Monday,
October 31, 2005

Part VIII

Department of Health and Human Services

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Office of the Secretary
21 CFR Ch. I
42 CFR Chs. I-V
45 CFR Subtitle A; Subtitle B, Chs. II, III, and XIII

Regulatory Agenda

AGENCY: Office of the Secretary, HHS.
ACTION: Semiannual 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>1197</td>
<td>Loan Forgiveness Criteria for the Health Care Infrastructure Loan Program (CMS-1320-F)</td>
<td>0938–AN93</td>
</tr>
<tr>
<td>1198</td>
<td>Health Care Infrastructure Improvement Program; Selection Criteria of Loan Program for Qualifying Hospitals Engaged in Cancer-Related Health Care (CMS-1287-F)</td>
<td>0938–AO03</td>
</tr>
<tr>
<td>1199</td>
<td>Medical Improvement Eligibility Group and Definition of Work (CMS-2143-P)</td>
<td>0938–AO10</td>
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### Centers for Medicare & Medicaid Services—Completed Actions

<table>
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<tr>
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<tbody>
<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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<tr>
<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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<tr>
<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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<tr>
<td>1203</td>
<td>Medicare Ambulance Fee Schedule Update (CMS-1492-IFC)</td>
<td>0938–AN24</td>
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<tr>
<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>
<td>0938–AN43</td>
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<tr>
<td>1206</td>
<td>Development of New Standards for Medigap Policies (CMS-4087-FN)</td>
<td>0938–AN50</td>
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<tr>
<td>1207</td>
<td>Fiscal Year 2006 SCHIP Allotments (CMS-2219-N)</td>
<td>0938–AN56</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>1209</td>
<td>Special Payment Provisions and Standards for Suppliers of Custom Fabricated Orthotics and Prosthetics (CMS-6012-P)</td>
<td>0938–AN63</td>
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<td>1210</td>
<td>Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities—Update for FY 2006 (CMS-1282-F)</td>
<td>0938–AN65</td>
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<td>1211</td>
<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>
<td>0938–AN78</td>
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<td>1212</td>
<td>Extending Sunset Date for the Interim Final Regulation on Mental Health Parity (CMS-4094-F3)</td>
<td>0938–AN80</td>
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<td>1213</td>
<td>Disproportionate Share Hospital Payments—Institutions for Mental Disease (IMDs) (CMS-2062-N2)</td>
<td>0938–AN88</td>
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<tr>
<td>1214</td>
<td>Hospice Wage Index for FY 2006 (CMS-1286-F)</td>
<td>0938–AN89</td>
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<td>1215</td>
<td>Inpatient Rehabilitation Facility Classification Rule Compliance (CMS-1480-N)</td>
<td>0938–AN92</td>
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<td>1216</td>
<td>Withdrawal of Ambulance Fee Schedule Issued in Accordance With Federal District Court Order in Lifestar Ambulance, Inc. v. U.S.—Medicare Covered Ambulance Services (CMS-1308-F)</td>
<td>0938–AN94</td>
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<td>1217</td>
<td>Immunization Standard for Long Term Care Facilities (CMS-3198-F)</td>
<td>0938–AN95</td>
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<td>1218</td>
<td>Disproportionate Share Hospital Payments — Institutions for Mental Disease (IMDs) (CMS-2209-N)</td>
<td>0938–AN96</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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<tr>
<td>1220</td>
<td>Inpatient Hospital Deductible and Hospital and Extended Care Services Coinsurance Amounts for Calendar Year 2006 (CMS-8026-N)</td>
<td>0938–AO00</td>
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<tr>
<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>
<td>0938–AO01</td>
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### Administration for Children and Families—Proposed Rule Stage

<table>
<thead>
<tr>
<th>Sequence Number</th>
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<tbody>
<tr>
<td>1223</td>
<td>Safeguarding Child Support and Expanded Federal Parent Locator Services (FPLS) Information</td>
<td>0970–AC01</td>
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Administration for Children and Families—Proposed Rule Stage (Continued)

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<tr>
<td>1224</td>
<td>Developmental Disabilities and Bill of Rights Act</td>
<td>0970–AC07</td>
</tr>
<tr>
<td>1225</td>
<td>Administrative Cost Sharing Under TANF</td>
<td>0970–AC15</td>
</tr>
<tr>
<td>1226</td>
<td>Care and Placement of Unaccompanied Alien Children</td>
<td>0970–AC20</td>
</tr>
<tr>
<td>1227</td>
<td>Chafee National Youth in Transition Database</td>
<td>0970–AC21</td>
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<tr>
<td>1228</td>
<td>Medical Support</td>
<td>0970–AC22</td>
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<tr>
<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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<tr>
<td>1230</td>
<td>Administrative Costs for Children in Title IV-E Foster Care</td>
<td>0970–AC14</td>
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<tr>
<td>1231</td>
<td>Head Start Transportation</td>
<td>0970–AC16</td>
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<tr>
<td>1232</td>
<td>Child Care and Development Fund State Match Provisions</td>
<td>0970–AC18</td>
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<tr>
<td>1233</td>
<td>Reasonable Quantitative Standard for Review and Adjustment of Child Support Orders</td>
<td>0970–AC19</td>
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</table>

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

Office of the Secretary (OS)

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 1396w–2

CFR Citation: 42 CFR 1003

Legal Deadline: None

Abstract: This proposed rule would revise part 1003, addressing the Office of Inspector General’s authority to propose the imposition of civil money penalties and assessments, by reorganizing and simplifying existing regulatory text and eliminating obsolete references contained in the current regulations. Among the proposed revisions, this rule would establish separate subparts within part 1003 for various categories of violations; modify the current definition for the term “claim;” update various references to managed care organization authorities; and clarify the application of section 1140 of the Social Security Act with respect to the misuse of certain Departmental symbols, emblems, or names through Internet and e-mail communications.

Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
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<td>NPRM</td>
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<td>NPRM Comment</td>
<td>06/00/06</td>
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<td>Regulatory Flexibility Analysis Required</td>
<td>No</td>
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<td>Small Entities Affected: None</td>
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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:

<table>
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<tr>
<th>Action</th>
<th>Date</th>
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<td>Period End</td>
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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:

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<tr>
<th>Action</th>
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<td>ANPRM</td>
<td>05/23/97</td>
<td>62 FR 28410</td>
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<td>06/09/97</td>
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<td>Interim Final Rule</td>
<td>11/19/99</td>
<td>64 FR 63504</td>
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<td>Final Action</td>
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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–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 final rule will 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(f)(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:

<table>
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<tr>
<th>Action</th>
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<td>NPRM</td>
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<td>67 FR 60202</td>
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<td>10/25/02</td>
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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–AB16

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:

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<th>Action</th>
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<td>NPRM</td>
<td>04/18/05</td>
<td>70 FR 20224</td>
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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  
**Legal Deadline:** Final, Statutory, December 8, 2004.  
**Abstract:** This rule will set forth standards for the new anti-kickback safe harbor addressing remuneration between federally qualified health centers and certain providers where significant community benefit exits.  
**Timetable:**  
<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
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<tbody>
<tr>
<td>NPRM</td>
<td>07/13/04</td>
<td>69 FR 42010</td>
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<td>Final Action</td>
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**Regulatory Flexibility Analysis Required:** No  
**Small Entities Affected:** No  
**Government Levels Affected:** None  
**Agency Contact:** Jeffrey S. Davis, Associate General Counsel, Department of Health and Human Services, Office of the Secretary, 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

## 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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<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
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<tbody>
<tr>
<td>NPRM</td>
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**Regulatory Flexibility Analysis Required:** No  
**Small Entities Affected:** No  
**Government Levels Affected:** None  
**Agency Contact:** Jeffrey S. Davis, Associate General Counsel, Department of Health and Human Services, Office of the Secretary, 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

**Priority:** Substantive, Nonsignificant  
**Unfunded Mandates:** Undetermined  
**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:**  
<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
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<tbody>
<tr>
<td>NPRM</td>
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**Regulatory Flexibility Analysis Required:** No  
**Small Entities Affected:** No  
**Government Levels Affected:** None  
**Agency Contact:** Jeffrey S. Davis, Associate General Counsel, Department of Health and Human Services, Office of the Secretary, 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

## 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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<th>Date</th>
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<tbody>
<tr>
<td>NPRM</td>
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<td>69 FR 42010</td>
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<td>Final Action</td>
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**Regulatory Flexibility Analysis Required:** No  
**Small Entities Affected:** No  
**Government Levels Affected:** Federal  
**Agency Contact:** Joel Jay Scher, 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–AB18
### Department of Health and Human Services (HHS) Completed Actions

<table>
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<tr>
<th>995.</th>
<th>AMENDING THE REGULATIONS GOVERNING NONDISCRIMINATION ON THE BASIS OF RACE, COLOR, NATIONAL ORIGIN, HANDICAP, SEX, AND AGE TO CONFORM TO THE CIVIL RIGHTS RESTORATION ACT OF 1987</th>
<th>Completed: Final Rule 05/09/05 70 FR 24314</th>
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<tbody>
<tr>
<td>Priority:</td>
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<td>Regulatory Flexibility Analysis Required: No</td>
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<td>CFR Citation:</td>
<td>45 CFR 80; 45 CFR 84; 45 CFR 86; 45 CFR 90; 45 CFR 91</td>
<td>Small Entities Affected: Businesses, Governmental Jurisdictions, Organizations</td>
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<td>Government Levels Affected:</td>
<td>Federal, Local, State, Tribal</td>
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</tr>
<tr>
<td>Agency Contact:</td>
<td>Robinsue Frohboese</td>
<td>Phone: 202 619–0403</td>
</tr>
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<td>RIN:</td>
<td>0991–AB33</td>
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### Department of Health and Human Services (HHS) Proposed Rule Stage

