Monday,
December 22, 2003

Part VIII

Department of
Health and Human
Services

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

Office of the Secretary

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

21 CFR Ch. I

42 CFR Chs. I-V

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

Regulatory Agenda

AGENCY: Office of the Secretary, HHS.

ACTION: Semiannual agenda.

SUMMARY: The Regulatory Flexibility Act of 1980 and Executive Order 12866 require the semiannual publication of an inventory of all rulemaking actions under development or review, known as the regulatory agenda. The purpose of this effort is to encourage public participation in the regulatory process by providing, at an early stage, summarized information about regulatory actions that the Department is working on. Citizens interested in communicating to the Department their views on the rulemakings prospectively outlined below are invited to do so.

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

SUPPLEMENTARY INFORMATION: The capsulized information provided below reflects an effort to present 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 a notice of proposed rulemaking, or a final rule within the next 12 months. Also included in the Long-Term Action sections below are summaries of actions that are under development, but which we will probably not complete within the next 12 months.

We welcome hearing the views of all concerned with regard to these planned regulatory or deregulatory actions.

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 warranted, comments should be sent to: Ann C. Agnew, Executive Secretary to the Department, Room 603H, 200 Independence Avenue SW., Washington, DC 20201.

The Office of Management and Budget requires that fall editions of the agenda be augmented by a regulatory plan, highlighting the most important regulatory issues across the executive branch. The HHS portion of the Plan appears in part II of this issue of the Federal Register with those of other Departments and Agencies. Our Plan entries are included in the table of contents below, denoted by a bracketed bold reference to the appropriate sequence number in part II.


Ann C. Agnew,
Executive Secretary to the Department.

Office of the Secretary—Proposed Rule Stage

<table>
<thead>
<tr>
<th>Sequence Number</th>
<th>Title</th>
<th>Regulation Identification Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>961</td>
<td>Safe Harbor for Arrangements Involving Federally Qualified Health Centers</td>
<td>0991–AB06</td>
</tr>
<tr>
<td>962</td>
<td>Claims Collection</td>
<td>0991–AB18</td>
</tr>
<tr>
<td>963</td>
<td>Salary Offset</td>
<td>0991–AB19</td>
</tr>
<tr>
<td>964</td>
<td>Health Insurance Portability and Accountability Act–Enforcement (Reg Plan Seq No. 40)</td>
<td>0991–AB29</td>
</tr>
</tbody>
</table>

Office of the Secretary—Final Rule Stage

<table>
<thead>
<tr>
<th>Sequence Number</th>
<th>Title</th>
<th>Regulation Identification Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>965</td>
<td>Shared Risk Exception to the Safe Harbor Provisions</td>
<td>0991–AA91</td>
</tr>
<tr>
<td>966</td>
<td>Safe Harbor for Waiver of Beneficiary Coinsurance and Deductible Amounts for a Medicare SELECT Policy</td>
<td>0991–AB16</td>
</tr>
<tr>
<td>967</td>
<td>Tax Refund Offset</td>
<td>0991–AB17</td>
</tr>
<tr>
<td>969</td>
<td>Clarification of Terms and Application of Program Exclusion Authority for Submitting Claims Containing Excessive Charges</td>
<td>0991–AB23</td>
</tr>
</tbody>
</table>

Office of the Secretary—Long-term Actions

<table>
<thead>
<tr>
<th>Sequence Number</th>
<th>Title</th>
<th>Regulation Identification Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>970</td>
<td>Revisions to Regulations Addressing the OIG’s Authority to Impose Civil Money Penalties and Assessments</td>
<td>0991–AB03</td>
</tr>
<tr>
<td>971</td>
<td>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</td>
<td>0991–AB10</td>
</tr>
</tbody>
</table>
### HHS

**Office of the Secretary—Completed Actions**

<table>
<thead>
<tr>
<th>Sequence Number</th>
<th>Title</th>
<th>Regulation Identification Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>972</td>
<td>Governmentwide Debarment and Suspension (Nonprocurement) and Governmentwide Requirements for Drug-Free Workplace (Grants)</td>
<td>0991–AB12</td>
</tr>
</tbody>
</table>

**Substance Abuse and Mental Health Services Administration—Proposed Rule Stage**

<table>
<thead>
<tr>
<th>Sequence Number</th>
<th>Title</th>
<th>Regulation Identification Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>973</td>
<td>Requirements Governing the Use of Seclusion and Restraint in Certain Nonmedical Community-Based Facilities for Children and Youth <em>(Reg Plan Seq No. 41)</em></td>
<td>0930–AA10</td>
</tr>
<tr>
<td>974</td>
<td>Mandatory Guidelines for the Federal Workplace Drug Testing Program</td>
<td>0930–AA12</td>
</tr>
</tbody>
</table>

References in boldface appear in the Regulatory Plan in part II of this issue of the *Federal Register*.

**Substance Abuse and Mental Health Services Administration—Final Rule Stage**

<table>
<thead>
<tr>
<th>Sequence Number</th>
<th>Title</th>
<th>Regulation Identification Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>975</td>
<td>Substance Abuse and Mental Health Services Administration (SAMHSA) Charitable Choice</td>
<td>0930–AA11</td>
</tr>
</tbody>
</table>

**Centers for Disease Control and Prevention—Proposed Rule Stage**

<table>
<thead>
<tr>
<th>Sequence Number</th>
<th>Title</th>
<th>Regulation Identification Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>976</td>
<td>Amendments to Quality Assurance and Administrative Provision for Approval of Respiratory Protective Devices</td>
<td>0920–AA04</td>
</tr>
</tbody>
</table>

**Centers for Disease Control and Prevention—Final Rule Stage**

<table>
<thead>
<tr>
<th>Sequence Number</th>
<th>Title</th>
<th>Regulation Identification Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>977</td>
<td>Procedures for Designating Classes of Employees as Members of the Special Exposure Cohort Under the Energy Employee Occupational Illness Compensation Act of 2000</td>
<td>0920–AA07</td>
</tr>
</tbody>
</table>

**Food and Drug Administration—Prerule Stage**

<table>
<thead>
<tr>
<th>Sequence Number</th>
<th>Title</th>
<th>Regulation Identification Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>978</td>
<td>Over-the-Counter (OTC) Drug Review</td>
<td>0910–AA01</td>
</tr>
<tr>
<td>979</td>
<td>Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food (Part 110) <em>(Section 610 Review)</em></td>
<td>0910–AC58</td>
</tr>
<tr>
<td>980</td>
<td>Health Claims</td>
<td>0910–AF09</td>
</tr>
<tr>
<td>981</td>
<td>Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements, and Administrative Procedures; Derivatives of Blood</td>
<td>0910–AF16</td>
</tr>
</tbody>
</table>

**Food and Drug Administration—Proposed Rule Stage**

<table>
<thead>
<tr>
<th>Sequence Number</th>
<th>Title</th>
<th>Regulation Identification Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>982</td>
<td>Foreign and Domestic Establishment Registration and Listing Requirements for Drugs and Biologics</td>
<td>0910–AA49</td>
</tr>
</tbody>
</table>
### Food and Drug Administration—Proposed Rule Stage (Continued)

<table>
<thead>
<tr>
<th>Sequence Number</th>
<th>Title</th>
<th>Regulation Identification Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>983</td>
<td>Blood Initiative</td>
<td>0910–AB26</td>
</tr>
<tr>
<td>984</td>
<td>Applications for FDA Approval To Market a New Drug; Complete Response Letter; Amendments To Unapproved Applications</td>
<td>0910–AB34</td>
</tr>
<tr>
<td>985</td>
<td>Current Good Manufacturing Practice for Medicated Feeds</td>
<td>0910–AB70</td>
</tr>
<tr>
<td>986</td>
<td>Requirements Pertaining to Sampling Services and Private Laboratories Used in Connection With Imported Food</td>
<td>0910–AB96</td>
</tr>
<tr>
<td>987</td>
<td>Prevention of Salmonella Enteritidis in Shell Eggs <em>(Reg Plan Seq No. 42)</em></td>
<td>0910–AC14</td>
</tr>
<tr>
<td>988</td>
<td>Institutional Review Boards: Registration Requirements</td>
<td>0910–AC17</td>
</tr>
<tr>
<td>989</td>
<td>Use of Materials Derived From Bovine and Ovine Animals in FDA-Regulated Products</td>
<td>0910–AC19</td>
</tr>
<tr>
<td>990</td>
<td>Chronic Wasting Disease: Control of Food Products and Cosmetics Derived From Exposed Animal Populations</td>
<td>0910–AC21</td>
</tr>
<tr>
<td>991</td>
<td>Exception From General Requirements for Informed Consent; Request for Comments and Information <em>(Reg Plan Seq No. 43)</em></td>
<td>0910–AC25</td>
</tr>
<tr>
<td>992</td>
<td>Medical Devices; Anesthesiology Devices; Proposed Reclassification of Pressure Regulators for Use With Medical Oxygen</td>
<td>0910–AC30</td>
</tr>
<tr>
<td>993</td>
<td>Toll-Free Number for Reporting Adverse Events on Labeling for Human Drugs <em>(Reg Plan Seq No. 44)</em></td>
<td>0910–AC35</td>
</tr>
<tr>
<td>994</td>
<td>Food Labeling: Trans Fatty Acids in Nutrition Labeling; Consumer Research To Consider Nutrient Content and Health Claims and Possible Footnote or Disclosure Statements</td>
<td>0910–AC50</td>
</tr>
<tr>
<td>995</td>
<td>Submission of Standardized Electronic Study Data From Clinical Studies Evaluating Human Drugs and Biologics</td>
<td>0910–AC52</td>
</tr>
<tr>
<td>996</td>
<td>Medical Gas Containers and Closures; Current Good Manufacturing Practice Requirements</td>
<td>0910–AC53</td>
</tr>
<tr>
<td>997</td>
<td>Food Standards: General Principles and Food Standards Modernization</td>
<td>0910–AC54</td>
</tr>
<tr>
<td>998</td>
<td>Positron Emission Tomography Drugs; Current Good Manufacturing Practices</td>
<td>0910–AC55</td>
</tr>
<tr>
<td>999</td>
<td>Revision of the Requirements for Spore-Forming Microorganisms</td>
<td>0910–AC57</td>
</tr>
<tr>
<td>1000</td>
<td>Definition of “Serious Adverse Health Consequences” Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 <em>(Reg Plan Seq No. 45)</em></td>
<td>0910–AF06</td>
</tr>
<tr>
<td>1002</td>
<td>Quality Standard Regulation Establishing Allowable Level for Arsenic in Bottled Water</td>
<td>0910–AF10</td>
</tr>
<tr>
<td>1003</td>
<td>Content and Format of Labeling for Human Prescription Drugs and Biologics: Requirements for Pregnancy and Lactation</td>
<td>0910–AF11</td>
</tr>
<tr>
<td>1004</td>
<td>Cochineal Extract and Carmine Label Declaration</td>
<td>0910–AF12</td>
</tr>
<tr>
<td>1005</td>
<td>Charging for Investigational Drugs</td>
<td>0910–AF13</td>
</tr>
<tr>
<td>1006</td>
<td>Treatment Use of Investigational Drugs</td>
<td>0910–AF14</td>
</tr>
<tr>
<td>1007</td>
<td>Human Subject Protection; Foreign Clinical Studies Not Conducted Under an Investigational New Drug Application</td>
<td>0910–AF15</td>
</tr>
<tr>
<td>1008</td>
<td>Use of Ozone-Depleting Substances: Removal of Essential Use Designation; Albuterol <em>(Reg Plan Seq No. 46)</em></td>
<td>0910–AF18</td>
</tr>
</tbody>
</table>

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### Food and Drug Administration—Final Rule Stage

