 CFR 483; 42 CFR 485


Abstract: This final rule amends the fire safety standard for religious nonmedical health care institutions, hospices, programs of all-inclusive care for the elderly, hospices, 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). We adopted the 2000 edition of the LSC in January 2003. The LSC change will allow facilities to place alcohol-based hand sanitizer dispensers in exit corridors under certain conditions. These sanitizers have proven to be effective in increasing hand hygiene and have the potential to improve infection control practice. Adopting the LSC change will increase a provider’s flexibility in meeting infection control goals while minimizing potential fire safety concerns. Additionally, this rule includes a requirement for placement of battery operated smoke alarms in resident rooms in non-sprinkled SNFs.

Timetable:

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Required: No

Small Entities Affected: No

Government Levels Affected: None

Additional Information: Provides request for publication of this regulation.

Agency Contact: Janice Graham, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of Clinical Standards and Quality, Mailstop S3–05–27, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786–6802

Email: janice.graham@cms.hhs.gov

RIN: 0938–AN30

1188. REVISED CIVIL MONEY PENALTIES, EXCLUSIONS, AND RELATED APPEALS PROCEDURES (CMS–6019–F)

Priority: Other Significant

Legal Authority: PL 108–173, sec 949 of MMA

CFR Citation: 42 CFR 402.400


Abstract: Section 949 of the Medicare Modernization Act changed the designation of authority to request waiver of a program exclusion under the Social Security Act from the State to the Administrator of a Federal health
care program. This rule proposes to outline a process for health care providers to follow if they wish CMS to request a waiver of exclusion on their behalf (effective December 8, 2003).

Timetable:

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<th>Action</th>
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<td>08/04/05</td>
<td>70 FR 44879</td>
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Regulatory Flexibility Analysis
Required: None

Small Entities Affected: None

Agency Contact: Gladys Wheeler, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–0273
Email: gwheeler@cms.hhs.gov

RIN: 0938–AN49

1190. MEDICARE PART B
COMPETITIVE ACQUISITION OF OUTPATIENT DRUGS AND BIOLOGICALS (CMS–1325–F)

Priority: Economically Significant. Major under 5 USC 801

Legal Authority: MMA of 2003, sec 303(d)

CFR Citation: 42 CFR 414

Legal Deadline: Final, Statutory, January 1, 2006, MMA of 2003, section 303(d) or section 1847(B)(a)(1) of the Social Security Act.

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 January 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:

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<th>Action</th>
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Regulatory Flexibility Analysis
Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Edmund E. Kasaitis, Health Insurance Specialist, Hospital & Ambulatory Policy Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop C4–01–26, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–0477
Email: edmund.kasaitis@cms.hhs.gov

RIN: 0938–AN58

1191. GROUP MARKET HEALTH INSURANCE REFORM: GUARANTEED AVAILABILITY, GUARANTEED RENEWABILITY, DISCLOSURES TO SMALL EMPLOYERS (CMS–4102–F)

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

Legal Authority: 42 USC 300gg–92

CFR Citation: 45 CFR 146.150; 45 CFR 146.152; 45 CFR 146.160


Abstract: This regulation finalizes the interim final regulation (BPD-890-IFC) guaranteeing the availability of health insurance coverage to small employers, and guaranteeing the renewability of health insurance coverage to small and large employers.

Timetable:

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

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: David R. Mlawsky, Health Insurance Specialist, Center for Beneficiary Choices, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Medicare Plan Policy Group, Mailstop S3–16–26, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 877 267–2323
Email: david.mlawsky@cms.hhs.gov

Related RIN: Related to 0938–AI08
RIN: 0938–AN60

1192. 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)

Priority: Other Significant. Major under 5 USC 801.

Legal Authority: 42 USC 300gg–92

CFR Citation: 42 CFR 148.11; 42 CFR 148.102; 42 CFR 148.103; 42 CFR 148.122; 42 CFR 148.1


Abstract: This regulation finalizes the interim final rule (BPD-890-IFC) that
guarantees availability of health coverage to certain individuals, guarantees renewability of coverage in the individual market, and sets standards for State alternative mechanisms for guaranteeing coverage to certain individuals.