<table>
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<th>996.</th>
<th>REQUIREMENTS GOVERNING THE USE OF SECLUSION AND RESTRAINT IN CERTAIN NONMEDICAL COMMUNITY–BASED FACILITIES FOR CHILDREN AND YOUTH</th>
<th>Regulatory Flexibility Analysis Required: Yes</th>
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<tbody>
<tr>
<td>Priority:</td>
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<td>Small Entities Affected: Businesses</td>
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<tr>
<td>Legal Authority:</td>
<td>PL 106–310</td>
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<td>CFR Citation:</td>
<td>Not Yet Determined</td>
<td>Government Levels Affected: State</td>
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<tr>
<td>Legal Deadline:</td>
<td>NPRM, Statutory, April 2001.</td>
<td>Federalism: This action may have federalism implications as defined in EO 13132.</td>
</tr>
<tr>
<td>Abstract:</td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>Timetable:</td>
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### Department of Health and Human Services (HHS) Final Rule Stage

<table>
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<tr>
<th>997.</th>
<th>MANDATORY GUIDELINES FOR THE FEDERAL WORKPLACE DRUG TESTING PROGRAM</th>
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<tr>
<td>Legal Authority:</td>
<td>PL 100–71; 5 USC 7301</td>
<td>Government Levels Affected:</td>
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<tr>
<td>CFR Citation:</td>
<td>None</td>
<td></td>
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<tr>
<td>Abstract:</td>
<td>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.</td>
<td></td>
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### 998. AMENDMENTS TO QUALITY ASSURANCE AND ADMINISTRATIVE PROVISION FOR APPROVAL OF RESPIRATORY PROTECTIVE DEVICES

**Department of Health and Human Services (HHS)**  
**Centers for Disease Control and Prevention (CDC)**  

**Proposed Rule Stage**

**Small Entities Affected:** Businesses  
**Government Levels Affected:** None  
**Agency Contact:** Jon Szalajada, Acting Chief, Policy and Standards Branch, HHS, CDC, NIOSH, Department of Health and Human Services, Centers for Disease Control and Prevention, NIOSH, P.O. Box 18070, 626 Cochrans Mill Road, Pittsburgh, PA 15236  
Phone: 412 386–4000  
**RIN:** 0920–AA04

**Abstract:** NIOSH plans to modify the Administrative/Quality Assurance sections of 42 CFR part 84, Approval of Respiratory Protective Devices. Areas for potential modification in this module are: 1) Upgrade of quality assurance requirements; 2) ability to use private sector quality auditors and private sector testing laboratories in the approval program; 3) revised approval label requirements; 4) updated and restructured fee schedule; and 5) fee retention in the respirator program.

**Timetable:**

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**Regulatory Flexibility Analysis Required:** Undetermined

**Small Entities Affected:** Businesses  
**Government Levels Affected:** None

**Agency Contact:** Jon Szalajada, Acting Chief, Policy and Standards Branch, HHS, CDC, NIOSH, Department of Health and Human Services, Centers for Disease Control and Prevention, NIOSH, P.O. Box 18070, 626 Cochrans Mill Road, Pittsburgh, PA 15236  
Phone: 412 386–4000  
**RIN:** 0920–AA10

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

**Department of Health and Human Services (HHS)**  
**Centers for Disease Control and Prevention (CDC)**  

**Proposed Rule Stage**

**Small Entities Affected:** Businesses  
**Government Levels Affected:** None  
**Agency Contact:** Jon Szalajada, Acting Chief, Policy and Standards Branch, HHS, CDC, NIOSH, Department of Health and Human Services, Centers for Disease Control and Prevention, NIOSH, P.O. Box 18070, 626 Cochrans Mill Road, Pittsburgh, PA 15236  
Phone: 412 386–4000  
**RIN:** 0920–AA11

**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  
**Government Levels Affected:** None

**Agency Contact:** Jon Szalajada, Acting Chief, Policy and Standards Branch, HHS, CDC, NIOSH, Department of Health and Human Services, Centers for Disease Control and Prevention, 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

**Department of Health and Human Services (HHS)**  
**Centers for Disease Control and Prevention (CDC)**  

**Final Rule Stage**

**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–AA12
### 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.

**Regulatory Flexibility Analysis**  
**Required:** No  
**Government Levels Affected:** Undetermined  
**Federalism:** Undetermined  
**Agency Contact:** Rebecca Buckner, Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, HFS–306, Center for Devices and Radiological Health, HFZ–215, 1350 Piccard Drive, Rockville, MD 20850  
**Phone:** 301 436–2632  
**Fax:** 301 594–4765  
**Email:** rebecca.buckner@cfsan.fda.gov

**Timetable:**  
**Action** | **Date** | **FR Cite**  
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Begin Review of Current Regulation | 11/00/05 |  

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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

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### 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.

**Regulatory Flexibility Analysis**  
**Required:** Yes  
**Small Entities Affected:** Businesses  
**Government Levels Affected:** Undetermined  
**Federalism:** Undetermined  
**Agency Contact:** Rebecca Buckner, Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, HFS–306, 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

**Timetable:**  
**Action** | **Date** | **FR Cite**  
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NPRM | 05/00/06 |  

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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

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

**Timetable:**  
**Action** | **Date** | **FR Cite**  
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NPRM | 05/00/06 |  

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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)).

**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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**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

### 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 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 (HFD–7), Rockville, MD 20852

**Phone:** 301 594–2041

**Fax:** 301 827–5562

**Email:** pendletonb@ceder.fda.gov

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

**RIN:** 0910–AC59

### 1010. CONTENT AND FORMAT OF LABELING FOR HUMAN PRESCRIPTION DRUGS AND BIOLOGICS; REQUIREMENTS FOR PREGNANCY AND LACTATION LABELING

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

**RIN:** 0910–AF14

### 1011. COCHINEAL EXTRACT AND CARMINE LABEL DECLARATION

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

**Legal Authority:** 21 USC 379e(b)

**CFR Citation:** 21 CFR 73.100(d); 21 CFR 73.1100(c); 21 CFR 73.2087(c); 21 CFR 101.22(k)

**Legal Deadline:** None

**Abstract:** 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.

### Timetable:

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### 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 (HFD–7), Center for Drug Evaluation and Research, 5515 Security Lane, Rockville, MD 20852

**Phone:** 301 594–2041

**Fax:** 301–827–5562

**Email:** rogersc@ceder.fda.gov

**RIN:** 0910–AF13

### 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–AF14

### 1014. DISTRIBUTION OF BLOOD DERIVATIVES BY REGISTERED BLOOD ESTABLISHMENTS THAT QUALIFY AS HEALTH CARE ENTITIES; PDMA OF 1997; PDA OF 1992; POLICIES, REQUIREMENTS, AND ADMINISTRATIVE PROCEDURES

**Priority:** Substantive, Nonsignificant

**Legal Authority:** 21 USC 351 to 353; 21 USC 371; 21 USC 373; 21 USC 374

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

**Legal Deadline:** None

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

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### Regulatory Flexibility Analysis

**Required:** No

**Government Levels Affected:** None
1015. REVOCATION OF THE STATUS OF SPECIFIC PRODUCTS; GROUP A STREPTOCOCCUS

Proposal Stage

Agency Contact: Valerie Butler, Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, Suite 200N (HFM–17), Center for Biologics Evaluation and Research, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852

Phone: 301 827–6210
Fax: 301 827–9434

RIN: 0910–AF20

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 884.5310; 21 CFR 884.5310

Legal Deadline: None

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

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

RIN: 0910–AF21

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 360b to 360d; 21 USC 360b to 360j; 21 USC 360l; 21 USC 371; 21 USC 372; 21 USC 374; 21 USC 381; 21 USC 383; 42 USC 216; 42 USC 243; 42 USC 262; 42 USC 263; 42 USC 263a; 42 USC 264; 42 USC 271

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

Legal Deadline: None

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

Timetable:

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NPRM | 12/00/05 | 
Regulatory Flexibility Analysis Required: Undetermined
Small Entities Affected: Businesses
Government Levels Affected: None

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–AF21
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) (Cardiovascular Warnings)</td>
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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, Rockville Pike, Rockville, MD 20852–1448

Phone: 301 827–6210
Fax: 301 827–9434
Email: rachanow@cdr.fda.gov

Related RIN: Split from 0910–AA01

RIN: 0910–AF37

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 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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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, Rockville, MD 20857

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

Related RIN: Split from 0910–AA01

RIN: 0910–AF37

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>
<td>03/00/06</td>
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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, Rockville Pike, Rockville, MD 20852–1448

Phone: 301 827–6210
Fax: 301 827–9434
Email: rachanow@cdr.fda.gov

Related RIN: Split from 0910–AA01

RIN: 0910–AF37
### 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:**

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<tr>
<td>NPRM (UVA/UVB)</td>
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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@cdrf.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:**

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<tr>
<td>NPRM (Phenylpropanolamine)</td>
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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@cdrf.fda.gov  
**Related RIN:** Split from 0910–AA01  
**RIN:** 0910–AF43

### 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:**

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

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

**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@cdrf.fda.gov  
**Related RIN:** Split from 0910–AA01  
**RIN:** 0910–AF45
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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**Agency Contact:** Gerald M. Rachanow, Regulatory Counsel, Division of Over-the-Counter Drug Products, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, 5600 Fishers Lane, HFD–560, Rockville, MD 20857

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Email: 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 to 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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<tr>
<td>Government Levels Affected: None</td>
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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

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Email: rachanow@cder.fda.gov

RIN: 0910–AF56
1029. • BLOOD VESSELS RECOVERED WITH ORGANS AND INTENDED FOR USE IN ORGAN TRANSPLANTATION

Priority: Substantive, Nonsignificant
Legal Authority: 42 USC 216; 42 USC 243; 42 USC 263a; 42 USC 264; 42 USC 271; 42 USC 273 to 274d; 42 USC 1302; 42 USC 1306
CFR Citation: 21 CFR 1271; 42 CFR 121
Legal Deadline: None
Abstract: FDA and Health Resources and Services Administration (HRSA) are issuing a direct final rule and companion proposed rule to amend the regulations to consider as part of an organ (and regulated by HRSA) those blood vessels recovered with vascularized human organs that are intended for use in organ transplantation; and to exclude such blood vessels from the definition of human cells, tissues, and cellular and tissue-based products (regulated by FDA). We are taking this action to provide that blood vessels recovered with organs and intended for use in organ transplantation will be governed by the regulations pertaining to organs. We believe this change will eliminate unnecessary burden resulting from an organ procurement organization’s efforts to comply with both FDA and HRSA requirements with respect to vascular tissue (FDA jurisdiction) and organs (HRSA jurisdiction).