<table>
<thead>
<tr>
<th>Sequence Number</th>
<th>Title</th>
<th>Regulation Identification Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>1009</td>
<td>Infant Formula: Requirements Pertaining to Good Manufacturing Practice, Quality Control Procedures, Quality Factors, Notification Requirements, and Records and Reports</td>
<td>0910–AA04</td>
</tr>
<tr>
<td>1010</td>
<td>Investigational New Drugs: Export Requirements for Unapproved Drug Products</td>
<td>0910–AA61</td>
</tr>
<tr>
<td>1011</td>
<td>Determination That Informed Consent Is Infeasible or Is Contrary to the Best Interest of Recipients</td>
<td>0910–AA89</td>
</tr>
<tr>
<td>1012</td>
<td>Labeling for Human Prescription Drugs; Revised Format <em>(Reg Plan Seq No. 47)</em></td>
<td>0910–AA94</td>
</tr>
<tr>
<td>1013</td>
<td>Safety Reporting Requirements for Human Drug and Biological Products <em>(Reg Plan Seq No. 48)</em></td>
<td>0910–AA97</td>
</tr>
<tr>
<td>1014</td>
<td>Supplements and Other Changes to an Approved Application</td>
<td>0910–AB61</td>
</tr>
<tr>
<td>1015</td>
<td>CGMP for Blood and Blood Components: Notification of Consignees and Transfusion Recipients Receiving Blood and Blood Components at Increased Risk of Transmitting HCV Infection (Lookback) <em>(Reg Plan Seq No. 49)</em></td>
<td>0910–AB76</td>
</tr>
<tr>
<td>1016</td>
<td>Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements <em>(Reg Plan Seq No. 50)</em></td>
<td>0910–AB88</td>
</tr>
<tr>
<td>1017</td>
<td>Requirements for Submission of Labeling for Human Prescription Drugs and Biologics in Electronic Format</td>
<td>0910–AB91</td>
</tr>
<tr>
<td>1018</td>
<td>Additional Safeguards for Children in Clinical Investigations of FDA-Regulated Products</td>
<td>0910–AC07</td>
</tr>
<tr>
<td>1019</td>
<td>Bar Code Label Requirements for Human Product and Blood <em>(Reg Plan Seq No. 51)</em></td>
<td>0910–AC26</td>
</tr>
<tr>
<td>1020</td>
<td>Medical Devices: Patient Examination and Surgeons’ Gloves: Adulteration</td>
<td>0910–AC32</td>
</tr>
<tr>
<td>1021</td>
<td>Amendments to the Performance Standard for Diagnostic X-Ray Systems and Their Major Components</td>
<td>0910–AC34</td>
</tr>
<tr>
<td>1022</td>
<td>Administrative Detention of Food for Human or Animal Consumption Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 <em>(Reg Plan Seq No. 52)</em></td>
<td>0910–AC38</td>
</tr>
</tbody>
</table>
## Food and Drug Administration—Final Rule Stage (Continued)

<table>
<thead>
<tr>
<th>Sequence Number</th>
<th>Title</th>
<th>Regulation Identification Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>1023</td>
<td>Establishment and Maintenance of Records Pursuant to the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Reg Plan Seq No. 53)</td>
<td>0910–AC39</td>
</tr>
<tr>
<td>1024</td>
<td>Registration of Food and Animal Feed Facilities</td>
<td>0910–AC40</td>
</tr>
<tr>
<td>1025</td>
<td>Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002</td>
<td>0910–AC41</td>
</tr>
<tr>
<td>1026</td>
<td>Requirements for Liquid Medicated Feed and Free-Choice Medicated Feed</td>
<td>0910–AC43</td>
</tr>
<tr>
<td>1027</td>
<td>Presubmission Conferences</td>
<td>0910–AC44</td>
</tr>
<tr>
<td>1028</td>
<td>Biological Products; Bacterial Vaccines and Toxoids; Implementation of Efficacy Review</td>
<td>0910–AC56</td>
</tr>
<tr>
<td>1029</td>
<td>Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; Revision of Certain Labeling Controls</td>
<td>0910–AF08</td>
</tr>
</tbody>
</table>

References in boldface appear in the Regulatory Plan in part II of this issue of the Federal Register.

## Food and Drug Administration—Long-term Actions

<table>
<thead>
<tr>
<th>Sequence Number</th>
<th>Title</th>
<th>Regulation Identification Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>1030</td>
<td>Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue–Based Products</td>
<td>0910–AB27</td>
</tr>
<tr>
<td>1031</td>
<td>Current Good Tissue Practice for Human Cell, Tissue, and Cellular and Tissue-Based Products Establishments; Inspection and Enforcement</td>
<td>0910–AB28</td>
</tr>
<tr>
<td>1032</td>
<td>Requirements for Submission of In Vivo Bioequivalence Data</td>
<td>0910–AC23</td>
</tr>
<tr>
<td>1033</td>
<td>Food Labeling: Food Allergen Ingredient Labeling</td>
<td>0910–AF07</td>
</tr>
</tbody>
</table>

## Food and Drug Administration—Completed Actions

<table>
<thead>
<tr>
<th>Sequence Number</th>
<th>Title</th>
<th>Regulation Identification Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>1034</td>
<td>Investigational Use New Animal Drug Regulations (Completion of a Section 610 Review)</td>
<td>0910–AB02</td>
</tr>
<tr>
<td>1035</td>
<td>Food Labeling: Trans Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims</td>
<td>0910–AB66</td>
</tr>
<tr>
<td>1036</td>
<td>Aluminum in Large- and Small-Volume Parenterals Used in Total Parenteral Nutrition</td>
<td>0910–AC18</td>
</tr>
<tr>
<td>1037</td>
<td>Regulation of Carcinogenic Compounds Used in Food-Producing Animals; Definition of “No Residue”</td>
<td>0910–AC45</td>
</tr>
<tr>
<td>1038</td>
<td>Applications for FDA Approval To Market a New Drug: Patent Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications</td>
<td>0910–AC48</td>
</tr>
</tbody>
</table>

## Health Resources and Services Administration—Proposed Rule Stage

<table>
<thead>
<tr>
<th>Sequence Number</th>
<th>Title</th>
<th>Regulation Identification Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>1039</td>
<td>National Practitioner Data Bank for Adverse Information on Physicians and Other Health Care Practitioners: Medical Malpractice Payments Reporting Requirements</td>
<td>0906–AA41</td>
</tr>
<tr>
<td>1040</td>
<td>Designation of Medically Underserved Populations and Health Professional Shortage Areas</td>
<td>0906–AA44</td>
</tr>
</tbody>
</table>

## Health Resources and Services Administration—Final Rule Stage

<table>
<thead>
<tr>
<th>Sequence Number</th>
<th>Title</th>
<th>Regulation Identification Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>1041</td>
<td>Interim Final Rule for the Smallpox Emergency Personnel Protection Program: Smallpox (Vaccinia) Vaccine Injury Table</td>
<td>0906–AA60</td>
</tr>
<tr>
<td>1042</td>
<td>Smallpox Vaccine Injury Compensation Program: Administrative Implementation (Reg Plan Seq No. 54)</td>
<td>0906–AA61</td>
</tr>
</tbody>
</table>

References in boldface appear in the Regulatory Plan in part II of this issue of the Federal Register.
### Health Resources and Services Administration—Long-term Actions

<table>
<thead>
<tr>
<th>Sequence Number</th>
<th>Title</th>
<th>Regulation Identification Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>1043</td>
<td>National Practitioner Data Bank for Adverse Information on Physicians and Other Health Care Practitioners: Reporting Adverse and Negative Actions</td>
<td>0906–AA57</td>
</tr>
</tbody>
</table>

### Indian Health Service—Completed Actions

<table>
<thead>
<tr>
<th>Sequence Number</th>
<th>Title</th>
<th>Regulation Identification Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>1044</td>
<td>Indian Child Protection and Family Violence Prevention Act Minimum Standards of Character</td>
<td>0917–AA02</td>
</tr>
</tbody>
</table>

### National Institutes of Health—Proposed Rule Stage

<table>
<thead>
<tr>
<th>Sequence Number</th>
<th>Title</th>
<th>Regulation Identification Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>1045</td>
<td>Undergraduate Scholarship Program Regarding Professions Needed by the National Institutes of Health (NIH)</td>
<td>0925–AA10</td>
</tr>
<tr>
<td>1046</td>
<td>National Institutes of Health Training Grants</td>
<td>0925–AA28</td>
</tr>
<tr>
<td>1047</td>
<td>Standards for a National Chimpanzee Sanctuary System</td>
<td>0925–AA31</td>
</tr>
<tr>
<td>1048</td>
<td>National Institutes of Health AIDS Research Loan Repayment Program</td>
<td>0925–AA32</td>
</tr>
<tr>
<td>1049</td>
<td>National Institutes of Health Extramural Loan Repayment Program for Clinical Researchers</td>
<td>0925–AA33</td>
</tr>
<tr>
<td>1050</td>
<td>National Institutes of Health Pediatric Research Loan Repayment Program</td>
<td>0925–AA34</td>
</tr>
<tr>
<td>1051</td>
<td>National Institutes of Health Loan Repayment Program for Health Disparities Research</td>
<td>0925–AA35</td>
</tr>
<tr>
<td>1052</td>
<td>National Institutes of Health Clinical Research Loan Repayment Program for Individuals From Disadvantaged Backgrounds</td>
<td>0925–AA36</td>
</tr>
<tr>
<td>1053</td>
<td>National Institute of Child Health and Human Development Contraception and Infertility Research Loan Repayment Program</td>
<td>0925–AA41</td>
</tr>
</tbody>
</table>

### National Institutes of Health—Final Rule Stage

<table>
<thead>
<tr>
<th>Sequence Number</th>
<th>Title</th>
<th>Regulation Identification Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>1054</td>
<td>National Institutes of Health Loan Repayment Program for Research Generally</td>
<td>0925–AA18</td>
</tr>
<tr>
<td>1055</td>
<td>Scientific Peer Review of Research Grant Applications and Research and Development Contract Projects</td>
<td>0925–AA20</td>
</tr>
<tr>
<td>1056</td>
<td>National Institutes of Health Center Grants</td>
<td>0925–AA24</td>
</tr>
</tbody>
</table>

### Office of Public Health and Science—Proposed Rule Stage

<table>
<thead>
<tr>
<th>Sequence Number</th>
<th>Title</th>
<th>Regulation Identification Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>1057</td>
<td>Public Health Service Policies on Research Misconduct</td>
<td>0940–AA04</td>
</tr>
<tr>
<td>1058</td>
<td>Human Subjects Protection Regulations: Institutional Review Boards Registration Requirements</td>
<td>0940–AA06</td>
</tr>
<tr>
<td>1059</td>
<td>Human Subjects Protection Regulations: Training and Education Requirements for Institutional Officials, Institutional Review Board Members and Staff, Human Protections Administrators, and Investigator</td>
<td>0940–AA08</td>
</tr>
</tbody>
</table>

### Office of Public Health and Science—Final Rule Stage

<table>
<thead>
<tr>
<th>Sequence Number</th>
<th>Title</th>
<th>Regulation Identification Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>1060</td>
<td>Public Health Service Standards for the Protection of Research Misconduct Whistleblowers</td>
<td>0940–AA01</td>
</tr>
</tbody>
</table>
### Centers for Medicare & Medicaid Services—Proposed Rule Stage