**Timetable:**

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**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** None

**Agency Contact:** David R. Mlawsky, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Beneficiary Choices, Medicare Plan Policy Group, Mailstop S3–16–16, 7500 Security Boulevard, Baltimore, MD 21244. Phone: 877 267–2323. Email: david.mlawsky@cms.hhs.gov

**Related RIN:** Related to 0938–AI08

**RIN:** 0938–AN61

1194. APPLICATION OF INHERENT REASONABLENESS TO ALL MEDICARE PART B SERVICES (OTHER THAN PHYSICIAN SERVICES) (CMS–1908–F)

**Priority:** Info./Admin./Other. Major status under 5 USC 801 is undetermined.

**Legal Authority:** BBA; BBRA

**CFR Citation:** 42 CFR 405

**Legal Deadline:** Final, Statutory, December 8, 2006, MMA sec. 902.

**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 that 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

**Federalism:** Undetermined

**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 C5–05–27, 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
1196. ELECTRONIC SUBMISSION OF COST REPORTS: REVISION TO COST REPORTING PERIOD (CMS–1199–F)

Priority: Substantive, Nonsignificant

Legal Authority: None

CFR Citation: None


Abstract: This final rule follows a August 26, 2003, final rule that requires ESRD facilities, hospices, rural health clinics, federally qualified health centers, and community mental health centers to file cost reports in a standardized electronic format. It provided a delay or waiver of this requirement if implementation would result in financial hardship. Because the software packages for accepting the cost reports are not available yet, this final rule changes the cost report ending date from December 31, 2004, to March 31, 2005.

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

Agency Contact: Darryl E. Simms, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C5–03–30, 7500 Security Boulevard, Baltimore, MD 21244 Phone: 410 786–4524 Email: dsimms@cms.hhs.gov

Related RIN: Related to 0938–AN93

RIN: 0938–AN93

1196. ELECTRONIC SUBMISSION OF COST REPORTS: REVISION TO COST REPORTING PERIOD (CMS–1199–F)

Priority: Substantive, Nonsignificant

Legal Authority: None

CFR Citation: None


Abstract: This final rule follows a August 26, 2003, final rule that requires ESRD facilities, hospices, rural health clinics, federally qualified health centers, and community mental health centers to file cost reports in a standardized electronic format. It provided a delay or waiver of this requirement if implementation would result in financial hardship. Because the software packages for accepting the cost reports are not available yet, this final rule changes the cost report ending date from December 31, 2004, to March 31, 2005.

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Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Darryl E. Simms, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C5–03–30, 7500 Security Boulevard, Baltimore, MD 21244 Phone: 410 786–4524 Email: dsimms@cms.hhs.gov

Related RIN: Related to 0938–AN93

RIN: 0938–AN93

1198. HEALTH CARE INFRASTRUCTURE IMPROVEMENT PROGRAM; SELECTION CRITERIA OF LOAN PROGRAM FOR QUALIFYING HOSPITALS ENGAGED IN CANCER–RELATED HEALTH CARE (CMS–1287–F)

Priority: Economically Significant. Major under 5 USC 801.

Legal Authority: Section 1016 of Public Law 108–173

CFR Citation: 42 CFR 505


Abstract: This rule would establish a loan program to improve certain hospital infrastructure, including capital improvement. To receive assistance, the applicant would 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. No later than 4 years after enactment, the Secretary must submit a report to 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: Tzvi Hefter, Director of the Division of Acute Care, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Hospital and Ambulatory Policy Group, 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–AN93

RIN: 0938–AO03

1198. HEALTH CARE INFRASTRUCTURE IMPROVEMENT PROGRAM; SELECTION CRITERIA OF LOAN PROGRAM FOR QUALIFYING HOSPITALS ENGAGED IN CANCER–RELATED HEALTH CARE (CMS–1287–F)

Priority: Economically Significant. Major under 5 USC 801.

Legal Authority: Section 1016 of Public Law 108–173

CFR Citation: 42 CFR 505


Abstract: This rule would establish a loan program to improve certain hospital infrastructure, including capital improvement. To receive assistance, the applicant would 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. No later than 4 years after enactment, the Secretary must submit a report to Congress summarizing the financial performance of the projects that have received assistance under the loan program.

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Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Tzvi Hefter, Director of the Division of Acute Care, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Hospital and Ambulatory Policy Group, 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–AN93

RIN: 0938–AO03

1199. 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.