Regulatory Flexibility Analysis Required: No
Small Entities Affected: Businesses Government Levels Affected: None
Agency Contact: Andrew J. Beaulieu, Director, Office of Minor Use and Minor Species Animal Drug Development, Department of Health and Human Services, Food and Drug Administration, Center for Veterinary Medicine, 7519 Standish Place, Room 180, HFV–50, MPN–4, Rockville, MD 20855 Phone: 240 276–9090 Fax: 240–276–9001 Email: abeaulie@cvm.fda.gov
RIN: 0910–AF60

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
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.

Regulatory Flexibility Analysis Required: No
Small Entities Affected: Businesses Government Levels Affected: None
Agency Contact: Paula S. McKeever, Regulatory Policy Analyst, Department of Health and Human Services, Food and Drug Administration, Center for Biologics Evaluation and Research, 1401 Rockville Pike, Rockville, MD 20852–1448 Phone: 301 827–6210 Fax: 301 827–9434 Email: mckeever@cinger.roc.gov
RIN: 0910–AF65

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 351 to 353; 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 the ingredient ipecac.

Timetable:

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

Timetable:

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<td>NPRM (Healthcare Antiseptics)</td>
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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 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 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 is 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.

Timetable:

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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; 21 USC 375 to 377; 21 USC 379a; 21 USC 381.
CFR Citation: 21 CFR 310; 21 CFR 312; 21 CFR 314; 21 CFR 320; 21 CFR 600; 21 CFR 601; 21 CFR 606
Legal Deadline: None

Abstract: This regulation is one component of the Secretary’s initiative to reduce medical errors. The final rule would amend the expedited and periodic safety reporting regulations for human drugs and biological products to revise certain definitions and reporting formats as recommended by the International Conference on Harmonisation and to define new terms; to add to or revise current reporting requirements; to revise certain reporting time frames; and propose other revisions to these regulations to enhance the quality of safety reports received by FDA.

Regulatory Flexibility Analysis Required: No

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. Email: pendletonb@cder.fda.gov

RIN: 0910–AB34

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 262; 42 USC 263a; 42 USC 264; 21 USC 372; 21 USC 381; 42 USC 263

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.

CFR Citation: 21 CFR 312; 21 CFR 314

RIN: 0910–AA97

1035. APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG; COMPLETE RESPONSE LETTER; AMENDMENTS TO UNAPPROVED APPLICATIONS

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

Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 371; 21 USC 374; 21 USC 379e
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 379c; 21 USC 381; 41 USC 216; 41 USC 241; 41 USC 262; 41 USC 263b to 263n

CFR Citation: 21 CFR 50; 21 CFR 56

Legal Deadline: None

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

Timetable:

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Regulatory Flexibility Analysis

Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Carol Drew, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, 5515 Security Lane, Suite 1101 (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 or egg test positive for SE; (5) egg testing when an environmental test is positive; and (6) refrigerated storage of eggs held at the farm.

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

The proposed rule is one step in a broader farm-to-table egg safety effort that includes FDA’s requirements for safe handling statements on egg cartons and refrigerated storage of 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: 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
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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 379c; 21 USC 381; 42 USC 216; 42 USC 241; 42 USC 262; 42 USC 263b to 263n
of investigational in vitro diagnostic devices to identify chemical, biological, radiological, or nuclear agents in a potential terrorist event or other public health emergency.

Abstract:

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

1042. MEDICAL DEVICES; PATIENT EXAMINATION AND SURGEONS’ GLOVES; ADULTERATION

Priority: Substantive, Nonsignificant

Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351; 21 USC 352; 21 USC 357; 21 USC 374

CFR Citation: 21 CFR 800.20

Abstract: 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.

Timetable:

Action | Date | FR Cite
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Interim Final Rule | 06/00/06 | No
Regulatory Flexibility Analysis Required: No
Small Entities Affected: None

RIN: 0910–AC25

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


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

Abstract: This rulemaking is one of a number of actions being taken to improve FDA’s ability to respond to threats of bioterrorism. Section 801(m) of the Federal Food, Drug, and Cosmetic Act (FFDCA), which was added by section 307 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), requires notification to FDA prior to the entry of imported food. The required prior notice would provide the identity of FDA...
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

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**RIN:** 0910–AC41

### 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)(i)(l)

**CFR Citation:** 21 CFR 312.120

**Legal Deadline:** None

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

**Timeframe:**

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**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** None

**Government Levels Affected:** None

**Agency Contact:** Brian L. Pendleton, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Suite 3037 (HFD–7), 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: pendletonb@cdrf.fda.gov

**RIN:** 0910–AF15

### 1046. BLOOD INITIATIVE—REVISED 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.

**Timeframe:**

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**Regulatory Flexibility Analysis Required:** No
**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; 21 USC 371a; 21 USC 331; 21 USC 360; 21 USC 371  
**CFR Citation:** 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358  
**Legal Deadline:** None  
**Abstract:** The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e. final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action addresses labeling 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 321; 21 USC 351 to 353; 21 USC 355; 21 USC 360a; 21 USC 371a; 21 USC 331; 21 USC 360; 21 USC 371

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

**Legal Deadline:** None

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

**Timetable:**

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**Regulatory Flexibility Analysis Required:** Yes

**Small Entities Affected:** Businesses

**Government Levels Affected:** 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

---

1051. OVER–THE–COUNTER (OTC) DRUG REVIEW—LAXATIVE DRUG PRODUCTS

**Priority:** Routine and Frequent

**Legal Authority:** 21 USC 321; 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 laxative 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–AF38

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1052. OVER–THE–COUNTER (OTC) DRUG REVIEW—SKIN PROTECTANT PRODUCTS

**Priority:** Routine and Frequent

**Legal Authority:** 21 USC 321; 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 360gg to 360ss; 21 USC 371; 21 USC 374; 21 USC 379e; 42 USC 216; 42 USC 241; 42 USC 262; 42 USC 264

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

**Legal Deadline:** None

**Abstract:** The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e. final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. One action addresses labeling for products formulated and marketed as lip protectants. The second action addresses skin protectant products to protect and treat fever blisters and cold sores.

**Timetable:**

**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

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1053. OVER–THE–COUNTER (OTC) DRUG REVIEW—VAGINAL CONTRACEPTIVE PRODUCTS

**Priority:** Routine and Frequent

**Legal Authority:** 21 USC 321; 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 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 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. Rachanow, Regulatory Counsel, Division of Over-the-Counter Drug Products, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, 5600 Fishers Lane, HFD–560, Rockville, MD 20857

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

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.

Timetable:

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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 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–AF47

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
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.

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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

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
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(ANADAs) to implement the manufacturing changes provision of the Food and Drug Modernization Act of 1997. The final rule requires manufacturers to assess the effect of a manufacturing change on the identity, strength, quality, purity, and potency of a drug as those factors relate to the safety or effectiveness of the drug. The final rule sets forth requirements for changes requiring submission and approval of a supplement before the distribution of the drug made using the change, changes requiring the submission of a supplement at least 30 days prior to the distribution of the drug, changes requiring the submission of a supplement at the time of distribution of the drug, and changes to be described in an annual report.

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 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).

Final Action 01/00/06

Regulatory Flexibility Analysis Required: No

Small Entities 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: 301 827–2315 Email: rachanow@cdr.fda.gov

RIN: 0910–AF52

1057. SUPPLEMENTS AND OTHER CHANGES TO APPROVED NEW ANIMAL DRUG APPLICATIONS

Priority: Substantive, Nonsignificant

Legal Authority: 21 USC 356a

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

Legal Deadline: None

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

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 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).

Final Action 01/00/06

Regulatory Flexibility Analysis Required: No

Small Entities Affected: None

Agency Contact: Dennis Bensley Jr., Chemist, 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: 301 827–2315 Email: dbensley@cvm.fda.gov

RIN: 0910–AF59

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 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
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

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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Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Christine F. Rodgers, 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

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.

Timetable:

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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
Phone: 301 436–2373
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

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 67492). These ANPRMs discussed the agencies’ regulations and policy governing food standards, the history of food standards, and the possible need to revise the food standards. Several comments in response to the ANPRMs recommended that the agencies establish general principles or a fundamental philosophy for reviewing food standards and revising them. The agencies agreed with these comments and determined that it would be appropriate to develop general principles for reviewing and revising food standards regulations. The agencies also agreed with the comments that stated that the agencies should work in concert to develop consistent food standards regulations. FDA and FSIS proposed a set of general principles that define how modern food standards should be structured (70 FR 29214, May 20, 2005). If this proposed rule is adopted, FDA and FSIS will require that a citizen petition for establishing, revising, or eliminating a food standard in 21 CFR parts 130 to 169 and 9 CFR part 319 be submitted in accordance with the general principles. Conversely, the agencies may find deficient a petition to establish, revise, or eliminate a food standard that does not follow these general principles.