<table>
<thead>
<tr>
<th>Sequence Number</th>
<th>Title</th>
<th>Regulation Identification Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>1061</td>
<td>End Stage Renal Disease (ESRD) Conditions for Coverage (CMS–3818–P) (Section 610 Review) (Reg Plan Seq No. 55)</td>
<td>0938–AG82</td>
</tr>
<tr>
<td>1062</td>
<td>Hospital Conditions of Participation: Requirements for Approval and Reapproval of Transplant Centers To Perform Organ Transplants (CMS–3835–P) (Reg Plan Seq No. 56)</td>
<td>0938–AH17</td>
</tr>
<tr>
<td>1063</td>
<td>Hospice Care—Conditions of Participation (CMS–3844–P)</td>
<td>0938–AH27</td>
</tr>
<tr>
<td>1065</td>
<td>Health Insurance Reform: Claims Attachments Standards (CMS–0050–P)</td>
<td>0938–AK62</td>
</tr>
<tr>
<td>1066</td>
<td>Organ Procurement Organization Conditions for Coverage (CMS–3064–P) (Reg Plan Seq No. 57)</td>
<td>0938–AK81</td>
</tr>
<tr>
<td>1067</td>
<td>Use of Restraint and Seclusion in Medicare and Medicaid Participating Facilities That Provide Inpatient or Residential Care (CMS–2130–P) (Reg Plan Seq No. 58)</td>
<td>0938–AL26</td>
</tr>
<tr>
<td>1068</td>
<td>Prospective Payment System for Inpatient Psychiatric Facilities FY 2004 (CMS–1213–F) (Reg Plan Seq No. 59)</td>
<td>0938–AL50</td>
</tr>
<tr>
<td>1069</td>
<td>Provider Reimbursement Determinations and Appeals (CMS–1727–P)</td>
<td>0938–AL54</td>
</tr>
<tr>
<td>1070</td>
<td>Health Coverage Portability's Request for Information on Benefit-Specific Waiting Periods (CMS–2150–NC)</td>
<td>0938–AL64</td>
</tr>
<tr>
<td>1071</td>
<td>DMERC Service Areas and Related Matters (CMS–1219–F)</td>
<td>0938–AL76</td>
</tr>
<tr>
<td>1072</td>
<td>Revisions to Conditions for Coverage for Ambulatory Surgical Centers (CMS–3887–P)</td>
<td>0938–AL80</td>
</tr>
<tr>
<td>1073</td>
<td>Health Coverage Portability: Tolling Certain Time Periods and Interactions With Family and Medical Leave Act (CMS–2158–P)</td>
<td>0938–AM13</td>
</tr>
<tr>
<td>1074</td>
<td>Criteria for Determining Whether a Drug is Considered Usually Self-Administered (CMS–1228–P)</td>
<td>0938–AM36</td>
</tr>
<tr>
<td>1076</td>
<td>Hospital Patients' Rights CoP—Standard Safety Compliance Committees (CMS–3120–P) (Reg Plan Seq No. 60)</td>
<td>0938–AM46</td>
</tr>
<tr>
<td>1077</td>
<td>Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities—Update for FY 2005 (CMS–1249–N)</td>
<td>0938–AM50</td>
</tr>
<tr>
<td>1078</td>
<td>Modifications to Electronic Transactions and Code Sets (CMS–0009–P)</td>
<td>0938–AM54</td>
</tr>
<tr>
<td>1079</td>
<td>Revised Civil Money Penalties, Assessments, Exclusions, and Related Appeals Procedures (CMS–6146–P)</td>
<td>0938–AM55</td>
</tr>
<tr>
<td>1080</td>
<td>Requirements for Nursing Homes To Identify the Number of Licensed and Unlicensed Nurses (CMS–3121–P)</td>
<td>0938–AM75</td>
</tr>
<tr>
<td>1081</td>
<td>Changes to the Hospital Outpatient Prospective System and Calendar Year 2005 Payment Rates (CMS–1427–P)</td>
<td>0938–AM80</td>
</tr>
<tr>
<td>1082</td>
<td>Changes to the Hospital Inpatient Prospective Payment System and FY 2005 Rates (CMS–1428–P)</td>
<td>0938–AM81</td>
</tr>
<tr>
<td>1083</td>
<td>Covered Outpatient Drugs Under the Medicaid Drug Rebate Program (CMS–2174–P)</td>
<td>0938–AM82</td>
</tr>
<tr>
<td>1084</td>
<td>Prospective Payment System for Inpatient Rehabilitation Facilities for FY 2005 (CMS–1360–P)</td>
<td>0938–AM84</td>
</tr>
<tr>
<td>1085</td>
<td>Prospective Payment System for Long-Term Care Hospitals: Annual Payment Rate Updates and Policy Changes (Effective 7/1/04) (CMS–1263–P)</td>
<td>0938–AM86</td>
</tr>
<tr>
<td>1086</td>
<td>Payment Error Rate Measurement (PERM) Program (CMS–2186–P)</td>
<td>0938–AM87</td>
</tr>
<tr>
<td>1087</td>
<td>Requirements for Long-Term Care Facilities: Hospice Services (CMS–3140–P)</td>
<td>0938–AM90</td>
</tr>
<tr>
<td>1088</td>
<td>Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005 (CMS–1429–P)</td>
<td>0938–AM93</td>
</tr>
<tr>
<td>1089</td>
<td>Home Health Prospective Payment System Rate Update FY 2005 (CMS–1265–P)</td>
<td>0938–AM94</td>
</tr>
<tr>
<td>1090</td>
<td>Revisions to Cost Sharing Regulations (CMS–2144–P)</td>
<td>0938–AM95</td>
</tr>
</tbody>
</table>

References in boldface appear in the Regulatory Plan in part II of this issue of the Federal Register.

### Centers for Medicare & Medicaid Services—Final Rule Stage

<table>
<thead>
<tr>
<th>Sequence Number</th>
<th>Title</th>
<th>Regulation Identification Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>1091</td>
<td>Home Health Agency (HHA) Conditions of Participation (CoPs) (CMS–3819–FC)</td>
<td>0938–AG81</td>
</tr>
<tr>
<td>1092</td>
<td>Requirements for Establishing and Maintaining Medicare Billing Privileges (CMS–6002–F)</td>
<td>0938–AH17</td>
</tr>
<tr>
<td>1093</td>
<td>Health Insurance Reform: Standard Unique Health Care Provider Identifier (CMS–0045–F)</td>
<td>0938–AH27</td>
</tr>
<tr>
<td>1094</td>
<td>Appeals of Carrier Determination That a Supplier Fails To Meet the Requirements for Medicare Billing Privileges (CMS–6003–F)</td>
<td>0938–AH99</td>
</tr>
<tr>
<td>1095</td>
<td>Coverage of Religious Nonmedical Health Care Institutions (CMS–1909–F)</td>
<td>0938–AI49</td>
</tr>
<tr>
<td>1096</td>
<td>Medicare Outcome and Assessment Information Set (OASIS) Data Reporting Requirements (CMS–3006–F)</td>
<td>0938–AJ93</td>
</tr>
<tr>
<td>1098</td>
<td>Hospital Conditions of Participation: Laboratory Services (CMS–3014–F)</td>
<td>0938–AJ29</td>
</tr>
<tr>
<td>1099</td>
<td>Medicare Hospice Care Amendments (CMS–1022–F)</td>
<td>0938–AJ36</td>
</tr>
<tr>
<td>1100</td>
<td>Use of Restraint and Seclusion in Residential Treatment Facilities Providing Inpatient Psychiatric Services to Individuals Under Age 21 (CMS–2065–F) (Reg Plan Seq No. 61)</td>
<td>0938–AJ86</td>
</tr>
<tr>
<td>1101</td>
<td>All Provider Bad Debt Payment (CMS–1126–F)</td>
<td>0938–AK02</td>
</tr>
</tbody>
</table>
### Centers for Medicare & Medicaid Services—Final Rule Stage (Continued)

<table>
<thead>
<tr>
<th>Sequence Number</th>
<th>Title</th>
<th>Regulation Identification Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>1102</td>
<td>Review of National Coverage Determinations and Local Coverage Determinations (CMS–3063–F)</td>
<td>0938–AK60</td>
</tr>
<tr>
<td>1103</td>
<td>Physicians’ Referrals to Health Care Entities With Which They Have Financial Relationships—Phase II (CMS–1810–FC)</td>
<td>0938–AK67</td>
</tr>
<tr>
<td>1104</td>
<td>Rate of Reimbursement of Photocopy Expenses for Quality Improvement Organizations (CMS–3055–F)</td>
<td>0938–AK68</td>
</tr>
<tr>
<td>1105</td>
<td>Elimination of Statement of Intent Procedures for Filing Medicare Claims (CMS–1185–F)</td>
<td>0938–AK79</td>
</tr>
<tr>
<td>1106</td>
<td>Extending Medicare Entitlement When Disability Benefit Entitlement Ends Because of Substantial Gainful Activity (CMS–4018–F)</td>
<td>0938–AK94</td>
</tr>
<tr>
<td>1107</td>
<td>Medicare Program; Interest Calculation (CMS–6014–F)</td>
<td>0938–AL14</td>
</tr>
<tr>
<td>1108</td>
<td>Health Coverage Portability for Group Health Plans and Group Health Insurance Issuers (CMS–2151–F)</td>
<td>0938–AL43</td>
</tr>
<tr>
<td>1109</td>
<td>Permitting Premium Reductions as Additional Benefits Under Medicare+Choice Plans (CMS–6016–F)</td>
<td>0938–AL49</td>
</tr>
<tr>
<td>1110</td>
<td>Revisions to the Medicare Appeals Process (CMS–4004–FC) (Reg Plan Seq No. 62)</td>
<td>0938–AL67</td>
</tr>
<tr>
<td>1111</td>
<td>Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2004 Payment Rates (CMS–1471–F)</td>
<td>0938–AL91</td>
</tr>
<tr>
<td>1112</td>
<td>Electronic Medicare Claims Submission (CMS–0008–F)</td>
<td>0938–AM22</td>
</tr>
<tr>
<td>1113</td>
<td>Inpatient Hospital Deductible and Hospital and Extended Care Services Coinsurance Amounts for Calendar Year 2004 (CMS–8016–N)</td>
<td>0938–AM31</td>
</tr>
<tr>
<td>1114</td>
<td>Monthly Actuarial Rates and Monthly Supplementary Medical Insurance Premium Rate Beginning January 1, 2004 (CMS–8017–N)</td>
<td>0938–AM32</td>
</tr>
<tr>
<td>1115</td>
<td>Part A Premiums for Calendar Year 2004 for the Uninsured Aged and for Certain Disabled Individuals Who Have Exhausted Other Entitlement (CMS–8018–N)</td>
<td>0938–AM33</td>
</tr>
<tr>
<td>1116</td>
<td>Grants to States for Operation of Qualified High Risk Pools (CMS–2179–F)</td>
<td>0938–AM42</td>
</tr>
<tr>
<td>1117</td>
<td>Fee Schedule for Payment of Ambulance Services Update for Calendar Year 2004 (CMS–1232–FC)</td>
<td>0938–AM44</td>
</tr>
<tr>
<td>1118</td>
<td>Non-Federal Governmental Plans Exempt From HIPAA Title I Requirements (CMS–2033–F)</td>
<td>0938–AM71</td>
</tr>
<tr>
<td>1119</td>
<td>Revisions to the Appeals Process for Initial Claim Determinations (CMS–4064–F) (Reg Plan Seq No. 63)</td>
<td>0938–AM73</td>
</tr>
<tr>
<td>1120</td>
<td>More Flexible Requirements for Powered-Operated Vehicles (CMS–3017–FC)</td>
<td>0938–AM74</td>
</tr>
<tr>
<td>1121</td>
<td>Hospice Wage Index FY 2005 (CMS–1264–N)</td>
<td>0938–AM78</td>
</tr>
<tr>
<td>1122</td>
<td>Ticket to Work: Defining Individuals with Potentially Severe Disabilities (CMS–2172–N)</td>
<td>0938–AM79</td>
</tr>
<tr>
<td>1123</td>
<td>Hospital Conditions of Participation: Requirements For History and Physical Examinations; Authentication of Verbal Orders, Securing Medications and Post-Anesthesia Evaluations (CMS–3122–F)</td>
<td>0938–AM88</td>
</tr>
<tr>
<td>1124</td>
<td>Disproportionate Share Hospital (DSH) Payments Institutions for Mental Disease (IMDs) (CMS–2062–N)</td>
<td>0938–AM89</td>
</tr>
</tbody>
</table>

References in boldface appear in the Regulatory Plan in part II of this issue of the Federal Register.