**Timetable:**

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**Regulatory Flexibility Analysis**

**Required:** No  
**Small Entities Affected:** No  
**Government Levels Affected:** State  
**Agency Contact:** Carey Appold, Technical Director, Disabled & Elderly Health Programs Group, Div. of Advocacy and Special Issues, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicaid and State Operations, Mailstop S2–14–26, 7500 Security Boulevard, Baltimore, MD 21244–1850  
Phone: 410 786–2117  
Fax: 410 786–9004  
Email: carey.appold@cms.hhs.gov  
**RIN:** 0938–AO10

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

**Centers for Medicare & Medicaid Services (CMS)**

<table>
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<th>Reason</th>
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<tr>
<td><strong>1200. SUPPLIER STANDARDS FOR HOME OXYGEN, THERAPEUTIC SHOES, AND HOME NUTRITION THERAPY (CMS–6010–P)</strong></td>
<td>42 CFR 424.57</td>
<td>Withdrawn</td>
<td>06/28/05</td>
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<td><strong>1201. EVALUATION CRITERIA AND STANDARDS FOR QUALITY IMPROVEMENT PROGRAM CONTRACTS (CMS–3142–FN)</strong></td>
<td>None</td>
<td>Final Action</td>
<td>07/22/05</td>
<td>70 FR 42331</td>
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<td><strong>1202. NONDISCRIMINATION IN POST–HOSPITAL REFERRAL TO HOME HEALTH AGENCIES AND OTHER ENTITIES (CMS–1224–F)</strong></td>
<td>42 CFR 482</td>
<td>Withdrawn</td>
<td>08/15/05</td>
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<td><strong>1203. MEDICARE AMBULANCE FEE SCHEDULE UPDATE (CMS–1492–IFC)</strong></td>
<td>42 CFR 414, subpart H</td>
<td>Withdrawn</td>
<td>08/29/05</td>
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<td><strong>1204. PROSPECTIVE PAYMENT SYSTEM FOR LONG TERM CARE HOSPITALS: ANNUAL PAYMENT RATE UPDATES AND POLICY CHANGES FOR 2006 (CMS–1483–F)</strong></td>
<td>None</td>
<td>Final Action</td>
<td>05/06/05</td>
<td>70 FR 24168</td>
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<td><strong>1205. PROSPECTIVE PAYMENT SYSTEM FOR INPATIENT REHABILITATION FACILITIES FOR FY 2006 (CMS–1290–F)</strong></td>
<td>None</td>
<td>Final Action</td>
<td>08/15/05</td>
<td>70 FR 47879</td>
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**Agency Contact:** Jérôme Chabert, Director, Medicare Fee-For-Service Programs, Div. of Quality Assurance, Centers for Medicare & Medicaid Services, Mailstop C13–24, 7500 Security Boulevard, Baltimore, MD 21244–1850  
Phone: 410 786–0516  
Fax: 410 786–0625  
Email: jerome.chabert@cms.hhs.gov  
**RIN:** 0938–AN28

**Related RIN:** Related to 0938–AO11  
**RIN:** 0938–AN24
### HHS—CMS Completed Actions

#### 1206. DEVELOPMENT OF NEW STANDARDS FOR MEDIGAP POLICIES (CMS–4087–FN)
**Priority:** Substantive, Nonsignificant  
**CFR Citation:** None

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**Regulatory Flexibility Analysis Required:** No  
**Small Entities Affected:** No  
**Government Levels Affected:** None  
**Agency Contact:** Julie Walton  
Phone: 410 786–4622  
Email: jwalton@cms.hhs.gov  
**RIN:** 0938–AN50

#### 1207. FISCAL YEAR 2006 SCHIP ALLOTMENTS (CMS–2219–N)
**Priority:** Other Significant  
**CFR Citation:** 42 CFR 457

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<td>70 FR 36615</td>
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**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  
**RIN:** 0938–AN78

#### 1208. CHANGES TO THE HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEM AND FY 2006 RATES (CMS–1500–F)
**Priority:** Economically Significant. Major under 5 USC 801.

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**Regulatory Flexibility Analysis Required:** Yes  
**Small Entities Affected:** Businesses  
**Government Levels Affected:** Federal  
**Agency Contact:** Marc Hartstein  
Phone: 410 786–6192  
Email: marc.hartstein@cms.hhs.gov  
**RIN:** 0938–AN65

#### 1209. SPECIAL PAYMENT PROVISIONS AND STANDARDS FOR SUPPLIERS OF CUSTOM FABRICATED ORTHOTICS AND PROSTHETICS (CMS–6012–P)
**Priority:** Economically Significant. Major under 5 USC 801.