**Timetable:**

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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
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Fax: 301 436–2636
Email: ritu.nalubola@fda.gov

**Related RIN:** Related to 0583–AC72

**RIN:** 0910–AC54

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**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
Fax: 301 827–5562
Email: mullerh@cdr.fda.gov

**RIN:** 0910–AF08

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**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 66404), 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.crane@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 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.

Timetable:

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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
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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 101.10; 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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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 oral health care products.

Timetable:
- Final Action (Plaque Gingivitis) 10/00/06

Regulatory Flexibility Analysis
- Required: Yes
- Small Entities Affected: Businesses

1070. OVER–THE–COUNTER (OTC) DRUG REVIEW—OVERINDULGENCE IN FOOD AND DRINK PRODUCTS

Priority: Routine and Frequent
Legal Authority: 21 USC 321p; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 360a; 21 USC 371; 21 USC 371a; 21 USC 331
CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358
Legal Deadline: None

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e. final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action addresses products containing bismuth subsalicylate for relief of symptoms of upset stomach due to overindulgence resulting from food and drink.
from nonambulatory disabled cattle, and material from cattle not inspected and passed for human consumption. The prohibitions would apply only to materials derived from animals slaughtered after the effective dates of the rules. The prohibitions would not apply to tallow that met a specified purity standard. The rule would provide criteria for deviations from the requirements based on a showing of safety or appropriate benefit to risk ratio.

**Timetable:**

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**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** 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, 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

### 1072. LABEL REQUIREMENT FOR FOOD THAT HAS BEEN REFUSED ADMISSION INTO THE UNITED STATES

**Priority:** Other Significant

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

**CFR Citation:** 21 CFR 1.98

**Legal Deadline:** None

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

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**Regulatory Flexibility Analysis Required:** Yes

**Small Entities Affected:** Businesses

**Government Levels Affected:** Undetermined

**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
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Email: philip.chao@fda.hhs.gov

**RIN:** 0910–AF61

### 1073. ● OVER–THE–COUNTER ANTIDIARRHEAL DRUG PRODUCTS

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

**Legal Authority:** 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 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 products containing antidiarrheal drug products.

**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

**Related RIN:** Related to 0910–AC82
**RIN:** 0910–AF63

### 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. Major status under 5 USC 801 is undetermined.

**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.

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**Regulatory Flexibility Analysis**

Required: Yes

**Government Levels Affected:** None

**Federalism:** Undetermined

**Agency Contact:** Myrna Hanna

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

RIN: 0910–AC34

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**1075. OVER-THE-COUNTER (OTC) DRUG REVIEW—URINARY ANALGESIC DRUG PRODUCTS**

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

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

Abstract: This action addresses the drug application, may be legally marketed. This action addresses the ingredient phenazopyridine.

**Timetable:**

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<td>NPRM (Urinary Analgesic)</td>
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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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**1076. REQUIREMENTS PERTAINING TO SAMPLING SERVICES AND PRIVATE LABORATORIES USED IN CONNECTION WITH IMPORTED FOOD**

Priority: Routine and Frequent

**CFR Citation:** 21 CFR 59

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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. Major status under 5 USC 801.

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

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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

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</table>

**Regulatory Flexibility Analysis**

Required: No
HHS—FDA

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Catherine Copp
Phone: 301 436–1589
Fax: 301 436–2637
Email: catherine.copp@cfsan.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:

Reason Date FR Cite
Final Rule 06/09/05 70 FR 33694

Regulatory Flexibility Analysis
Required: Yes

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–AA44

Department of Health and Human Services (HHS)

Health Resources and Services Administration (HRSA)

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@cfsan.fda.gov

RIN: 0910–AF10

1081. NATIONAL PRACTITIONER DATA BANK FOR ADVERSE INFORMATION ON PHYSICIANS 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, Rockville, MD 20857

**Email:** lstmartin@hrsa.gov

**Phone:** 301 443–4423

**Fax:** 301 443–8196

**RIN:** 0906–AA62

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**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, 300aa–15

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

**Legal Deadline:** None

**Abstract:** The Department of Health and Human Services (HHS) is proposing to revise the current method for calculating the average cost of a health insurance policy, which is an amount deducted from the award of compensation in certain cases.

**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

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

**Priority:** Other Significant. Major status under 5 USC 601 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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### Legal Deadline:
None
### Priority:
Other Significant
### Legal Authority:
PL 108–20, 117 Stat 638
### CFR Citation:
42 CFR 102
### Legal Deadline:
None
### Priority:
Other Significant
### Legal Authority:
42 USC 300ff–71
### CFR Citation:
Not Yet Determined
### Legal Deadline:
None
### Priority:
Other Significant
### Legal Authority:
42 USC 300ff–71
### CFR Citation:
Not Yet Determined
### 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.

#### Timetable:

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

Priority: Other Significant
Legal Authority: 42 USC 216
CFR Citation: 42 CFR 50.402
Legal Deadline: None
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.

Timetable:

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Department of Health and Human Services (HHS)

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

Priority: Substantive, Nonsignificant
Legal Authority: 42 USC 11131
CFR Citation: 45 CFR 60.7
Legal Deadline: None
Abstract: This notice of proposed rulemaking (NPRM) proposes to require that, in addition to reporting to the National Practitioner Data Bank medical malpractice payments made where physicians or other health care practitioners are named in medical malpractice actions or claims, judgments, or settlements, payments be reported where they are made for the benefit of physicians or other health care practitioners not named in the judgments or settlements but who furnished or failed to furnish the health care services upon which the actions or claims were based. The purpose of this NPRM is to prevent the evasion of the medical malpractice payment reporting requirement of the Data Bank through the agreement of the parties to a lawsuit to use the corporate health care entity to “shield” practitioners. It would also require malpractice payers, in very limited circumstances, when it is impossible to identify the practitioner who furnished or failed to furnish the health care services upon which the actions or claims were based, to report why the practitioner could not be identified, and to provide the name of the corporate health care entity.

Timetable:

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Regulatory Flexibility Analysis
Required: No

Government Levels Affected: Undetermined
Agency Contact: Gail Ellen Lipton, Director, Division of Grants Policy, Department of Health and Human Services, Health Resources and Services Administration, Room 11A–55, 5600 Fishers Lane, Rockville, MD 20857
Phone: 301 443–6509
Email: glipton@hrsa.gov
RIN: 0906–AA69

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

Priority: Other Significant. Major status under 5 USC 801 is undetermined.
Legal Authority: 42 USC 274e, sec 301, 1984; 42 USC 273 to 274d, sec 371 to 376; 42 USC 1320b–8, sec 1138
CFR Citation: 42 CFR 121
Legal Deadline: None
Abstract: The Department of Health and Human Services (HHS) proposes to amend the final rule governing the operation of the OPTN.

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

Timetable: Next Action Undetermined

Regulatory Flexibility Analysis
Required: No

Small Entities Affected: No

Government Levels Affected: None
Agency Contact: Dr. Hui—Hsing Wong, Medical Officer, Department of Health and Human Services, Health Resources and Services Administration, 5600 Fishers Lane, Mail Stop 16C–17, Parklawn Bldg., Rockville, MD 20857
Phone: 301 443–8104
Fax: 301 594–6095
Email: hwong@hrsa.gov
RIN: 0906–AA63
### Department of Health and Human Services (HHS)

**Indian Health Service (IHS)**

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**Regulatory Flexibility Analysis**

**Required:** No

**Government Levels Affected:** None

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

Phone: 301 443–1116

Email: bgould@hq.ihs.gov

**RIN:** 0917–AA07

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

**Legal Deadline:** None

**CFR Citation:** 42 USC 276b; 42 USC 288–5; 42 USC 288–5a; 42 USC 288–6; 42 USC 288–6a; 42 USC 288–6b

**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.

**Timetable:**

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### National Institutes of Health (NIH)

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<td>04/00/06</td>
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**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

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

**Legal Deadline:** None

**CFR Citation:** 42 CFR 64

**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 68a 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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### National Institutes of Health (NIH)

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**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–AA43

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**Legal Authority:** 42 USC 216

**Legal Deadline:** None

**CFR Citation:** 42 CFR 64

**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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**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–AA43
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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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.

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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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<td>01/28/05</td>
<td>70 FR 4080</td>
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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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### 1099. UNDERGRADUATE SCHOLARSHIP PROGRAM REGARDING PROFESSIONS NEEDED BY THE NATIONAL INSTITUTES OF HEALTH (NIH)

**Priority:** Substantive, Nonsignificant  
**CFR Citation:** 42 CFR 68b

Completed:  
- Reason: Withdrawn  
- Date: 08/05/05  
- FR Cite:  

**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–AA10

### 1100. NATIONAL INSTITUTES OF HEALTH LOAN REPAYMENT PROGRAM FOR RESEARCH GENERALLY

**Priority:** Substantive, Nonsignificant  
**CFR Citation:** 42 CFR 68d

Completed:  
- Reason: Withdrawn  
- Date: 08/05/05  
- FR Cite:  

**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–AA10

### 1101. NATIONAL INSTITUTES OF HEALTH AIDS RESEARCH LOAN REPAYMENT PROGRAM

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

Completed:  
- Reason: Withdrawn  
- Date: 08/05/05  
- FR Cite:  

**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:  
- Reason: Withdrawn  
- Date: 10/20/05  
- FR Cite:  

**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:  
- Reason: Withdrawn  
- Date: 10/20/05  
- FR Cite:  

**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:  
- Reason: Withdrawn  
- Date: 10/20/05  
- FR Cite:  

**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:  
- Reason: Withdrawn  
- Date: 10/20/05  
- FR Cite:  

**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
### 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–AA36

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### 1107. HUMAN SUBJECTS PROTECTION REGULATIONS: ADDITIONAL PROTECTIONS FOR ADULT INDIVIDUALS WITH IMPAIRED DECISIONMAKING CAPACITY

**Priority:** Substantive, Nonsignificant  
**Legal Authority:** 5 USC 301; 42 USC 289  
**CFR Citation:** 45 CFR 46  
**Legal Deadline:** None  
**Abstract:** Through this advance notice of proposed rulemaking (ANPRM), the Office for Human Research Protections (OHRP), Office of Public Health and Science, and the Food and Drug Administration (FDA) of the Department of Health and Human Services (HHS) are seeking comment on whether it is necessary to develop additional safeguards to help protect adult individuals with impaired decisionmaking capacity who are potential subjects in research, and if so, suggestions for appropriate safeguards. This ANPRM stems from the recommendation of an HHS working group, generated in response to the report published by the National Bioethics Advisory Commission entitled “Research Involving Persons with Mental Disorders That May Affect Decisionmaking Capacity” (December 1998), and from subsequent recommendations by the National Human Research Protections Advisory Committee. The goal of these efforts is to maximize the safety and welfare of adult subjects with impaired decisionmaking capacity who participate in research supported, conducted, or regulated by HHS.