### Centers for Medicare & Medicaid Services—Long-term Actions

<table>
<thead>
<tr>
<th>Sequence Number</th>
<th>Title</th>
<th>Regulation Identification Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>1125</td>
<td>Standard Unique National Health Plan Identifiers (CMS–6017–P)</td>
<td>0938–AH87</td>
</tr>
<tr>
<td>1126</td>
<td>Exclusion of Medicare Benefits for Aliens Not Lawfully Present in the United States (CMS–1222–FC)</td>
<td>0938–AM47</td>
</tr>
<tr>
<td>1127</td>
<td>Changes to the Criteria for Being Classified as an Inpatient Rehabilitation Facility (CMS–1262–F)</td>
<td>0938–AM72</td>
</tr>
</tbody>
</table>

### Centers for Medicare & Medicaid Services—Completed Actions

<table>
<thead>
<tr>
<th>Sequence Number</th>
<th>Title</th>
<th>Regulation Identification Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>1128</td>
<td>Conditions of Participation of Intermediate Care Facilities for Persons With Mental Retardation (CMS–3046–P)</td>
<td>0938–AK23</td>
</tr>
<tr>
<td>1129</td>
<td>Laboratory Requirements Relating to Quality Systems and Certain Personnel Qualifications (CMS–2226–CN)</td>
<td>0938–AK24</td>
</tr>
<tr>
<td>1130</td>
<td>Fire Safety Requirements for Certain Health Care Facilities (CMS–3047–F)</td>
<td>0938–AK35</td>
</tr>
<tr>
<td>1131</td>
<td>Hospital Conditions of Participation: Quality Assessment and Performance Improvements (QAPI) (CMS–3050–F)</td>
<td>0938–AK40</td>
</tr>
<tr>
<td>1133</td>
<td>Modifications to Medicare Managed Care Rules (CMS–4041–F)</td>
<td>0938–AK71</td>
</tr>
<tr>
<td>1134</td>
<td>Inpatient Disproportionate Share Hospital (DSH) Adjustment: Calculation of Medicaid Patient and Total Patient Days in the Medicare DSH Adjustment (CMS–1171–P)</td>
<td>0938–AK77</td>
</tr>
<tr>
<td>1135</td>
<td>Modifications to the State Children’s Health Insurance Program (SCHIP) (CMS–2006–F)</td>
<td>0938–AL00</td>
</tr>
<tr>
<td>1136</td>
<td>Requirements for Paid Feeding Assistants in Long-Term Care Facilities (CMS–2131–F)</td>
<td>0938–AL18</td>
</tr>
</tbody>
</table>
## Centers for Medicare & Medicaid Services—Completed Actions (Continued)

<table>
<thead>
<tr>
<th>Sequence Number</th>
<th>Title</th>
<th>Regulation Identification Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>1137</td>
<td>Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2003 Payment Rates; Changes to Payment Suspension for Unfiled Cost Reports; Correction to Final Rule (CMS–1206–CN2)</td>
<td>0938–AL27</td>
</tr>
<tr>
<td>1138</td>
<td>Payment for Respiratory Assist Devices With Bi-Level Capability and a Back-Up Rate (CMS–1167–F)</td>
<td>0938–AL27</td>
</tr>
<tr>
<td>1139</td>
<td>Interim Final Amendment for Mental Health Parity (CMS–2152–IFC)</td>
<td>0938–AL44</td>
</tr>
<tr>
<td>1140</td>
<td>Electronic Submission of Cost Reports (CMS–1199–F)</td>
<td>0938–AL51</td>
</tr>
<tr>
<td>1141</td>
<td>Exclusions from the Definition of &quot;Optional Targeted Low-Income Child&quot; and Purchase of Family Coverage—Benefit Flexibility in Parent Coverage (CMS–2148–P)</td>
<td>0938–AL62</td>
</tr>
<tr>
<td>1142</td>
<td>State Allotments for Payment of Medicare Part B Premiums for Qualifying Individuals; Federal FY 2002 (CMS–2136–FN)</td>
<td>0938–AL79</td>
</tr>
<tr>
<td>1143</td>
<td>Medicaid Coverage Rules for Inmates of Public Institutions (CMS–2077–P)</td>
<td>0938–AL85</td>
</tr>
<tr>
<td>1144</td>
<td>Targeted Case Management (CMS–2061–P)</td>
<td>0938–AL87</td>
</tr>
<tr>
<td>1145</td>
<td>Changes to the Hospital Inpatient Prospective Payment System and FY 2004 Rates (CMS–1470–F)</td>
<td>0938–AL89</td>
</tr>
<tr>
<td>1146</td>
<td>Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities—Update for FY 2004 (CMS–1469–F)</td>
<td>0938–AL90</td>
</tr>
<tr>
<td>1147</td>
<td>Prospective Payment System for Long-Term Care Hospitals for FY 2004 (CMS–1472–P)</td>
<td>0938–AL92</td>
</tr>
<tr>
<td>1148</td>
<td>Home Health Prospective Payment System Rate Update for FY 2004 (CMS–1473–NC)</td>
<td>0938–AL94</td>
</tr>
<tr>
<td>1149</td>
<td>Prospective Payment System for Inpatient Rehabilitation Hospitals for FY 2004 (CMS–1474–F)</td>
<td>0938–AL95</td>
</tr>
<tr>
<td>1150</td>
<td>Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2004 (CMS–1476–P)</td>
<td>0938–AL96</td>
</tr>
<tr>
<td>1151</td>
<td>Nondiscrimination In Post-Hospital Referral to Home Health Agencies and Other Entities (CMS–1224–F)</td>
<td>0938–AM01</td>
</tr>
<tr>
<td>1152</td>
<td>Update of the List of Covered Procedures for Ambulatory Surgical Centers (CMS–1885–FC)</td>
<td>0938–AM02</td>
</tr>
<tr>
<td>1153</td>
<td>Medicaid Home and Community Based Services Waivers (CMS–2162–P)</td>
<td>0938–AM05</td>
</tr>
<tr>
<td>1154</td>
<td>Payment Reform for Part B Drugs (CMS–1229–F)</td>
<td>0938–AM12</td>
</tr>
<tr>
<td>1155</td>
<td>Nondiscrimination in Health Coverage in the Group Market (CMS–2022–F)</td>
<td>0938–AM14</td>
</tr>
<tr>
<td>1156</td>
<td>Bona Fide Wellness Programs (CMS–2078–F)</td>
<td>0938–AM15</td>
</tr>
<tr>
<td>1157</td>
<td>Time Limitation on Recalculations and Disputes Under the Drug Rebate Program (CMS–2175–FC)</td>
<td>0938–AM20</td>
</tr>
<tr>
<td>1158</td>
<td>Medicaid Estate Recoveries (CMS–2083–P)</td>
<td>0938–AM30</td>
</tr>
<tr>
<td>1159</td>
<td>Application of the Emergency Medical Treatment and Labor Act (EMTALA) (CMS–1063–F)</td>
<td>0938–AM34</td>
</tr>
<tr>
<td>1160</td>
<td>Physician Ownership in Specialty Hospitals (CMS–1240–P)</td>
<td>0938–AM35</td>
</tr>
<tr>
<td>1161</td>
<td>Approval of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) for Deeming Authority for Hospices (CMS–2177–FC)</td>
<td>0938–AM38</td>
</tr>
<tr>
<td>1162</td>
<td>Hospital Cost-to-Charge Ratios Used To Calculate Cost Outlier Payments Under the Medicare Short–Term Inpatient Prospective Payment System (CMS–1243–F)</td>
<td>0938–AM41</td>
</tr>
<tr>
<td>1163</td>
<td>Ambulance Fee Schedule Condition Codes (CMS–1247–P)</td>
<td>0938–AM45</td>
</tr>
<tr>
<td>1164</td>
<td>Hospice Wage Index for FY 2004 (CMS–1233–N)</td>
<td>0938–AM56</td>
</tr>
<tr>
<td>1165</td>
<td>Announcement of Applications From Hospitals Requesting Waivers for Organ Procurement Service Areas in Calendar Year 2003 (CMS–1246–NC)</td>
<td>0938–AM59</td>
</tr>
<tr>
<td>1166</td>
<td>Centers for Medicare and Medicaid Services Action on Liability Insurance Regulations (CMS–1475–FC)</td>
<td>0938–AM64</td>
</tr>
</tbody>
</table>

## Administration for Children and Families—Proposed Rule Stage

<table>
<thead>
<tr>
<th>Sequence Number</th>
<th>Title</th>
<th>Regulation Identification Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>1167</td>
<td>Safeguarding Child Support and Expanded Federal Parent Locator Services (FPLS) Information</td>
<td>0970–AC01</td>
</tr>
<tr>
<td>1168</td>
<td>Developmental Disabilities and Bill of Rights Act</td>
<td>0970–AC07</td>
</tr>
<tr>
<td>1169</td>
<td>Administrative Costs for Children in Title IV–E Foster Care</td>
<td>0970–AC14</td>
</tr>
<tr>
<td>1170</td>
<td>Administrative Cost Sharing Under TANF</td>
<td>0970–AC15</td>
</tr>
</tbody>
</table>

## Administration for Children and Families—Final Rule Stage

<table>
<thead>
<tr>
<th>Sequence Number</th>
<th>Title</th>
<th>Regulation Identification Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>1171</td>
<td>Child Support Enforcement for Indian Tribes</td>
<td>0970–AB73</td>
</tr>
<tr>
<td>1172</td>
<td>Child Support Enforcement Program; Federal Tax Refund Offset</td>
<td>0970–AC09</td>
</tr>
<tr>
<td>1173</td>
<td>Charitable Choice Provisions Applicable to the Temporary Assistance for Needy Families Program</td>
<td>0970–AC12</td>
</tr>
</tbody>
</table>
Administration for Children and Families—Final Rule Stage (Continued)

<table>
<thead>
<tr>
<th>Sequence Number</th>
<th>Title</th>
<th>Regulation Identification Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>1174</td>
<td>Community Services Block Grant Charitable Choice</td>
<td>0970–AC13</td>
</tr>
</tbody>
</table>

Administration for Children and Families—Completed Actions

<table>
<thead>
<tr>
<th>Sequence Number</th>
<th>Title</th>
<th>Regulation Identification Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>1175</td>
<td>Construction and Major Renovation of Head Start and Early Head Start Facilities</td>
<td>0970–AB54</td>
</tr>
<tr>
<td>1176</td>
<td>Child Support Enforcement Program Omnibus Conforming Regulation</td>
<td>0970–AB81</td>
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<tr>
<td>1177</td>
<td>Technical Revision of Head Start Regulations To Make Them Conform to Recent Statutory Revisions</td>
<td>0970–AC00</td>
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<tr>
<td>1178</td>
<td>Child Support Enforcement Program; Expenditures for Caseworker Costs</td>
<td>0970–AC11</td>
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Administration on Aging—Proposed Rule Stage

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<td>1179</td>
<td>Grants for State and Community Programs on Aging, Training, Research, and Discretionary Programs; Vulnerable Elder Rights; Grants to Indians and Native Hawaiians</td>
<td>0985–AA00</td>
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Department of Health and Human Services (HHS) Proposed Rule Stage

Office of the Secretary (OS)

961. SAFE HARBOR FOR ARRANGEMENTS INVOLVING FEDERALLY QUALIFIED HEALTH CENTERS

Priority: Substantive, Nonsignificant

Legal Authority: PL 100–93, sec 14(a)

CFR Citation: 42 CFR 1001

Legal Deadline: None

Abstract: This rule would set forth a new anti-kickback safe harbor addressing remuneration between federally qualified health centers and certain service providers where a significant community benefit exists.