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**Regulatory Flexibility Analysis Required:** Yes  
**Small Entities Affected:** Businesses  
**Government Levels Affected:** None  
**Agency Contact:** Theresa Linkowich  
Phone: 410 786–9249  
Email: tlinkowich@cms.hhs.gov  
Ralph Goldberg  
Phone: 410 786–8864  
**RIN:** 0938–AN63

#### 1210. PROSPECTIVE PAYMENT SYSTEM AND CONSOLIDATED BILLING FOR SKILLED NURSING FACILITIES—UPDATE FOR FY 2006 (CMS–1282–F)
**Priority:** Economically Significant. Major under 5 USC 801.

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<td>70 FR 45025</td>
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**Regulatory Flexibility Analysis Required:** No  
**Small Entities Affected:** Businesses, Organizations  
**Government Levels Affected:** None  
**Agency Contact:** Bill Ullman  
Phone: 401 786–5667  
Email: bill.ullman@cms.hhs.gov  
**RIN:** 0938–AN56

#### 1211. STATE CHILDREN’S HEALTH INSURANCE PROGRAM (SCHIP); REDISTRIBUTION OF UNEXPENDED SCHIP FUNDS FROM THE APPROPRIATION FOR FISCAL YEAR (FY) 2002 (CMS–2230–FN)
**Priority:** Other Significant  
**CFR Citation:** 42 CFR 457.600 to 457.630

<table>
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**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  
**RIN:** 0938–AN78

#### 1212. EXTENDING SUNSET DATE FOR THE INTERIM FINAL REGULATION ON MENTAL HEALTH PARITY (CMS–4094–F)
**Priority:** Other Significant  
**CFR Citation:** 42 CFR 146

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**Regulatory Flexibility Analysis Required:** No  
**Small Entities Affected:** No  
**Government Levels Affected:** None  
**Agency Contact:** David Mlawsky  
Phone: 410 786–6851  
Email: david.mlawsky@cms.hhs.gov  
**Related RIN:** Related to 0938–AN22  
**RIN:** 0938–AN80

#### 1213. ● DISPROPORTIONATE SHARE HOSPITAL PAYMENTS—INSTITUTIONS FOR MENTAL DISEASE (IMDS) (CMS–2062–N2)
**Timetable:**

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**RIN:** 0938–AN88
1214. • HOSPICE WAGE INDEX FOR FY 2006 (CMS–1286–F)

Priority: Other Significant
Legal Authority: Sec. 408 and 946 of the MMA of 2003; Sec. 1861(dd) of the Social Security Act
CFR Citation: 42 CFR 418.306c
Legal Deadline: Final, None, August 2005. Rates are updated October 1st of each year—need at least 3 months to implement.

Abstract: This rule announces the annual update to the hospice wage index for FY 2006. 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
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NPRM | 04/29/05 | 70 FR 22393
Final Action | 08/04/05 | 70 FR 45129

Regulatory Flexibility Analysis Required: No
Small Entities Affected: Businesses

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, Hospital and Ambulatory Policy Group, Mailstop C5–26–07, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–4597
Email: terri.deutsch@cms.hhs.gov
RIN: 0938–AN92

1216. • WITHDRAWAL OF AMBULANCE FEE SCHEDULE ISSUED IN ACCORDANCE WITH FEDERAL DISTRICT COURT ORDER IN LIFESTARAMBULANCE, INC. V. U.S.—MEDICARE COVERED AMBULANCE SERVICES (CMS–1308–)

Priority: Info./Admin./Other
Legal Authority: None

Agency Contact: None
Legal Deadline: None

Abstract: This notice would withdraw the fee schedule that was put in place to effect compliance with the Court Order in Lifestar Ambulance, Inc. v. United States. That Order was vacated by the U.S. Court of Appeals for the Eleventh Circuit in Lifestar Ambulance, Inc. v. United States and, accordingly, is no longer in force.