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**Regulatory Flexibility Analysis**  
**Required:** No  
**Small Entities Affected:** No  
**Government Levels Affected:** None  
**Agency Contact:** 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–AA11

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### 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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<td>65 FR 70830</td>
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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
### 1107. 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 current OHRP IRB registration system, the submission of certain registration information is required by human subjects protection regulations, and certain other information may be submitted voluntarily. This proposed information collection was submitted to the Office of Management and Budget under the Paperwork Reduction Act. Under the proposed rule, all registration information will be required, making the IRB registration system uniform with IRB registration requirements of the Food and Drug Administration (FDA), and creating a single, HHS IRB Registration system. FDA simultaneously published a proposed rule regarding FDA IRB registration requirements.

### 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 Wootton Parkway, Rockville, MD 20852  
Phone: 240 453–6900  
Fax: 301 402–2071

**RIN:** 0940–AA06

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### 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.

### Timetable:

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**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–AA10

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**Department of Health and Human Services (HHS)**  
**Office of Public Health and Science (OPHS)**

### 1111. HUMAN SUBJECTS PROTECTION REGULATIONS: TRAINING AND ED. REQUIREMENTS FOR INSTITUTIONAL OFFICIALS, INSTITUTIONAL REVIEW BOARD MEMBERS AND STAFF, HUMAN PROTECTIONS ADMINISTRATORS, AND INVESTIGATORS

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

**Legal Authority:** 5 USC 301; 42 USC 289

**CFR Citation:** 45 CFR 46

**Legal Deadline:** None

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

### Timetable:

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HHS—OPHS

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

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:
Reason Date FR Cite
Final Action 05/17/05 70 FR 28370
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

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

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

1114. HOME HEALTH AGENCY (HHA) CONDITIONS OF PARTICIPATION (COP) (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

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

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
This proposed rule would implement a standard identifier to identify health plans that process and pay certain electronic health care transactions. It would implement one of the requirements for administrative simplification that have a national scope beyond Medicare and Medicaid.

**Timetable:**

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**Regulatory Flexibility Analysis**

**Priority:** Substantive, Nonsignificant

**Legal Deadline:** Final, Statutory, February 21, 1998.

**Abstract:** This proposed rule would implement a standard identifier to identify health plans that process and pay certain electronic health care transactions. It would implement one of the requirements for administrative simplification that have a national scope beyond Medicare and Medicaid. This rule would incorporate provisions from section 936 of the Medicare Modernization Act.
### Proposed Rule Stage

<table>
<thead>
<tr>
<th>Proposed Rule Stage</th>
<th>Certification Group, Department of Health and Human Services, Centers for Medicare &amp; Medicaid Services, Mailstop S2–11–27, 7500 Security Boulevard, Baltimore, MD 21244–1850 Phone: 410 786–0663 Email: <a href="mailto:carla.mcgregor@cms.hhs.gov">carla.mcgregor@cms.hhs.gov</a></th>
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#### 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
- **Agency Contact:** Gladys C. Wheeler, 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: 410 786–0273 Email: gladys.wheeler@cms.hhs.gov
- **RIN:** 0938–AM50

- **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.

- **Timetable:**

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- **Regulatory Flexibility Analysis**
  - **Required:** Yes

- **Small Entities Affected:** Businesses
- **Government Levels Affected:** Federal, State, Tribal

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

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

- **Priority:** Other Significant. Major status under 5 USC 801 is undetermined.
- **Unfunded Mandates:** Undetermined
- **Legal Authority:** Sec 1171 to 1179 of the Social Security Act
- **CFR Citation:** 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 detailed in regulations published by HHS on August 17, 2000, and February 20, 2003.

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

- **Priority:** Economically Significant. Major status under 5 USC 801 is undetermined.
- **Unfunded Mandates:** Undetermined
- **Legal Authority:** 42 USC 1395l–3; 42 USC 1396r
- **CFR Citation:** 42 CFR 483
- **Legal Deadline:** None
- **Abstract:** This proposed rule establishes requirements that hospice agencies and long term care (LTC) facilities must meet to participate in the Medicare and Medicaid programs. We are proposing these new requirements to ensure that quality hospice care is provided to eligible residents.

- **Timetable:**

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- **Regulatory Flexibility Analysis**
  - **Required:** Yes

- **Small Entities Affected:** Businesses
- **Government Levels Affected:** Federal, State, Tribal

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

#### 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.

- **Timetable:**

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- **Regulatory Flexibility Analysis**
  - **Required:** Yes

- **Small Entities Affected:** Businesses
- **Government Levels Affected:** Federal, State, Tribal

- **Federalism:** This action may have federalism implications as defined in EO 13132.
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)(8) of the MMA; Sec 416 of the MMA; PL 108–173
CFR Citation: Final, Statutory, July 1, 2004.
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.
Timetable:
Action | Date | FR Cite
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NPRM | 05/00/06 | 42 CFR, 488.1 to 488.9
Regulatory Flexibility Analysis | Required: Yes
Small Entities Affected: Businesses
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.
Timetable:
Action | Date | FR Cite
--- | --- | ---
NPRM | 10/07/05 | 70 FR 58649
Final Action | 10/00/08 | 70 FR 58649
Regulatory Flexibility Analysis | Required: No
Small Entities Affected: No
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–AN31

1126. LIMITATION ON RECOUPMENT OF OVERPAYMENTS (CMS–6025–P)
Priority: Other Significant. Major status 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.
Timetable:
Action | Date | FR Cite
--- | --- | ---
NPRM | 07/00/06 | 64603
Regulatory Flexibility Analysis | Required: No
Small Entities Affected: No
Government Levels Affected: None
Agency Contact: Nancy Braymer, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop C3–14–21, 7500 Security Boulevard, Baltimore, MD 21244 Phone: 410 786–4323 Email: nancy.braymer@cms.hhs.gov
RIN: 0938–AN42

1127. REVISIONS TO THE OVERSIGHT AND VALIDATION PROGRAM FOR ACCREDITING ORGANIZATIONS APPROVED FOR DEEMING AUTHORITY (CMS–2255–P)
Priority: Other Significant. Major under 5 USC 801.
Legal Authority: Sec 1864; Social Security Act, sec 1865; Social Security Act, sec 1875
CFR Citation: 42 CFR 488.1 to 488.9
Legal Deadline: None
Abstract: This proposed rule would respond to the recommendations in the GAO Report, “CMS Needs Additional Authority to Adequately Oversee Patient Safety in Hospitals” (GAO-04-850). With respect to the oversight and validation of hospital accreditation programs, a rate of disparity calculation is specified in Federal regulations at 42 CFR, 488.8. This rule proposes to consider additional alternative measures to assess the performance of the accreditation organizations.
Timetable:
Action | Date | FR Cite
--- | --- | ---
NPRM | 07/00/06 | 64603
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]0][B]

CFR Citation: 42 CFR 411.357


Abstract: This rule proposes an exception to the physician self-referral prohibition for certain nonmonetary remuneration related to electronic prescribing (section 1860D-4 of the Medicare Modernization Act).

Timetable:

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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 1329d to 1320d–8); NPI final rule (01/23/2004); NPI 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.

Timetable:

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Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Helen Dietrick, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of Financial Management, Program Integrity Group, Mailstop C3–02–16, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786–7448

Email: helen.dietrick@cms.hhs.gov

RIN: 0938–AN71

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.

**Timetable:**

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**Regulatory Flexibility Analysis**

**Required:** No

**Small Entities Affected:** Businesses

**Government Levels Affected:** None

**Agency Contact:** Danielle N. Shearer, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Clinical Standards Group, Mailstop 53–02–01, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786–6617
Fax: 410 786–8532
Email: danielle.shearer@cms.hhs.gov

**RIN:** 0938–AN79

### 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.

**Timetable:**

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**Regulatory Flexibility Analysis**

**Required:** No

**Small Entities Affected:** Businesses

**Government Levels Affected:** None

**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–AN82

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### 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.

**Timetable:**

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**Regulatory Flexibility Analysis**

**Required:** Universally available.

**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

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### 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.)

**Timetable:**

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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

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### 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

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

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1136. ● 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 revise the fee schedule for payment of ambulance services specifically with respect to the definition of Specialty Care Transport (SCT) and the Metropolitan Statistical Area (MSA) geographic breakdown in relation to payment of ambulance services under Medicare. In addition, this proposed rule, discusses the conversion factor and the effect of low billers.

Timetable:

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Regulatory Flexibility Analysis
Required: Undetermined
Small Entities Affected: Governmental Jurisdictions
Government Levels Affected: Undetermined
Federalism: Undetermined
Agency Contact: Ellen W. Blackwell, Disability & Elderly Health Programs Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicaid State Operations, Mailstop S2–26–12, 7500 Security Boulevard, Baltimore, MD 21244–1850 Phone: 410 786–4498 Fax: 410 786–3262 Email: ellen.blackwell@cms.hhs.gov
RIN: 0938–AO07

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

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 CFR 416

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).