Timetable:

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Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

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

RIN: 0991–AB06

962. 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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Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

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

RIN: 0991–AB18

963. 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:**  

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**Government Levels Affected:** None  

**Agency Contact:** Katherine M. Drews, Associate General Counsel, Department of Health and Human Services, Office of the Secretary, Office of the General Counsel, Room 5362, HHS Cohen Building, 330 Independence Avenue SW., Washington, DC 20201  

Phone: 202 619–0150  

RIN: 0991–AB19  

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

**Priority:** Substantive, Nonsignificant  

**Legal Authority:** 42 USC 1302; 42 USC 1320a900–7b; 42 USC 1395hh; PL 104–191, sec 216(b)  

**CFR Citation:** 42 CFR 1001  

**Legal Deadline:** Final, Statutory, January 1, 1997, Final.  

**Abstract:** This final rule establishes a new statutory exception for risk-sharing arrangements under the Federal health care programs’ anti-kickback provisions. The rule sets forth an exception from liability for remuneration between an eligible organization and an individual or entity providing items or services in accordance with a written agreement between these parties. The rule allows remuneration between an organization and an individual or entity if a written agreement places the individual or entity at “substantial financial risk” for the cost or utilization of the items or services that the individual or entity is obligated to provide.

**Timetable:**  

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**Regulatory Flexibility Analysis Required:** No  

**Small Entities Affected:** No  

**Government Levels Affected:** None  

**Agency Contact:** Joel Jay Schaar, Regulations Officer, Department of Health and Human Services, Office of the Secretary, Office of Inspector General (OCIG), 330 Independence Avenue SW., Washington, DC 20201  

Phone: 202 619–0089  

RIN: 0991–AA91  

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

**Priority:** Substantive, Nonsignificant  

**Legal Authority:** PL 100–93, sec 14(a)  

**CFR Citation:** 42 CFR 1001  

**Legal Deadline:** None  

**Abstract:** This final rule will expand the existing safe harbor for certain waivers of beneficiary coinsurance and deductible amounts to benefit the Medicare program owed by Medicare program, which provides Medicare SELECT policy issued in accordance with section 1882(l)(1) of the Social Security Act, if a 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:**  

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**Regulatory Flexibility Analysis Required:** No  

**Small Entities Affected:** No  

**Government Levels Affected:** None  

**Agency Contact:** Joel Jay Schaar, Regulations Officer, Department of Health and Human Services, Office of the Secretary, Office of Inspector General (OCIG), 330 Independence Avenue SW., Washington, DC 20201  

Phone: 202 619–0089  

RIN: 0991–AB16  

### 967. TAX REFUND OFFSET  

**Priority:** Other Significant  

**Legal Authority:** 31 USC 3720A; 31 CFR 285.2  

**CFR Citation:** 45 CFR 31  

**Legal Deadline:** None  

**Abstract:** The Department will amend part 31 to title 45 of the Code of Federal Regulations (CFR) to reflect amendments to 31 U.S.C. 3720A made by the tax refund offset provisions of the Debt Collection Improvement Act of 1996 (DCIA), Public Law 104–134, 110 Stat. 1321–1358, as implemented by the Department of the Treasury at 31 CFR 285.2. The proposed rule revises the process by which the Department collects its debts. The
proposed rule is required in order to bring the Department’s tax refund offset provisions in compliance with the Department of the Treasury regulations.

**Timetable:**

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**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** None

**Federalism:** Undetermined

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

**RIN:** 0991–AB17

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**968. IMPLEMENTATION OF THE EQUAL ACCESS TO JUSTICE ACT IN AGENCY PROCEEDINGS**

**Priority:** Other Significant

**Legal Authority:** 5 USC 504(c)(1)

**CFR Citation:** 45 CFR 13

**Legal Deadline:** None

**Abstract:** The Equal Access to Justice Act requires agencies to pay fees to parties prevailing against the Government in certain administrative proceedings. The Act has been amended several times since its 1980 enactment, most recently by the Contract with America Advancement Act of 1996, which increased the amount of the hourly fees payable. The proposed rule revises 45 CFR part 13 (HHS’s regulation implementing the Equal Access to Justice Act) to conform with statutory changes.

**Timetable:**

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**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** None

**Additional Information:** Transferred from RIN 0990–AA02

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

**RIN:** 0991–AB22

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**970. REVISIONS TO REGULATIONS ADDRESSING THE OIG’S AUTHORITY TO IMPOSE CIVIL MONEY PENALTIES AND ASSESSMENTS**

**Priority:** Substantive, Nonsignificant

**Legal Authority:** 42 USC 1320a–7a; 42 USC 1395mm; 42 USC 1395w–27; 42 USC 1396b; 42 USC 1396u–2

**CFR Citation:** 42 CFR 1003

**Legal Deadline:** None

**Abstract:** This proposed rule would revise part 1003, addressing the Office of Inspector General’s authority to 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:**

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**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** None

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

**RIN:** 0991–AB03
971. 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

Priority: Other Significant
Legal Authority: PL 100–259, Civil Rights Restoration Act of 1987
CFR Citation: 45 CFR 80; 45 CFR 84; 45 CFR 86; 45 CFR 90; 45 CFR 91
Legal Deadline: None
Abstract: The Secretary proposes to amend the Department’s regulations implementing title VI of the Civil Rights Act of 1964, as amended, section 504 of the Rehabilitation Act of 1973, as amended, title IX of the Education Amendments of 1972, and the Age Discrimination Act of 1975, as amended. The principal proposed conforming change is to amend the regulations to add the definitions of “program or activity” or “program” that correspond to the statutory definitions enacted under the Civil Rights Restoration Act of 1987.

Timetable:

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Regulatory Flexibility Analysis Required: Undetermined
Small Entities Affected: Businesses, Governmental Jurisdictions, Organizations
Government Levels Affected: State, Local, Federal, Tribal
Agency Contact: Robinsue Frohboese, Principal Deputy Director, Office for Civil Rights, Department of Health and Human Services, Office of the Secretary, 200 Independence Avenue SW, Washington, DC 20202
Phone: 202 619–0403
RIN: 0991–AB10

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

972. GOVERNMENTWIDE DEBARMENT AND SUSPENSION (NONPROCUREMENT) AND GOVERNMENTWIDE REQUIREMENTS FOR DRUG-FREE WORKPLACE (GRANTS)

Completed:

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Regulatory Flexibility Analysis Required: No
Government Levels Affected: None
Agency Contact: Diane Osterhus
Phone: 202 690–5729
Fax: 202 690–6901
Email: diane.osterhus@hhs.gov
RIN: 0991–AB12

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

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

Regulatory Plan: This entry is Seq. No. 41 in part II of this issue of the Federal Register.
RIN: 0930–AA10

974. MANDATORY GUIDELINES FOR THE FEDERAL WORKPLACE DRUG TESTING PROGRAM

Priority: Other Significant
Legal Authority: PL 100–71; 5 USC 7301
CFR Citation: None
Legal Deadline: NPRM, Statutory, December 2003, NPRM.
Abstract: HHS is proposing to establish scientific and technical guidelines for the testing of hair, sweat, and oral fluid specimens in addition to urine specimens; scientific and technical guidelines for using on-site tests to test urine and oral fluids at the collection site; requirements for the certification of instrumented initial test facilities; and added standards for collectors, on-site testers, and medical review officers.

Timetable:

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Regulatory Flexibility Analysis Required: No
Small Entities Affected: No
Government Levels Affected: Federal
Agency Contact: Joseph Denis Faha, Director, DLEA, SAMHSA, Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, Room 12C–15, 5600 Fishers Lane, Rockville, MD 20857
Phone: 301 443–7017
Fax: 301 443–1450
Email: jfaha@samhsa.gov
RIN: 0930–AA12
975. SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION (SAMHSA) CHARITABLE CHOICE

Priority: Other Significant
Legal Authority: Not Yet Determined
CFR Citation: 42 CFR 54, sec. 54.1–13; 42 CFR 54a, sec. 54a.1–14
Legal Deadline: None
Abstract: This proposed rule would implement the Charitable Choice statutory provisions of section 581–584 and section 1955 of the Public Health Service Act, applicable to the Substance Abuse Prevention and Treatment (SAPT) Block Grant Program, the Project for Assistance in Transition from Homelessness (PATH) formula grant program, insofar as recipients provide substance abuse services, and to SAMHSA discretionary grants for substance abuse treatment or prevention services, which are all administered by SAMSHA of the U.S. Department of Health and Human Services.

Timetable:

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Regulatory Flexibility Analysis Required: No

Small Entities Affected: No
Government Levels Affected: Federal
Federalism: This action may have federalism implications as defined in EO 13132.
Agency Contact: Winnie Mitchell, Public Health Analyst, Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, 12C–05, 5600 Fishers Lane, Rockville, MD 20857
Phone: 301 443–2324
Fax: 301 443–0247
RIN: 0930–AA11

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

Priority: Other Significant
Legal Authority: 29 USC 651 et seq; 30 USC 3; 30 USC 5; 30 USC 7; 30 USC 811; 30 USC 842(h); 30 USC 844
CFR Citation: 42 CFR 84
Legal Deadline: None
Abstract: NIOSH plans to modify the Administrative/Quality Assurance sections of 42 CFR part 84, Approval of Respiratory Protective Devices. Areas for potential modification in this module are: 1) upgrade of quality assurance requirements; 2) ability to use private sector quality auditors and private sector testing laboratories in the approval program; 3) revised approval label requirements; 4) updated and restructured fee schedule; and 5) fee retention in the respirator program.

Timetable:

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Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses
Government Levels Affected: None
Agency Contact: Roland Berry Ann, Acting Chief, Respirator Branch, National Personal Protection Technology Laboratory, 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

977. PROCEDURES FOR DESIGNATING CLASSES OF EMPLOYEES AS MEMBERS OF THE SPECIAL EXPOSURE COHORT UNDER THE ENERGY EMPLOYEE OCCUPATIONAL ILLNESS COMPENSATION ACT OF 2000

Priority: Substantive, Nonsignificant
Legal Authority: 42 USC 7384g; EO 13179
CFR Citation: 42 CFR 83
Legal Deadline: None
Abstract: Pursuant to the Energy Employees Occupational Illness Compensation Program Act, HHS plans to finalize procedures to petition the Secretary to be added to the Special Exposure Cohort.

Timetable:

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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, 5555 Ridge Avenue, Cincinnati, OH 45213
Phone: 513 841–4498
RIN: 0920–AA07
978. OVER-THE-COUNTER (OTC) DRUG REVIEW

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 360b; 21 USC 361; 21 USC 371

CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 350

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.

SMALL ENTITIES AFFECTED: The effects, if any, vary depending on the individual rulemaking. However, the Agency anticipates that the rules would not have a significant economic impact on a substantial number of small entities as defined by the Regulatory Flexibility Act.