Timetable:

Action | Date | FR Cite
--- | --- | ---
NPRM | 08/15/05 | 70 FR 47759
Final Action | 10/07/05 | 70 FR 58834

Regulatory Flexibility Analysis Required: No
Small Entities Affected: No

Government Levels Affected: None

Agancy Contact: Anita Panicker, 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: 410 786–5646
Fax: 410 786–8532
Email: anita.panicker@cms.hhs.gov
RIN: 0938–AN95

1217. • IMMUNIZATION STANDARD FOR LONG TERM CARE FACILITIES (CMS–3198–F)

Priority: Economically Significant. Major under 5 USC 801.
Legal Authority: 42 USC 1395i–3; SSA 1819; 42 USC 1396r; SSA 1919

Agency Contact: Robert Kuhl, Division Director, Chronic Care Policy Group, Division of Institutional Post Acute Care, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Centers for Medicare Management, Mailstop C5–26–07, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–4597
Email: bob.kuhl@cms.hhs.gov
RIN: 0938–AN94

Abstract: This rule would mandate nursing facilities to immunize each resident for influenza and pneumonia and would reinforces the residents’ rights to receive the immunizations for vaccine-preventable diseases. The residents will have the right to refuse the immunizations, if they choose to or if contraindication exist.

Timetable:

Action | Date | FR Cite
--- | --- | ---
NPRM | 08/15/05 | 70 FR 47759
Final Action | 10/07/05 | 70 FR 58834

Regulatory Flexibility Analysis Required: No
Small Entities Affected: No

Government Levels Affected: None

Agency Contact: None
Legal Deadline: None

1218. • DISPROPORTIONATE SHARE HOSPITAL PAYMENTS — INSTITUTIONS FOR MENTAL DISEASE (IMDS) (CMS–2209–N)

Priority: Other Significant
Legal Authority: 42 USC 1396r–4; PL 108–173, Sec 1001(a)

Agency Contact: Ann Taylor, Health Insurance Specialist, CMS/CMM/HAPG/DAS, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, C4–07–07, Baltimore, MD 21244
Phone: 410 786–7452
Email: ataylor@cms.hhs.gov

RIN: 0938–AN99

Abstract: This notice would withdraw the immunization standard for long term care facilities. The notice announces the Secretary’s determination that the requirements for classification of a hospice or an inpatient rehabilitation facility (IRF) specified in section 412.23(b)(2) were inconsistent with a report that the Government Accountability Office (GAO) issued concerning classification of a facility as an IRF.

Timetable:

Action | Date | FR Cite
--- | --- | ---
Notice | 09/01/05 | 70 FR 52105

Regulatory Flexibility Analysis Required: No
Small Entities Affected: No

Government Levels Affected: None

Agency Contact: None
Legal Deadline: None
Abstract: Section 1001(a) of the MMA amended the Act to revise the methodology for calculating States Disproportionate Share Hospital (DSH) allotments. CMS published a notice describing this methodology and States’ preliminary FY 2003, and 2004 DSH allotments and preliminary FY 2003 and 2004 IMD DSH limits in the Federal Register on 3/26/04. This notice announces the final Federal DSH allotments for Federal fiscal years (FFYs) 2003 and 2004, and the preliminary Federal share DSH allotments for FFY 2005. It also announces the final FFYs 2003 and 2004, and the preliminary FFY 2005, limitations on aggregate DSH payments that States may make to institutions for mental disease and other mental health facilities. This notice also includes a background describing the methodology for determining the amounts of States’ FFY DSH allotments for FFY 1998 and thereafter.

Timetable:

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<tr>
<td>Final Action</td>
<td>09/01/05</td>
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Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Richard Strauss, Acting Director, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786–7407

Email: richard.strauss@cms.hhs.gov

Related RIN: Previously reported as 0938–AN88

RIN: 0938–AN96

1221. • PART A PREMIUMS FOR CALENDAR YEAR 2006 FOR THE UNINSURED AGED AND FOR CERTAIN DISABLED INDIVIDUALS WHO HAVE EXHAUSTED OTHER ENTITLEMENT (CMS–8025–N)

Priority: Economically Significant.

Major under 5 USC 801.

Legal Authority: 42 USC 1395–2(d)(2); 42 USC 1395i thru 2a[d](2); Sec 1818(d)(2) of the Social Security Act; Sec 1818A[d](2) of the Social Security Act

CFR Citation: None

Legal Deadline: NPRM, Statutory, September 15, 2005.