Timetable:

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<th>Action</th>
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Regulatory Flexibility Analysis
Required: Yes
Small Entities Affected: Businesses
Government Levels Affected: Federal
**Federalism:** This action may have federalism implications as defined in EO 13132.

**Agency Contact:** Rebecca Kane, Health Insurance Specialist, Center for Medicare Management, Hospital & Ambulatory Policy Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Division Group of Outpatient Care, Mailstop C5–01–28, 7500 Security Boulevard, Baltimore, MD 21244–1850
Phone: 410 786–1589
Email: rebecca.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:**  
**Action:** NPRM  
**Date:** 08/00/06  
**FR Cite:**  

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

**Agency Contact:** Jeremy Silanskis, Health Insurance Specialist, Center for Medicare Services, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Division Group of Outpatient Care, Mailstop C5–01–28, 7500 Security Boulevard, Baltimore, MD 21244–1850
Phone: 410 786–1589
Fax: 410 786–8533
Email: jeremy.silanskis@cms.hhs.gov

| RIN: | 0938–AO22 |

### 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 Medicaid program. The purpose of this amendment is to clarify the scope of services available for federal financial participation (FFP) under the outpatient hospital services benefit category.

**Timetable:**  
**Action:** NPRM  
**Date:** 08/00/06  
**FR Cite:**  

**Regulatory Flexibility Analysis Required:** Undetermined  
**Small Entities Affected:** Businesses

**Government Levels Affected:** Undetermined  
**Federalism:** Undetermined

**Agency Contact:** Jeremy Silanskis, Health Insurance Specialist, Center for Medicare Services, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Division Group of Outpatient Care, Mailstop C5–01–28, 7500 Security Boulevard, Baltimore, MD 21244–1850
Phone: 410 786–1589
Fax: 410 786–8533
Email: jeremy.silanskis@cms.hhs.gov

| RIN: | 0938–AO17 |

### 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
Proposed notice. Comments to be addressed as part of final physician fee.
Final, Statutory, November 1, 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:**  
**Action:** NPRM  
**Date:** 07/00/06  
**FR Cite:**  

**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 C5–01–28, 7500 Security Boulevard, Baltimore, MD 21244–1850
Phone: 410 786–4597
Email: bkuhl@cms.hhs.gov

| RIN: | 0938–AO16 |

### 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:**  
**Action:** NPRM  
**Date:** 07/00/06  
**FR Cite:**
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: Reference to Section 1893(i)(1) of the Social Security Act as amended by Section 701 of the 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, 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

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 21244–1850
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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<td>65 FR 69416</td>
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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 441; 42 CFR 442; 42 CFR 483  
**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  
Email: mary.clarkson@cms.hhs.gov  
**Related RIN:** Related to 0938–AL27  
**RIN:** 0938–AN02

### 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.  
**Timetable:**  
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**Regulatory Flexibility Analysis Required:** No  
**Small Entities Affected:** Businesses  
**Government Levels Affected:** None  
**Agency Contact:** Mary Clarkson, Health Insurance Specialist, Disabled & Elderly Health Programs Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop C5–02–24, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786–5650  
Email: mary.clarkson@cms.hhs.gov  
**Related RIN:** Related to 0938–AH73  
**RIN:** 0938–AJ36

### 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–AJ96

### 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)).  
**Timetable:**  
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**Regulatory Flexibility Analysis Required:** Yes  
**Small Entities Affected:** Businesses

### 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:** Joel Kaiser, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop C5–02–24, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786–5499  
Email: joel.kaiser@cms.hhs.gov  
**Related RIN:** Related to 0938–AL27  
**RIN:** 0938–AN02
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.

| Timetable: |  
| --- | --- | --- |  
| Action | Date | FR Cite |  
| NPRM | 11/26/04 | 69 FR 69178 |  
| Interim Final Rule | 05/04/05 | 70 FR 23690 |  
| Final Action | 01/06/06 |  |  

**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–AN09 |

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 rule updates the 60-day national episode rates and the national per-visit amounts under the Medicare prospective payment system for home health agencies.

| Timetable: |  
| --- | --- | --- |  
| Action | Date | FR Cite |  
| NPRM | 07/14/05 | 70 FR 40788 |  
| Final Action | 11/06/05 |  |  

**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, 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 |

1155. CHANGES TO THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM AND CALENDAR YEAR 2006 PAYMENT RATES (CMS–1501–FC)

**Regulatory Plan:** This entry is Seq. No. 54 in part II of this issue of the Federal Register.  
**RIN:** 0938–AN46

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  
**Legal Deadline:** Final, Statutory, February 10, 2006, MMA sec. 902.  
**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.

| Timetable: |  
| --- | --- | --- |  
| Action | Date | FR Cite |  
| NPRM | 02/10/06 | 68 FR 6682 |  
| Final Action | 02/06/06 |  |  

**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 C5–03–03, 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>69 FR 52620</td>
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<td>Interim Final Rule</td>
<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)

Timetable:

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Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: 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.

Timetable:

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Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: State


Phone: 410 786–2019

Email: richard.strauss@cms.hhs.gov

RIN: 0938–ΛΟ04

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
Legal Deadline: None
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.

Timetable:

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<tr>
<td>Agency Contact</td>
<td>Janice A. Graham RN, Health Insurance Specialist, Clinical Standards Group, Department of Health and Human Services, Centers for Medicare &amp; Medicaid Services, Office of Clinical Standards and Quality, Mailstop S3–02–01, 7500 Security Boulevard, Baltimore, MD 21244–1850</td>
<td></td>
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<tr>
<td>Phone</td>
<td>410 786–8020</td>
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<td>Fax</td>
<td>410 786–2532</td>
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<tr>
<td>Email: <a href="mailto:janice.graham@cms.hhs.gov">janice.graham@cms.hhs.gov</a></td>
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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
Abstract: This notice announces the hospital insurance premium for Calendar Year 2007 under Medicare’s Hospital Insurance program (Medicare Part A) for the uninsured aged and for certain disabled individuals who have exhausted other entitlement.

Timetable:

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<td>Agency Contact</td>
<td>Clare McFarland, Division Director, Medicare and Medicaid Cost Estimates Group, Department of Health and Human Services, Centers for Medicare &amp; Medicaid Services, Office of Actuary, Mailstop N3–26–00, 7500 Security Boulevard, Baltimore, MD 21244–1850</td>
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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
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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<td>Agency Contact</td>
<td>Clare McFarland, Division Director, Medicare and Medicaid Cost Estimates Group, Department of Health and Human Services, Centers for Medicare &amp; Medicaid Services, Office of Actuary, Mailstop N3–26–00, 7500 Security Boulevard, Baltimore, MD 21244–1850</td>
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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
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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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:
Action Date FR Cite
Final Action 09/00/06
Regulatory Flexibility Analysis Required: No
Small Entities Affected: No
Government Levels Affected: None
Agency Contact: Suzanne Codespote, Division Director of 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 Phone: 410 786–7737 Email: suzanne.codespote@cms.hhs.gov RIN: 0938–AO23

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:
Action Date FR Cite
Final Action 07/00/06
Regulatory Flexibility Analysis Required: Undetermined
Small Entities Affected: Businesses
Government Levels Affected: Undetermined
Federalism: Undetermined
Agency Contact: Bill Ullman, Health Insurance Specialist, Division of Institutional Post Acute Care, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Hospital and Ambulatory Policy Group, Mailstop C5–08–18, 7500 Security Boulevard, Baltimore, MD 21244–1850 Phone: 410 786–9462 Email: bill.ullman@cms.hhs.gov RIN: 0938–AO25

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:
Action Date FR Cite
Final Action 08/00/06
Regulatory Flexibility Analysis Required: Undetermined
Small Entities Affected: Businesses
Government Levels Affected: Undetermined
Federalism: Undetermined
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

1169. END STAGE RENAL DISEASE (ESRD) CONDITIONS FOR COVERAGE (CMS–3818–F) (SECTION 610 REVIEW)
Priority: Other Significant
Legal Authority: 42 USC 1395rr et al
CFR Citation: 42 CFR 400; 42 CFR 405; 42 CFR 410; 42 CFR 412 to 414; 42 CFR 488; 42 CFR 494
Abstract: This final rule revises the requirements that end stage renal disease (ESRD) facilities must meet to be certified under the Medicare program.

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

Timetable:
Action Date FR Cite
NPRM 02/04/05 70 FR 6184
Final Action 02/00/08
Regulatory Flexibility Analysis Required: Yes
Small Entities Affected: Businesses
Government Levels Affected: None
Agency Contact: Teresa Casey, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Clinical Standards Group, Mailstop S3–02–01, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–6797
Email: mary.casey@cms.hhs.gov

Rebecca Donnay, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Clinical Standards Group, Mailstop S3–02–01, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–1428
Email: rebecca.donnay@hhs.gov

Robert Miller, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Clinical Standards Group, Division of Non–Institutional Quality Standards, S3–04–25, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–6051
Email: robert.miller@cms.hhs.gov

1171. HOSPICE CARE—CONDITIONS OF PARTICIPATION (CMS–3844–F) (SECTION 610 REVIEW)

Priority: Other Significant
Legal Authority: 42 USC 1302; 42 USC 1395(hh)
CFR Citation: 42 CFR 418
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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<td>05/27/08</td>
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Regulatory Flexibility Analysis
Required: Undetermined

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

1172. MEDICARE OUTCOME AND ASSESSMENT INFORMATION SET (OASIS) DATA REPORTING REQUIREMENTS (CMS–3006–F)

Priority: Other Significant. Major under 5 USC 801.

Unfunded Mandates: This action may affect State, local or tribal governments and the private sector.