Timetable:

Anorectal Products (0910–AC65)
Final Action (Amendment) 08/26/03 (68 FR 51167)

Antidiarrheal Products (0910–AC82)
NPRM (Amendment) (Trav. Diar) 04/17/03 (68 FR 18915)
Final Action (Amendment) (Trav. Diar) 04/00/04

Antimetic Products (0910–AC71)
Final Action (Amendment) (Warning) 12/06/02 (67 FR 72555)

Antiperspirant Products (0910–AC89)
Final Action 06/09/03 (68 FR 34273)

Cough/Cold (Antihistamine) Products (0910–AD31)
Final Action (Amendment) (Common Cold) 04/00/04

Cough/Cold (Antitussive) Products (0910–AD24)
Final Action (Amendment) (Warning) 12/06/02 (67 FR 72555)

Cough/Cold (Bromchodilator) Products (0910–AD33)
NPRM (Amendment) 06/00/04

Cough/Cold (Combination) Products (0910–AD25)
Final Action 12/23/02 (67 FR 78158) NPRM (Amendment) 06/00/04

Cough/Cold (Nasal Decongestant) Products (0910–AD43)
NPRM (Phenylephrine Bitartrate) 04/00/04
NPRM (Phenylpropanolamine) 04/00/04
NPRM (Amendment) (Sinusitis Claim) 06/00/04

External Analgesic Products (0910–AD06)
Final Action (Amendment)(Warning) 12/06/02 (67 FR 72555) NPRM (Amendment) (Patches) 07/17/03 (68 FR 42324)

Ingrown Toenail Relief Products (0910–AD21)
NPRM 10/04/02 (67 FR 62218)
Final Action 05/07/03 (68 FR 24347)

Internal Analgesic Products (0910–AD07)
NPRM (Amendment) (Ibuprofen) 08/21/02 (67 FR 54339)
NPRM (Amendment) (Labeling) 04/00/04
NPRM (Amendment) (Pediatric) 04/00/04

Labeling of Drug Products for OTC Human Use (0910–AD47)
NPRM (Convenience Sizes) 02/00/04
NPRM (Sodium Labeling) 02/00/04
Final Action (Sodium Labeling) 02/00/04
Final Action (Ca/Mg/K/Na) 02/00/04

Laxative Drug Products (0910–AC85)
NPRM (Amendment) (Psyllium Granular Dosage Form) 08/05/03 (68 FR 46133)

Nighttime Sleep Aid Products (0910–AD11)
Final Action (Amendment) (Warning) 12/06/02 (67 FR 72555)

Ophthalmic Products (0910–AC72)
NPRM (Emergency First Aid Eyewashes) 02/19/03 (68 FR 7951)
Final Action (Technical Amendment) 02/19/03 (68 FR 7919)
Final Action (Name Change) 06/03/03 (68 FR 32981)

Oral Health Care Products (0910–AC98)
ANPRM (Plaque/Gingivitis) 05/29/03 (68 FR 32232)

Pediculicide Products (0910–AC79)
NPRM (Labeling Amendment) 05/10/02 (67 FR 31739)
Final Action (Labeling Amendment) 02/00/04

Salicylate (Reye’s Syndrome) (0910–AD13)
Final Action (Warning) 04/17/03 (68 FR 18861)

Skin Protectant Products (0910–AC96)
Final Action 06/04/03 (68 FR 33362)
NPRM (Astringent) 06/13/03 (68 FR 35346)
Final Action (Astringent) 06/13/03 (68 FR 35290)
Final Action (Astringent) (Confirm Effective Date) 10/09/03 (68 FR 58273)
Final Action (Technical Amendment) 12/00/03

Sunscreen Products (0910–AC68)
Final Action (Names) 06/02/02 (67 FR 41821)
ANPRM (and Insect Repellent) 04/00/04
NPRM (UVA/UVB) 04/00/04

Vaginal Contraceptive Products (0910–AD19)
NPRM (Amendment) 01/16/03 (68 FR 2254)
Final Action (Warnings) 06/00/04

Weight Control Products (0910–AC93)
NPRM (Phenylpropanolamine) 04/00/04

Regulatory Flexibility Analysis
Required: Yes

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, HFD–560, Center for Drug Evaluation and Research, 5600 Fishers Lane, Rockville, MD 20857
Phone: 301 827–2241
Fax: 301 827–2315
Email: rachanow@cder.fda.gov

RIN: 0910–AA01

979. CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKING, OR HOLDING HUMAN FOOD (PART 110)

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

Unfunded Mandates: Undetermined

Legal Authority: 21 USC 342; 21 USC 371; 21 USC 374; 42 USC 264

CFR Citation: 21 CFR 110

Legal Deadline: None

Abstract: Part 110 (21 CFR part 110) describes regulations for current good manufacturing practice in manufacturing, packing, and holding human food. Part 110 contains regulations describing sanitary practices for personnel, buildings and facilities, and equipment. It also includes regulations on production and process controls for manufacturing practices and on defect action levels for natural or unavoidable defects in food for human use that present no health hazard. FDA is undertaking a review of part 110 under section 610 of the Regulatory Flexibility Act. The purpose of this review is to determine whether the regulations in part 110 should be continued without change, or whether they should be amended or rescinded, consistent with the stated objectives of applicable statutes, to minimize adverse impacts on a substantial number of small entities. FDA will consider, and is soliciting comments on, the following: (1) the continued need for the regulations in part 110; (2) the nature of complaints or comments received concerning the regulations in part 110; (3) the complexity of the regulations in part 110; (4) the extent to which the regulations in part 110 overlap, duplicate, or conflict with other Federal, State, or governmental rules; and (5) the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulations in part 110.
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 current good manufacturing practices in ways that will maintain or increase the effectiveness of preventive and sanitary controls, and, at the same time, reduce compliance and other costs associated with the regulations.

**Timetable:**

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**Regulatory Flexibility Analysis Required:** Undetermined

**Government Levels Affected:** Undetermined

**Federalism:** Undetermined

**Agency Contact:** Richard A. Williams, Director, Division of Market Studies, OSAS, CFSAN, FDA, HHS, Department of Health and Human Services, Food and Drug Administration, HFS–725, 5100 Paint Branch Parkway, College Park, MD 20740

Phone: 301 436–1989
Fax: 301 436–2636
Email: richard.williams@cfsan.fda.gov

**RIN:** 0910–AC58

### 980. HEALTH CLAIMS

**Priority:** Other Significant

**Unfunded Mandates:** Undetermined

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

### 981. PRESCRIPTION DRUG MARKETING ACT OF 1987; PRESCRIPTION DRUG AMENDMENTS OF 1992; POLICIES, REQUIREMENTS, AND ADMINISTRATIVE PROCEDURES; DERIVATIVES OF BLOOD

**Priority:** Substantive, Nonsignificant.

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

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

**CFR Citation:** Not Yet Determined

**Legal Deadline:** None

**Abstract:** This advance notice of proposed rulemaking (ANPRM) was signaled in the July 11, 2003 (68 FR 41387) notice that announced the availability of the Report of Task Force on Consumer Health Information for Better Nutrition (the Task Force) and two guidance documents. The July 11, 2003, notice states that in the near future, the agency intends to publish an ANPRM consistent with the recommendations of the Task Force.

**Timetable:**

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**Regulatory Flexibility Analysis Required:** Yes

**Government Levels Affected:** None

**Federalism:** Undetermined

**Agency Contact:** Paulette Gaynor, Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, HFS–800, 5100 Paint Branch Parkway, College Park, MD 20740

Phone: 301 436–1450
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Email: pgaynor@cfsan.fda.gov

**RIN:** 0910–AF09

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

**Legal Deadline:** Other, Statutory, April 1, 2004, Other.

**Date final rule takes effect:** Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements, and Administrative Procedures.

**Abstract:** FDA is proposing to amend the implementing regulation of the Prescription Drug Marketing Act of 1987, as modified by the Prescription Drug Amendments of 1992 and the FDA Modernization Act of 1997. The final rule (12/3/99; 64 FR 67720), does not allow a registered blood establishment that provides health care services related to its activities as a blood establishment to concurrently distribute derivatives of blood. The effective date of that rule is April 1, 2004. FDA is amending the final rule to allow a registered blood establishment that concurrently provides health care services to also distribute derivatives of blood.

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**Regulatory Flexibility Analysis Required:** Undetermined

**Government Levels Affected:** None

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

Phone: 301 827–6210
Fax: 301 827–9434

**RIN:** 0910–AF16

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

**Legal Deadline:** Other, Statutory, April 1, 2004, Other.

**Date final rule takes effect:** Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements, and Administrative Procedures.

**Abstract:** FDA is proposing to amend the implementing regulation of the Prescription Drug Marketing Act of 1987, as modified by the Prescription Drug Amendments of 1992 and the FDA Modernization Act of 1997. The final rule (12/3/99; 64 FR 67720), does not allow a registered blood establishment that provides health care services related to its activities as a blood establishment to concurrently distribute derivatives of blood. The effective date of that rule is April 1, 2004. FDA is amending the final rule to allow a registered blood establishment that concurrently provides health care services to also distribute derivatives of blood.

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**Regulatory Flexibility Analysis Required:** Undetermined

**Government Levels Affected:** None

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

Phone: 301 827–6210
Fax: 301 827–9434

**RIN:** 0910–AF16

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

**Legal Deadline:** Other, Statutory, April 1, 2004, Other.

**Date final rule takes effect:** Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements, and Administrative Procedures.

**Abstract:** FDA is proposing to amend the implementing regulation of the Prescription Drug Marketing Act of 1987, as modified by the Prescription Drug Amendments of 1992 and the FDA Modernization Act of 1997. The final rule (12/3/99; 64 FR 67720), does not allow a registered blood establishment that provides health care services related to its activities as a blood establishment to concurrently distribute derivatives of blood. The effective date of that rule is April 1, 2004. FDA is amending the final rule to allow a registered blood establishment that concurrently provides health care services to also distribute derivatives of blood.

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**Regulatory Flexibility Analysis Required:** Undetermined

**Government Levels Affected:** None

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

Phone: 301 827–6210
Fax: 301 827–9434

**RIN:** 0910–AF16

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

**Legal Deadline:** Other, Statutory, April 1, 2004, Other.

**Date final rule takes effect:** Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements, and Administrative Procedures.

**Abstract:** FDA is proposing to amend the implementing regulation of the Prescription Drug Marketing Act of 1987, as modified by the Prescription Drug Amendments of 1992 and the FDA Modernization Act of 1997. The final rule (12/3/99; 64 FR 67720), does not allow a registered blood establishment that provides health care services related to its activities as a blood establishment to concurrently distribute derivatives of blood. The effective date of that rule is April 1, 2004. FDA is amending the final rule to allow a registered blood establishment that concurrently provides health care services to also distribute derivatives of blood.
and modify current regulations concerning who must register establishments and list drug or biologics regulated as drugs. The proposal describes when, how, and where to register and list, and what information must be submitted for registration and listing. The proposed regulations would also revise the requirements for the National Drug Code number and would require the electronic submission of most registration and listing information.

**Timetable:**

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**Regulatory Flexibility Analysis**

**Required:** Yes

**Government Levels Affected:** None

**Agency Contact:** Mary H. Keyes, Office of Policy, Department of Health and Human Services, Food and Drug Administration, Suite 3037 (HFD-7), Center for Drug Evaluation and Reserach, 1451 Rockville Pike, Rockville, MD 20852

Phone: 301 594–2041
Fax: 301 827–5562

**RIN:** 0910–AA49

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### 983. BLOOD INITIATIVE

**Priority:** Other Significant. 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 371; 21 USC 374; 42 USC 216; 42 USC 262; 42 USC 263; 42 USC 263a; 42 USC 264


**Legal Deadline:** None

**Abstract:** In multiple rulemakings, the Food and Drug Administration (FDA) is amending the biologics regulations by removing, revising, or updating specific regulations applicable to blood, blood components, Source Plasma, and blood-derivative products 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’s, Subcommittee on House Resources and Intergovernmental Relations, the General Accounting Office, and the Institute of Medicine, as well as on public comments. The remaining subjects intended to be addressed in the rulemakings include: labeling of blood and blood components and donor eligibility requirements. These actions are intended to help ensure the continued safety of the Nation’s blood supply.