Abstract: This notice announces the hospital insurance premium for Calendar Year 2006 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

Government Levels Affected: None

Agency Contact: Clare McFarland, Division Director, Medicare and Medicaid Cost Estimates Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, N3–26–00, Office of the Actuary, 7500 Security Boulevard, Mailstop N3–26–00, Baltimore, MD 21244

Phone: 410 786–6390

Email: clare.mcfarland@cms.hhs.gov

RIN: 0938–AO00

1220. • INPATIENT HOSPITAL DEDUCTIBLE AND HOSPITAL AND EXTENDED CARE SERVICES COINSURANCE AMOUNTS FOR CALENDAR YEAR 2006 (CMS–8026–N)

Priority: Economically Significant.

Major under 5 USC 801.

Legal Authority: 42 USC 1395g–2(b)|2); Sec 1813(b)|2) of the Social Security Act

CFR Citation: None

Legal Deadline: NPRM, Statutory, September 15, 2005.

Abstract: This notice announces the inpatient hospital deductible and the hospital and extended care services coinsurance amounts for services furnished in calendar year 2006 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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<td>70 FR 55896</td>
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Regulatory Flexibility Analysis Required: No

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Clare McFarland, Division Director, Medicare and Medicaid Cost Estimates Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, N3–26–00, Office of the Actuary, 7500 Security Boulevard, Mailstop N3–26–00, Baltimore, MD 21244

Phone: 410 786–6390

Email: clare.mcfarland@cms.hhs.gov

RIN: 0938–AO00

1219. • MEDICARE PRESCRIPTION DRUG DISCOUNT CARD (CMS–4063–F)

Priority: Other Significant

Legal Authority: SSA 1851(d)(1); SSA 1860D–1(c); SSA 1860D–31(h)(7)(B); SSA 1860D–31(h)(8)

CFR Citation: 42 CFR 403; 42 CFR 408

Legal Deadline: None

Abstract: The regulation will finalize the marketing rules for the drug card program; specifically it will provide current drug card sponsors who become prescription drug plans (PDPs) the ability to market their PDP offerings to their current Medicare members. CMS is making the change because the current regulation provides that an endorsed sponsor’s information and outreach materials may describe only those products or services within the scope of the Medicare endorsement for the drug card. The intended effect is to increase Medicare beneficiaries’ awareness and knowledge of PDP offerings for Part D enrollment effective in 2006. The current draft of the marketing section in the interim final rule contradicts the intention of the Medicare Modernization Act to facilitate efficient enrollment into Part D. The revised final rule will reflect the actual intention of the law.

Timetable:

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Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Jessica Shapiro, Acting Director, of the Division of Drug Card Management, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786–7407

Fax: 410 786–1048

Related RIN: Related to 0938–AM71

RIN: 0938–AN97

1209. • INPATIENT HOSPITAL DEDUCTIBLE AND HOSPITAL AND EXTENDED CARE SERVICES COINSURANCE AMOUNTS FOR CALENDAR YEAR 2006 (CMS–8026–N)

Priority: Economically Significant.

Major under 5 USC 801.

Legal Authority: 42 USC 1395g–2(b)|2); Sec 1813(b)|2) of the Social Security Act

CFR Citation: None

Legal Deadline: NPRM, Statutory, September 15, 2005.

Abstract: This notice announces the inpatient hospital deductible and the hospital and extended care services coinsurance amounts for services furnished in calendar year 2006 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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<th>Action</th>
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<td>09/23/05</td>
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Regulatory Flexibility Analysis Required: No

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Clare McFarland, Division Director, Medicare and Medicaid Cost Estimates Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, N3–26–00, Office of the Actuary, 7500 Security Boulevard, Mailstop N3–26–00, Baltimore, MD 21244

Phone: 410 786–6390

Email: clare.mcfarland@cms.hhs.gov

RIN: 0938–AO00
### Proposed Rule Stage

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

**Administration for Children and Families (ACF)**

<table>
<thead>
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<th>RIN: 0938–AO02</th>
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#### 1222. MEDICARE PART B MONTHLY ACTUARIAL RATES AND PREMIUM RATE BEGINNING JANUARY 1, 2006 (CMS–8027–N)

**Priority:** Economically Significant

**Legal Authority:** 42 USC 1395r; Sec 1839 of the Social Security Act; Sec 629 of MMA; Sec 811 of MMA

**CFR Citation:** None

**Legal Deadline:** 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 2006. It also announces the monthly Part B premium to be paid by all enrollees, and the Part B deductible, during 2006. Section 629 of the Medicare Modernization Act requires indexing the Part B deductible to the increase in the Part B aged actuarial rate beginning 1/1/06.