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@hhs.gov
RIN: 0938–AJ10

1173. STANDARDS FOR ELECTRONIC HEALTH CARE CLAIM ATTACHMENTS (CMS–0050–P)

Priority: Economically Significant. Major under 5 USC 801.

Unfunded Mandates: This action may affect State, local or tribal governments.

Legal Authority: 42 USC 1320d–2(a)(2)(B)
CFR Citation: 45 CFR 162
Abstract: This rule finalizes an electronic standard for claims

Timetable:

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Regulatory Flexibility Analysis
Required: No

Small Entities Affected: Businesses, Organizations

Government Levels Affected: None

Agency Contact: Mary Rossi–Coajou, 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: 410 786–6051
Email: mary.rossicoajou@cms.hhs.gov
RIN: 0938–AH27
attachment. The standard is required by the Health Insurance Portability and Accountability Act of 1996. It will be used to transmit clinical data, in addition to the data contained in the claims standard, to help establish medical necessity for coverage and payment.

**Timetable:**

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**Regulatory Flexibility Analysis**

**Required:** No

**Small Entities Affected:** Businesses

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

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

**Agency Contact:** 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–25–02, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786–6597

Email: lorraine.doo@cms.hhs.gov

RIN: 0938–AK62

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

**Priority:** Other Significant

**Legal Authority:** 42 USC 300gg; PL 104–191

**CFR Citation:** 42 CFR 146.113; 45 CFR 146.115; 45 CFR 146.117; 45 CFR 146.120; 45 CFR 146.145

**Legal Deadline:** None

**Abstract:** This final rule will clarify certain portability requirements for group health plans and issuers of health insurance coverage offered in connection with a group health plan. It also implements changes made to the Internal Revenue Code, the Employee Retirement Income Security Act, and the Public Health Service Act enacted as part of the Health Insurance Portability and Accountability Act of 1996.

**Timetable:**

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**Regulatory Flexibility Analysis**

**Required:** No

**Small Entities Affected:** Businesses, Organizations

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

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

**Agency Contact:** David Mlawsky, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare Management, Chronic Care Policy Group, Mailstop C4–25–02, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786–6851

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.
Required:
Regulatory Flexibility Analysis
Final Action 02/00/07

NPRM 02/27/04 69 FR 9282
Action Date FR Cite
Interim Final Rule 08/15/03 68 FR 48805
Interim Final Rule 10/16/03
Comment Period End
Final Action 12/00/06

Timetable:

Regulatory Flexibility Analysis
Required: Undetermined

Government Levels Affected: None

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

Legal Deadline: None

RIN: 0938–AM22

1178. REQUIREMENTS FOR 
LONG–TERM CARE FACILITIES;
NURSING SERVICES; POSTING OF 
NURSE STAFFING INFORMATION 
(CMS–3121–F)

Priority: Other Significant

Legal Authority: Sec 1819(b) of the Social Security Act; 42 USC 1395i–3(b)

CFR Citation: 42 CFR 483

Legal Deadline: Final, Statutory, February 27, 2007, MMA sec. 902.

Abstract: This final rule implements section 941 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 and requires nursing homes to post daily, for each shift, the number of registered nurses, licensed practical nurses, licensed vocational nurses, and certified nurse aides who are directly responsible for resident care.

Timetable:

Action Date FR Cite
NPRM 02/27/04 69 FR 9282
NPRM Comment Period End
Final Action 02/00/07

Regulatory Flexibility Analysis
Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Anita Panicker,
Health Insurance Specialist,
Department of Health and Human
Services, Centers for Medicare &
Medicaid Services, Clinical Standards
Group, S3–02–01, 7500 Security
Boulevard, Baltimore, MD 21244
Phone: 410 786–5646
Fax: 410 786–8532
Email: anita.panicker@cms.hhs.gov

RIN: 0938–AM55

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

Priority: Economically Significant. Major under 5 USC 801.

Legal Authority: Sec 521 of BIPA

CFR Citation: 42 CFR 401 and 405


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).

Timetable:

Action Date FR Cite
Interim Final Rule 03/08/05 70 FR 11419
Interim Final Rule 06/30/05 70 FR 37700
Final Action 06/00/08

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 & Medicaid 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

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

Priority: Economically Significant. Major under 5 USC 801.

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.

Timetable:

Action Date FR Cite
Interim Final Rule 08/26/05 70 FR 50939
Final Rule 08/00/08

Regulatory Flexibility Analysis
Required: No

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Karen Daily, Health Insurance Specialist Coverage & Analysis Group, Department of Health and Human Services, Centers for Medicare & Medicaid 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

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 1396d; 42 USC 1395bb

CFR Citation: 42 CFR 482

Abstract: This rule will reduce the burden on hospitals and allow hospitals to conform to current standards of practice. Hospitals would meet these final requirements to participate in Medicare and Medicaid. They must establish and maintain policies and procedures that would ensure their hospital would meet these requirements by using standard practices for history and physical examinations, securing medications, authenticating verbal orders, and completing post-anesthesia evaluations.

Timetable:

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Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Organizations

Government Levels Affected: None

Additional Information: Decreases burden for hospitals and clinicians.

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

Phone: 410 786–6899

Email: patricia.chmielewski@cms.hhs.gov

RIN: 0938–AM88

1183. PRIOR DETERMINATION PROCESS FOR CERTAIN ITEMS AND SERVICES (CMS–6024–P)

Priority: Other Significant

Legal Authority: Sec 938 of the Medicare Modernization Act of 2003

CFR Citation: 42 CFR 146.121

Legal Deadline: Not Yet Determined

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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Final Action 12/00/06

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–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

Government Levels Affected: None

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: 410 786–8020

Email: janice.graham@cms.hhs.gov

RIN: 0938–AN30

1186. 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 final rule amends, 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 plans.

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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, Center for Beneficiary Choices, Medicare Plan Policy Group, Mailstop S3–16–26, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786–6851

Email: david.mlawsky@cms.hhs.gov

RIN: 0938–AN35

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, hospitals, long-term care facilities, intermediate care facilities for the mentally retarded, and critical access hospitals that participate in Medicare and Medicaid. The rule adopts a change made to the 2000 edition of the Life Safety Code (LSC) published by the National Fire Protection Association (NFPA). 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.

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Comments Final Action 03/00/08

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, Clinical Standards Group, Mailstop S3–02–01, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786–6617

Email: danielle.shearer@cms.hhs.gov

RIN: 0938–AN36

1188. REVISED CIVIL MONEY PENALTIES, ASSESSMENTS, 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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### 1189. ELECTRONIC PRESCRIBING STANDARDS (CMS–0011–F)

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

**Legal Authority:** 42 USC 1395

**CFR Citation:** None


**Abstract:** This final rule requires Medicare part D plans and Medicare Advantage Plans to support electronic transmission of basic prescription data to, and from, doctors and pharmacies, and to adopt a number of the initial standards required for electronic prescribing by section 1860(d) of the Medicare Modernization Act.

**Timetable:**

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### 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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**Regulatory Flexibility Analysis Required:** Yes

**Small Entities Affected:** Businesses

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

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

**Agency Contact:** 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

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

**Priority:** Other Significant. Major 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

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

**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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**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

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

**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

### 1193. MEDICARE INTEGRITY PROGRAM, FISCAL INTERMEDIARY AND CARRIER FUNCTIONS, AND CONFLICT OF INTEREST REQUIREMENTS (CMS–6030–F)

**Priority:** Other Significant

**Legal Authority:** Sec 902 of the MMA

**CFR Citation:** Not Yet Determined

**Legal Deadline:** Final, Statutory, June 17, 2008, MMA sec. 902.

**Abstract:** This rule finalizes certain sections of the Medicare regulations concerning fiscal intermediaries and carriers and brings them into conformity with the Medicare statute. The rule would distinguish between those functions that the statute requires to be included in agreements with fiscal intermediaries and those that may be included in carrier contracts. Currently all these functions are mandatory for carrier contracts.

**Timetable:**

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**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** Businesses

**Government Levels Affected:** None

**Agency Contact:** Lauren Haley, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop C5–08–27, 7500 Security Boulevard, Baltimore, MD 21244 Phone: 410 786–5655 Email: lauren.haley@cms.hhs.gov

**Related RIN:** Related to 0938–AL09

**RIN:** 0938–AN72

### 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 the December 13, 2002, interim final rule and sets forth the process for establishing realistic and equitable payment amounts for all Medicare part B items and services (other than physician services) when the existing payment amounts are inherently unreasonable because they are either grossly excessive or grossly deficient. The rule describes the factors CMS (or its carriers) will consider, and the procedures that will be followed in establishing realistic and equitable payment amounts. This rule implements section 4316 of the BBA, and section 223 of the BBRA that required CMS to publish this subsequent final rule.

**Timetable:**

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**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** None

**Agency Contact:** Bill Long, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare Management, Mailstop C5–08–27, 7500 Security Boulevard, Baltimore, MD 21244 Phone: 410 786–3137 Email: bill.long@cms.hhs.gov

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

**RIN:** 0938–AN81

### 1195. PROGRAM FOR ALL–INCLUSIVE CARE FOR THE ELDERLY (PACE): PROGRAM REVISIONS (CMS–1201–F)

**Priority:** Other Significant

**Legal Authority:** PL 108–173, sec 902 of MMA; BIPA, sec 903

**CFR Citation:** 42 CFR 460

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

1197. ● LOAN FORGIVENESS CRITERIA FOR THE HEALTH CARE INFRASTRUCTURE LOAN PROGRAM (CMS–1320–F)

Priority: Other Significant
Legal Authority: sec 1016 of PL 108–173
CFR Citation: 42 CFR 505
Abstract: The Secretary is authorized to forgive such loans awarded in the Health Care Infrastructure Improvement Program if the hospital establishes an outreach program for cancer prevention, early diagnosis, and treatment for a substantial majority of the residents of the state, a similar program for multiple Indian tribes, and either unique research resources or an affiliation with an entity that has unique research resources.