**Timetable:**

- **Albumin (Human), Plasma Protein Fraction (Human) and Immune Globulin (Human):**
  - Revision of Requirements (0910–AE95)
    - NPRM 05/14/99 (64 FR 26344)
    - Direct Final Rule 05/14/99 (64 FR 26282)
    - Direct Final Rule—Confirmation in Part and Technical Amendment 03/14/00 (65 FR 13678)
    - Final Action 08/28/00 (65 FR 52016)

- **General Requirements for Blood, Blood Components, and Plasma Derivatives; Notification of Deferred Donors (0910–AE99):**
  - NPRM 08/19/99 (64 FR 45355)
  - Final Action 06/11/01 (66 FR 31165)

- **Plasma Derivatives and Similar Recombinant-Based Products; Requirements for Notification of Recalls and Withdrawals (0910–AF02):**
  - ANPRM 08/19/99 (64 FR 45383)

- **Regulations for Human Blood and Blood Components Intended for Transfusion or for Further Manufacturing Use (0910–AF00):**
  - NPRM 11/00/04

- **Requirements for Testing Human Blood Donors for Evidence of Infection Due to Communicable Disease Agents (0910–AE98):**
  - NPRM 08/19/99 (64 FR 45340)
  - Final Action 06/11/01 (66 FR 31146)

- **Revisions to Labeling and Storage Requirements for Blood and Blood Components, Including Source Plasma (0910–AE96):**
  - NPRM 07/30/03 (68 FR 44678)
  - Correction Notice 10/27/03 (68 FR 61172)
  - NPRM Comment Period End 10/30/03
  - Final Action 10/00/04

- **Revisions to the Requirements Applicable to Blood, Blood Components, and Source Plasma (0910–AE98):**
  - NPRM 08/19/99 (64 FR 45375)
  - Direct Final Rule 08/19/99 (64 FR 45366)
  - Direct Final Rule—Confirmation in Part and Technical Amendment 01/10/01
  - Final Action 08/06/01 (66 FR 40883)

**Regulatory Flexibility Analysis**

**Required:** No

**Small Entities Affected:** Businesses

**Government Levels Affected:** None

**Agency Contact:** Paula S. McKeever, Regulatory Policy Analyst, Department of Health and Human Services, Food and Drug Administration, Suite 200N (HFM–17), Center for Biologics Evaluation and Research, 1401 Rockville Pike, Rockville, MD 20852

Phone: 301 827–6210
Fax: 301 827–9434

**RIN:** 0910–AB26

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### 984. 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.

**Unfunded Mandates:** 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 379

**CFR Citation:** 21 CFR 312; 21 CFR 314

**Legal Deadline:** None

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

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**Regulatory Flexibility Analysis**

**Required:** Undetermined

**Government Levels Affected:** Undetermined

**Federalism:** Undetermined

**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, 1451 Rockville Pike, Rockville, MD 20852

Phone: 301 594–5649
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Email: pendletonb@cdr.fda.gov

**RIN:** 0910–AB34
985. CURRENT GOOD MANUFACTURING PRACTICE FOR MEDICATED FEEDS

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

Unfunded Mandates: Undetermined

Legal Authority: 21 USC 351; 21 USC 352; 21 USC 366b; 21 USC 371; 21 USC 374

CFR Citation: 21 CFR 225

Legal Deadline: None

Abstract: This proposal is in response to a citizen petition request to merge the separate requirements of the current good manufacturing practice (CGMP) regulations, 21 CFR part 225 applicable to licensed and unlicensed feed manufacturing facilities, respectively. The merger would produce a single set of updated, streamlined CGMPs that apply to all medicated feed manufacturers. This consolidation of existing CGMPs would preserve and strengthen food safety, be more appropriate given the changing structure of the medicated feed industry, and enhance uniformity and enforcement.

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

Priority: Routine and Frequent

Legal Authority: 21 USC 331 to 334; 21 USC 355b; 21 USC 355c; 21 USC 341 to 344; 21 USC 346; 21 USC 351; 21 USC 352; 21 USC 355; 21 USC 360; 21 USC 360c to 360f; 21 USC 361; 21 USC 362; 21 USC 371; 21 USC 372; 21 USC 374; 21 USC 376; 21 USC 381; 21 USC 393; 42 USC 262; 42 USC 264

CFR Citation: 21 CFR 50

Legal Deadline: None

Abstract: The proposed rule would establish requirements for importers and other persons who use sampling services and private laboratories in connection with imported food. For example, the proposed rule would pertain to persons who use sample collection services and private laboratories, and would describe some responsibilities for such persons, sample collection services, and private laboratories. These responsibilities would include recordkeeping requirements to ensure that the correct sample is collected and analyzed, and a notification requirement if a person intends to use a private laboratory in connection with imported food. The proposed rule is intended to help ensure the integrity and scientific validity of data and results submitted to FDA.

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Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: No

Government Levels Affected: Undetermined

Agency Contact: George Graber, Director, Division of Animal Feeds, Department of Health and Human Services, Food and Drug Administration, HFV–220, Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855 Phone: 301 827–6651 Email: ggraber@cvm.fda.gov

RIN: 0910–AB70

987. PREVENTION OF SALMONELLA ENTERITIDIS IN SHELL EGGS

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

RIN: 0910–AC14

988. 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 361; 21 USC 371; 21 USC 376; 21 USC 381; 42 USC 216; 42 USC 241; 42 USC 262; 42 USC 263b to 263n

CFR Citation: 21 CFR 56.106

Legal Deadline: None

Abstract: The proposed rule would require institutional review boards (IRB) to register with FDA. The registration information would include the name of the IRB, the name of the institution operating the IRB, and names, addresses, phone numbers, facsimile (fax) numbers, and electronic mail (e-mail) addresses of the senior officer of the institution and IRB chair or contact, the range of active protocols (small, medium, or large) involving FDA-regulated products reviewed in the previous calendar year, and a description of the types of FDA-regulated products reviewed. The proposed rule would make it easier for FDA to inspect IRBs and to convey information to IRBs.

Regulatory Flexibility Analysis Required: Undetermined

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, Rockville, MD 20857 Phone: 301 827–0587 Fax: 301 827–4774 Email: pchao@oc.fda.gov

RIN: 0910–AC17

989. USE OF MATERIALS DERIVED FROM BOVINE AND OVINE ANIMALS IN FDA-REGULATED PRODUCTS

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

Legal Authority: Not Yet Determined

CFR Citation: Not Yet Determined

Legal Deadline: None

Abstract: The U.S. Department of Agriculture’s Animal and Plant Health Inspection Service maintains, by regulation in 9 CFR 94.18(a), a list of countries: 1) where bovine spongiform encephalopathy (BSE) exists; and 2) that present an undue risk of
introducing BSE into the United States. This proposed rule would restrict, in FDA-regulated products, the use of most materials derived from bovine and ovine animals born, raised, or slaughtered in a country listed in 9 CFR 94.18(a). In addition, there would be a waiver provision that could be used under appropriate criteria.

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**Regulatory Flexibility Analysis**

**Required:** Undetermined

**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, College Park, MD 20740

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

RIN: 0910–AC21

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**990. 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.

In addition to this proposed rule, FDA intends to issue guidance within the next few months on the use in animal feed or material from deer and elk that are positive for CWD or are at high risk of CWD.

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 Creutzfeld-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 animal 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, FDA is proposing to require that food or cosmetic products derived from animals exposed to CWD not enter into commerce.

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**Regulatory Flexibility Analysis**

**Required:** Yes

**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, College Park, MD 20740

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

RIN: 0910–AC21

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**991. EXCEPTION FROM GENERAL REQUIREMENTS FOR INFORMED CONSENT; REQUEST FOR COMMENTS AND INFORMATION**

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

RIN: 0910–AC25

**992. 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(e)(1); 21 USC 371

**CFR Citation:** 21 CFR 868.2700; 21 CFR 868.5905

**Legal Deadline:** None

**Abstract:** The Food and Drug Administration (FDA) is proposing to reclassify pressure regulators for use with medical oxygen from class I to class II and to establish a special control for oxygen pressure regulators to address problems of fire and explosion associated with use of these devices. The special control will be a guidance document that includes standardized testing, performance, and labeling guidance for industry. Devices that meet the special control will be exempt from the premarket notification requirements of the act. The agency believes it is taking a least burdensome approach for industry. This proposed rule will phase-in a compliance approach that will minimize the cost. FDA seeks to reclassify these devices under section 513(e)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(e)(1)).
 dividend. If you are going to use a different dividend, then you'll need to adjust the other numbers accordingly. For example, if you want to use an annual dividend of 2.5%, then the number of shares would need to be multiplied by 94.44% to get the same present value.

If you want to use a different annual percentage, then you'll need to multiply the dividends by that percentage to get the present value of the dividends. For example, if you want to use a monthly percentage of 0.2%, then the dividends would need to be multiplied by 12 to get the present value of the dividends.

If you want to use a different monthly percentage, then you'll need to multiply the dividends by the appropriate factor to get the present value of the dividends. For example, if you want to use a daily percentage of 0.1%, then the dividends would need to be multiplied by 365 to get the present value of the dividends.

If you want to use a different daily percentage, then you'll need to multiply the dividends by the appropriate factor to get the present value of the dividends. For example, if you want to use a weekly percentage of 0.02%, then the dividends would need to be multiplied by 52 to get the present value of the dividends.

If you want to use a different weekly percentage, then you'll need to multiply the dividends by the appropriate factor to get the present value of the dividends. For example, if you want to use a quarterly percentage of 0.04%, then the dividends would need to be multiplied by 4 to get the present value of the dividends.

If you want to use a different quarterly percentage, then you'll need to multiply the dividends by the appropriate factor to get the present value of the dividends. For example, if you want to use a semi-annual percentage of 0.08%, then the dividends would need to be multiplied by 2 to get the present value of the dividends.

If you want to use a different semi-annual percentage, then you'll need to multiply the dividends by the appropriate factor to get the present value of the dividends. For example, if you want to use a bi-annual percentage of 0.16%, then the dividends would need to be multiplied by 1 to get the present value of the dividends.

If you want to use a different bi-annual percentage, then you'll need to multiply the dividends by the appropriate factor to get the present value of the dividends. For example, if you want to use an annual percentage of 0.32%, then the dividends would need to be multiplied by 1 to get the present value of the dividends.