**Timetable:**

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### Completed Actions

#### 1223. 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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#### 1224. 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

**Legal Deadline:** Final, Statutory, October 30, 2001.

**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.

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#### 1225. 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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<th>Action</th>
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**Small Entities Affected**

| No       |         |

**Government Levels Affected**

| Local, State |         |

**Agency Contact**

- **Maureen Dunn**, Deputy Director, Department of Health and Human Services, Administration for Children and Families, 370 L’Enfant Promenade SW., Washington, DC 20447
- Phone: 202 401–6953
- Email: mdunn@acf.hhs.gov

---

### 1227. 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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**Small Entities Affected**

| No       |         |

**Government Levels Affected**

| State |         |

**Agency Contact**

- **Grant Collins**, Associate Director, Administration for Children and Families, 5th Floor East, 370 L’Enfant Promenade SW., Washington, DC 20447
- Phone: 202 401–5523
- Email: gcollins@acf.hhs.gov

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### 1228. MEDICAL SUPPORT

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

**Legal Authority:** 42 USC 1302

**CFR Citation:** 45 CFR 302; 45 CFR 303; 45 CFR 304; 45 CFR 305

**Legal Deadline:** None

**Abstract:** These rules would require that all support orders in the IV-D program address medical support, redefine reasonable-cost health insurance, require health insurance to be accessible, and make conforming changes to audit and self-assessment requirements.

### Timetable:

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**Small Entities Affected**

| No       |         |

**Government Levels Affected**

| State |         |

**Agency Contact**

- **Kathleen McHugh**, Division Director, Children’s Bureau Policy, Department of Health and Human Services, Administration for Children and Families, Room 2411, 330 C Street SW., Washington, DC 20447
- Phone: 202 401–5789
- Fax: 202 205–8221
- Email: kmchugh@acf.hhs.gov

---

### 1229. 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 (P.L. 108-145).

### Timetable:

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**Small Entities Affected**

| No       |         |

**Government Levels Affected**

| 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.dhhs.gov

**RIN:** 0970–AC22

---
1230. ADMINISTRATIVE COSTS FOR CHILDREN IN TITLE IV-E FOSTER CARE

Priority: Other Significant
Legal Authority: 42 USC 672; 42 USC 674; 42 USC 1302
CFR Citation: 45 CFR 1356.60(c)
Legal Deadline: None

Abstract: This notice of proposed rulemaking implements the title IV-E foster care eligibility and administrative cost provisions in sections 472 and 474 of the Social Security Act. We propose to prohibit the reimbursement of administrative costs claimed on behalf of children in unlicensed foster family homes, with the exception of children in relative foster family homes while the State is in the process of licensing the home. We also propose to prohibit the reimbursement of administrative costs claimed on behalf of children in unallowable facilities, with the exception of the month prior to a child’s transition into an allowable facility.

Timetable:

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Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: State

Agency Contact: Kathleen McHugh, Division Director, Children’s Bureau Policy, Department of Health and Human Services, Administration for Children and Families, Room 2411, 330 C Street SW., Washington, DC 20447
Phone: 202 401–5783
Fax: 202 205–8221
Email: kmchugh@acf.hhs.gov
RIN: 0970–AC14

1232. CHILD CARE AND DEVELOPMENT FUND STATE MATCH PROVISIONS

Priority: Other Significant
Legal Authority: 42 USC 9858C
CFR Citation: 45 CFR 98.16
Legal Deadline: None

Abstract: This proposed rule revises the Child Care and Development Fund (CCDF) regulations to permit States to designate multiple public and/or private entities as eligible to receive private donations that may be certified as child care expenditures for purposes of receiving Federal CCDF matching funds.

Timetable:

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<td>11/09/04</td>
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Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

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.dhhs.gov
RIN: 0970–AC19

1233. REASONABLE QUANTITATIVE STANDARD FOR REVIEW AND ADJUSTMENT OF CHILD SUPPORT ORDERS

Priority: Other Significant
Legal Authority: 42 USC 1302
CFR Citation: 45 CFR 303
Legal Deadline: None

Abstract: This interim final rule permits States to use reasonable quantitative standards in adjusting an existing child support award amount after conducting review of the order, regardless of the method review.

Timetable:

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<th>Action</th>
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<td>12/28/04</td>
<td>69 FR 77659</td>
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Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: Local, State

Agency Contact: Karen Tvedt, 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: ktvedt@acf.hhs.gov
RIN: 0970–AC18