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.
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.

Regulatory Flexibility Analysis
Required: Undetermined
Small Entities 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 21244–1850
Phone: 410 786–4524
Email: dsimms@cms.hhs.gov
Related RIN: Related to 0938–AL51
RIN: 0938–AN87

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 Medicare 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

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

1200. SUPPLIER STANDARDS FOR HOME OXYGEN, THERAPEUTIC SHOES, AND HOME NUTRITION THERAPY (CMS–6010–P)
Priority: Substantive, Nonsignificant
CFR Citation: 42 CFR 424.57
Completed:

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Regulatory Flexibility Analysis
Required: Yes
Small Entities Affected: Businesses
Government Levels Affected: None
Agency Contact: Ralph Goldberg
Phone: 410 786–4870
RIN: 0938–AJ98

1201. EVALUATION CRITERIA AND STANDARDS FOR QUALITY IMPROVEMENT PROGRAM CONTRACTS (CMS–3142–FN)
Priority: Info./Admin./Other
CFR Citation: None
Completed:

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Regulatory Flexibility Analysis
Required: No
Small Entities Affected: No
Government Levels Affected: None
Agency Contact: Maria L. Hammel
Phone: 410 786–1775
Email: maria.hammel@cms.hhs.gov
RIN: 0938–AN13

1202. NONDISCRIMINATION IN POST–HOSPITAL REFERRAL TO HOME HEALTH AGENCIES AND OTHER ENTITIES (CMS–1224–F)
Priority: Substantive, Nonsignificant
CFR Citation: 42 CFR 482
Completed:

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Required: No
Small Entities Affected: No
Government Levels Affected: None
Agency Contact: Sarah Shipey
Phone: 410 786–0187
RIN: 0938–AN19

1203. MEDICARE AMBULANCE FEE SCHEDULE UPDATE (CMS–1492–IFC)
Priority: Other Significant
CFR Citation: 42 CFR 414, subpart H
Completed:

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Regulatory Flexibility Analysis
Required: Yes
Small Entities Affected: Businesses
Government Levels Affected: Local
Agency Contact: Robert Niemann
Phone: 410 786–4596
Email: rniemann@cms.hhs.gov
Related RIN: Related to 0938–AO11
RIN: 0938–AN24

1204. PROSPECTIVE PAYMENT SYSTEM FOR LONG TERM CARE HOSPITALS: ANNUAL PAYMENT RATE UPDATES AND POLICY CHANGES FOR 2006 (CMS–1483–F)
Priority: Economically Significant. Major under 5 USC 801.
CFR Citation: None
Completed:

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Regulatory Flexibility Analysis
Required: Yes
Small Entities Affected: Businesses
Government Levels Affected: None
Agency Contact: Judy Richter
Phone: 410 786–2590
Email: jrichter@cms.hhs.gov
RIN: 0938–AN28

1205. PROSPECTIVE PAYMENT SYSTEM FOR INPATIENT REHABILITATION FACILITIES FOR FY 2006 (CMS–1290–F)
Priority: Economically Significant. Major under 5 USC 801.
CFR Citation: None
Completed:

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Regulatory Flexibility Analysis
Required: No
Small Entities Affected: Businesses
Government Levels Affected: None
Agency Contact: Robert Kuhl
Phone: 410 786–4597
Email: bob.kuhl@cms.hhs.gov
RIN: 0938–AN43
### HHS—CMS

#### 1206. DEVELOPMENT OF NEW STANDARDS FOR MEDIGAP POLICIES (CMS–4087–FN)

**Priority:** Substantive, Nonsignificant  
**CFR Citation:** None  
**Completed:**

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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  
**Related RIN:** Related to 0938–AN08  
**RIN:** 0938–AN50

### 1207. FISCAL YEAR 2006 SCHIP ALLOTMENTS (CMS–2219–N)

**Priority:** Other Significant  
**CFR Citation:** 42 CFR 457  
**Completed:**

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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.  
**CFR Citation:** 42 CFR 409; 42 CFR 411; 42 CFR 424; 42 CFR 489  
**Completed:**

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**Regulatory Flexibility Analysis Required:** Yes  
**Small Entities Affected:** Businesses  
**Government Levels Affected:** None  
**Agency Contact:** Marc Hartstein  
Phone: 410 786–6192  
Email: marc.hartstein@cms.hhs.gov  
**RIN:** 0938–AN57

### 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.  
**CFR Citation:** 42 CFR 410; 42 CFR 414; 42 CFR 424  
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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.  
**CFR Citation:** 42 CFR 146  
**Completed:**

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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–AN65

### 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  
**Completed:**

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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–F3)

**Priority:** Other Significant  
**CFR Citation:** 42 CFR 146  
**Completed:**

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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:  
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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 C5–08–28, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786–4597  
Email: bob.kuhl@cms.hhs.gov  
RIN: 0938–AN92

1215. • INPATIENT REHABILITATION FACILITY CLASSIFICATION RULE COMPLIANCE (CMS–1480–N)  
Priority: Other Significant  
Legal Authority: Public Law 108–477, in accordance with the Consolidated Appropriations Act of 2005  
CFR Citation: 420CFR 412.23(b)(2)  
Legal Deadline: None  
Abstract: In accordance with the provisions of the Consolidated Appropriations Act of 2005, the notice announces the Secretary’s determination that the requirements for classification as 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.  
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Regulatory Flexibility Analysis  
Required: No  
Small Entities Affected: No  
Government Levels Affected: None  
Agency Contact: Ann Tayloe, 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: atayloe@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  
CFR Citation: 42 CFR 483  
Legal Deadline: None  
Abstract: This rule would mandate nursing facilities to immunize each resident for influenza and pneumonia and would reinforce 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:  
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Regulatory Flexibility Analysis  
Required: No  
Small Entities Affected: No  
Government Levels Affected: None  
Agency 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

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)  
CFR Citation: None  
Legal Deadline: None
Government Levels Affected: 1219.

RIN: 0938–AN88

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 1395i–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) for the uninsured aged and for certain disabled individuals who have exhausted other entitlement.

Timetable:

Action
Notice
Regulatory Flexibility Analysis
Required: No
Small Entities Affected: No
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 1395e–2(b)[2]; 42 USC 1395i thru 2a(d)[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:

Action
Notice
Regulatory Flexibility Analysis
Required: No
Small Entities Affected: No
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(b)(7)[B]; SSA 1860D–31(b)[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:

Action
Final Action
Regulatory Flexibility Analysis
Required: No
Small Entities Affected: No
Agency Contact: Richard Strauss, Technical Director, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Centers for Medicaid Operations Services, Mailstop S3–13–15, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786–2019
Email: richard.strauss@cms.hhs.gov

Related RIN: Related to 0938–AM71

RIN: 0938–AN97

RIN: 0938–AN96

RIN: 0938–AN88
### 1222. **MEDICARE PART B MONTHLY ACTUARIAL RATES AND PREMIUM RATE BEGINNING JANUARY 1, 2006** (CMS–8027–N)

**Priority:** Economically Significant  
Major under 5 USC 801.  
**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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<td>70 FR 55897</td>
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### 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.  
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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.  
**Timetable:**  
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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.

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**Regulatory Flexibility Analysis**

**Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** State

**Agency Contact:** Grant Collins, Deputy Director, Department of Health and Human Services, Administration for Children and Families, 370 L’Enfant Promenade SW., Washington, DC 20447

**Email:** gcollins@acf.hhs.gov

**Phone:** 202 401–6953

**Fax:** 202 205–8221

**C Street SW., Washington, DC 20447**

**370 L’Enfant Promenade SW., Washington, DC 20447**

**Drug Abuse Resistance Education (DARE) Program**

**Priority:** Other Significant

**Legal Authority:** 42 USC 679

**CFR Citation:** 45 CFR 1355

**Legal Deadline:** None

**Abstract:** This rule amends the Drug Abuse Resistance Education (DARE) Program to include the term “drug-resistant.” This rule would also require that the Drug Abuse Resistance Education (DARE) Program use the term “drug-resistant” when referring to illicit drugs in the program’s literature, web pages, and other material.

**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

**Email:** kmchugh@acf.hhs.gov

**Phone:** 202 401–5789

**Fax:** 202 205–8221

**AFCARS penalty requirements of the Adoption and Foster Care Analysis and Reporting System (AFDCARS)**

**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 (AFDCARS) 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 AFDCARS penalty requirements of the Adoption Promotion Act of 2003 (P.L. 108–145).

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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

**Email:** kmchugh@acf.hhs.gov

**Phone:** 202 401–5789

**Fax:** 202 205–8221

**AFCARS penalty requirements of the Adoption and Foster Care Analysis and Reporting System (AFDCARS)**

**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 (AFDCARS) 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 AFDCARS penalty requirements of the Adoption Promotion Act of 2003 (P.L. 108–145).

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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

**Email:** kmchugh@acf.hhs.gov

**Phone:** 202 401–5789

**Fax:** 202 205–8221
Department of Health and Human Services (HHS)
Administration for Children and Families (ACF)

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:
Action Date FR Cite
NPRM 01/31/05 70 FR 4803
Final Action 11/00/05
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: 202 401–5789 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:
Action Date FR Cite
NPRM 11/09/04 69 FR 64881
Final Action 12/00/05
Regulatory Flexibility Analysis Required: No
Small Entities Affected: No

Government Levels Affected: Local, State
Agency Contact: Windy Hill, Associate Commissioner, Head Start Bureau, Department of Health and Human Services, 330 C Street SW., Washington, DC 20447 Phone: 202 205–8573 Email: whill@acf.hhs.gov
RIN: 0970–AC16

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:
Action Date FR Cite
Interim Final Rule 12/28/04 69 FR 77659
Final Action 12/00/05
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