If you want to use an annual percentage of 0.64%, then the dividends would need to be multiplied by 1 to get the present value of the dividends. For example, if you want to use a semi-annual percentage of 0.32%, then the dividends would need to be multiplied by 1 to get the present value of the dividends.
### 997. FOOD STANDARDS: GENERAL PRINCIPLES AND FOOD STANDARDS MODERNIZATION

**Priority:** Other Significant  
**Legal Authority:** 21 USC 321; 21 USC 336; 21 USC 341; 21 USC 343; 21 USC 371  
**CFR Citation:** 21 CFR 130.5  
**Legal Deadline:** None  
**Abstract:** In 1995, the FDA and FSIS reviewed their regulatory procedures and requirements for food standards to determine whether any were still needed, and if so, whether any 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 (61 FR 47453 and 61 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 are now proposing a set of general principles that define how modern food standards should be structured. 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 7 CFR part 410 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.  
**Regulatory Flexibility Analysis Required:** Yes  
**Government Levels Affected:** None  
**Agency Contact:** Elaine H. Tseng, Office of Regulatory Policy, Department of Health and Human Services, Food and Drug Administration, Suite 3037 (HFD–7), Center for Drug Evaluation and Research, 1451 Rockville Pike, Rockville, MD 20852  
**Phone:** 301 594–2041  
**Fax:** 301 827–5562  
**RIN:** 0910–AC53

### 998. POSITRON EMISSION TOMOGRAPHY DRUGS; CURRENT GOOD MANUFACTURING PRACTICES

**Priority:** Other Significant  
**Legal Authority:** 42 USC 262; 42 USC 263; 42 USC 264; 42 USC 216; 42 USC 263; 42 USC 360i; 21 USC 360; 21 USC 362; 21 USC 374; 21 USC 371; 21 USC 361; 21 USC 355; 21 USC 353 to 351; 21 USC 355; 21 USC 360; 21 USC 361; 21 USC 371; 21 USC 374; 42 USC 216; 42 USC 262; 42 USC 263; 42 USC 263a; 42 USC 264; 42 USC 300aa–25  
**CFR Citation:** 21 CFR 600.10(c); 21 CFR 600.11(e)  
**Legal Deadline:** None  
**Abstract:** The Food and Drug Administration (FDA) is issuing a direct final rule and a companion proposed rule to amend the biologics regulations by providing options to the existing requirement for separate, dedicated facilities and equipment for work with spore-forming microorganisms. FDA is taking this action due to advances in facility, system and equipment design, and sterilization technologies, that would allow work with spore-forming microorganisms to be performed in multi-product manufacturing areas.  
**Regulatory Flexibility Analysis Required:** No  
**Government Levels Affected:** None  
**Agency Contact:** Valerie Butler, Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, HFS–820, Center for Drug Evaluation and Research, 5100 Paint Branch Parkway, College Park, MD 20740  
**Phone:** 301 594–2041  
**Fax:** 301 827–5562  
**Email:** mitchellw@cder.fda.gov  
**RIN:** 0910–AC54

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**Timetable:**

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**Regulatory Flexibility Analysis Required:** Yes  
**Government Levels Affected:** Federal, State  
**URL For More Information:** www.fda.gov/cder/regulatory/positron

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**Regulatory Flexibility Analysis Required:** Yes  
**Government Levels Affected:** None  
**Agency Contact:** Wayne H. Mitchell, Regulatory Counsel, Office of Regulatory Policy, Department of Health and Human Services, Food and Drug Administration, Suite 3037 (HFD–7), Suite 3037 (HFD–7), Center for Drug Evaluation and Research, 1451 Rockville Pike, Rockville, MD 20852  
**Phone:** 301 594–2041  
**Fax:** 301 827–5562  
**Email:** ritu.nalubola@cfsan.fda.gov  
**RIN:** 0910–AC55
1001. DEFINITION OF “SERIOUS ADVERSE HEALTH CONSEQUENCES” UNDER THE PUBLIC HEALTH SECURITY AND BIOTERRORISM PREPAREDNESS AND RESPONSE ACT OF 2002

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

RIN: 0910–AC57

1002. QUALITY STANDARD REGULATION ESTABLISHING ALLOWABLE LEVEL FOR ARSENIC IN BOTTLED WATER

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

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

CFR Citation: 21 CFR 70.3; 21 CFR 71.1; 21 CFR 170.3; 21 CFR 171.1; 21 CFR 312.3; 21 CFR 312.56; 21 CFR 510.3; 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 falsified data in the course of proposing, designing, performing, recording, supervising, or reviewing research, or in reporting research results.

Timetable:

Action Date FR Cite
NPRM 12/00/03

Regulatory Flexibility Analysis Required: Undetermined

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), Suite 3059 (HFD–7), Center for Drug Evaluation and Research, 1451 Rockville Pike, Rockville, MD 20852 Phone: 301 594–2041 Fax: 301 827–5562

RIN: 0910–AC59

1003. CONTENT AND FORMAT OF LABELING FOR HUMAN PRESCRIPTION DRUGS AND BIOLOGICS; REQUIREMENTS FOR PREGNANCY AND LACTATION

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

Unfunded Mandates: Undetermined

Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 358; 21 USC 360; 21 USC 360(b); 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 201.57

Legal Deadline: None

Abstract: The proposed rule would amend FDA regulations concerning the format and content of the “Pregnancy,” “Labor and Delivery,” and “Nursing
Mothers’ subsections of the “Use in Specific Populations” section of the labeling for human prescription drugs. The proposal would require that labeling include a summary of the risks of using a drug during pregnancy and lactation and a discussion of the data supporting that summary.

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**Regulatory Flexibility Analysis**

**Required:** Undetermined

**Small Entities Affected:** Businesses

**Government Levels Affected:** Underdetermined

**Federalism:** Undetermined

**Agency Contact:** Christine F. Rogers, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Suite 3059 (HFD–7), Suite 3059 (HFD–7), Center for Drug Evaluation and Research, 1451 Rockville Pike, Rockville, MD 20852

**Phone:** 301 594–2041

**Fax:** 301 827–5562

**Email:** mhonigfo@cfsan.fda.gov

**RIN:** 0910–AF12

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**1006. ● TREATMENT USE OF INVESTIGATIONAL DRUGS**

**Priority:** Substantive, Nonsignificant.

Major status under 5 USC 801 is undetermined.

**Unfunded Mandates:** Undetermined

**Legal Authority:** 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 371; 42 USC 262

**CFR Citation:** 21 CFR 312.42; 21 CFR 312.400; 21 CFR 312.405; 21 CFR 312.410; 21 CFR 312.415; 21 CFR 312.420; 21 CFR 312.425; 21 CFR 312.430; 21 CFR 312.435

**Legal Deadline:** None

**Abstract:** The proposed rule would amend FDA’s investigational new drug applications (INDs) to describe the way patients may obtain investigational drugs for treatment use. Treatment use of investigational drugs would be available to: (1) individual patients, including in emergencies; (2) intermediate size patient; and (3) larger populations under a treatment protocol or IND.

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**Regulatory Flexibility Analysis**

**Required:** Undetermined

**Small Entities Affected:** Businesses

**Government Levels Affected:** Underdetermined

**Federalism:** Undetermined

**Agency Contact:** Christine F. Rogers, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Suite 3059 (HFD–7), Suite 3059 (HFD–7), Center for Drug Evaluation and Research, 1451 Rockville Pike, Rockville, MD 20852

**Phone:** 301 594–2041

**Fax:** 301 827–5562

**Email:** mhonigfo@cfsan.fda.gov

**RIN:** 0910–AF14

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**1007. ● 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.

**Unfunded Mandates:** Undetermined
1009. INFANT FORMULA: REQUIREMENTS PERTAINING TO GOOD MANUFACTURING PRACTICE, QUALITY CONTROL PROCEDURES, QUALITY FACTORS, NOTIFICATION REQUIREMENTS, AND 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.

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Regulatory Flexibility Analysis

Required: No

Small Entities Affected: None

Government Levels Affected: None

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

Phone: 301 436–1589

Email: cchristi@cfsan.fda.gov

RIN: 0910–AA04

1010. INVESTIGATIONAL NEW DRUGS: EXPORT REQUIREMENTS FOR UNAPPROVED NEW DRUG PRODUCTS

Priority: Routine and Frequent

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

CFR Citation: 21 CFR 312.110

Legal Deadline: None

Abstract: The final rule would amend the regulations on the exportation of unapproved new drug products, including biological products, for investigational use. In general, the rule would provide four different routes for exporting an unapproved new drug product for investigational use. One route would permit exportation, if the drug is the subject of an investigational new drug application (IND) and is being exported for use in the investigation. A second route would permit exportation, without prior Food and Drug Administration (FDA) approval and without an IND, if the product 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.

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### Regulatory Flexibility Analysis

**Required:** No

**Government Levels Affected:** Federal

**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, Rockville, MD 20857 Phone: 301 827–0587 Fax: 301 827–4774 Email: pchao@oc.fda.gov

**RIN:** 0910–AA99

### 1011. DETERMINATION THAT INFORMED CONSENT IS INFEASIBLE OR IS CONTRARY TO THE BEST INTEREST OF RECIPIENTS

**Priority:** Other Significant

**Legal Authority:** 21 USC 321; 21 USC 346; 21 USC 346a; 21 USC 348; 21 USC 352; 21 USC 353; 21 USC 355; 21 USC 360; 21 USC 360c to 360f; 21 USC 360h to 360j; 21 USC 371; 21 USC 379e; 21 USC 381; 42 USC 216; 42 USC 241; 42 USC 262; 42 USC 263b to 263n

**CFR Citation:** 21 CFR 50; 21 CFR 312

**Legal Deadline:** None

### Abstract:

The final rule would establish criteria and standards for the President to apply in making a determination that informed consent is not feasible or is contrary to the best interest of military personnel engaged in specific military operations. Under Federal law, the President is authorized to waive the Federal Food, Drug, and Cosmetic Act’s informed consent requirements in military operations, if the President finds that obtaining consent is infeasible, contrary to the best interests of recipients, or contrary to national security interests.

### Timetable:

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### Regulatory Flexibility Analysis

**Required:** No

**Government Levels Affected:** Federal

**Agency Contact:** Howard P. Muller, Office of Regulatory Policy, Department of Health and Human Services, Food and Drug Administration, Suite 3037 (HFD–7), Center for Drug Evaluation and Research, 1451 Rockville Pike, Rockville, MD 20852 Phone: 301 594–5601 Fax: 301 827–5562 Email: mullerh@cdr.fda.gov

**RIN:** 0910–AB61

### 1012. LABELING FOR HUMAN PRESCRIPTION DRUGS; REVISED FORMAT

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

**RIN:** 0910–AA94

### 1013. SAFETY REPORTING REQUIREMENTS FOR HUMAN DRUG AND BIOLOGICAL PRODUCTS

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

**RIN:** 0910–AA97

### 1014. SUPPLEMENTS AND OTHER CHANGES TO AN APPROVED APPLICATION

**Priority:** Other Significant

**Legal Authority:** 21 USC 356a

**CFR Citation:** 21 CFR 314

**Legal Deadline:** None

### Abstract:

Section 116 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) added section 506A to the Food, Drug, and Cosmetic Act (21 U.S.C. 356a). Pursuant to section 116, the rulemaking will revise current procedures for approving manufacturing changes and generally classify such changes into four categories. Major manufacturing changes, which are of a type determined by the Secretary to have a substantial potential to adversely affect the identity, strength, quality, purity, and potency of the drug as they may relate to the safety and effectiveness of a drug, require prior approval of a supplemental application. A second category of changes may be made if FDA has not notified the company within 30 days after the submission of a supplement that prior approval is required. A third category of changes may be made upon submission of a supplement to the agency. The rule will also identify another category of changes that may be made without the submission of a supplement but which must be reported in an annual report.

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### Regulatory Flexibility Analysis

**Required:** No

**Government Levels Affected:** None

**Agency Contact:** Howard P. Muller, Office of Regulatory Policy, Department of Health and Human Services, Food and Drug Administration, Suite 3037 (HFD–7), Center for Drug Evaluation and Research, 1451 Rockville Pike, Rockville, MD 20852 Phone: 301 594–5601 Fax: 301 827–5562 Email: mullerh@cdr.fda.gov

**RIN:** 0910–AB61

### 1015. CGMP FOR BLOOD AND BLOOD COMPONENTS: NOTIFICATION OF CONSIGNEES AND TRANSFUSION RECIPIENTS RECEIVING BLOOD AND BLOOD COMPONENTS AT INCREASED RISK OF TRANSMITTING HCV INFECTION (LOOKBACK)

**Regulatory Plan:** This entry is Seq. No. 49 in part II of this issue of the Federal Register.

**RIN:** 0910–AB76
### 1016. CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKING, OR HOLDING DIETARY INGREDIENTS AND DIETARY SUPPLEMENTS

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

**RIN:** 0910–AB88

### 1017. REQUIREMENTS FOR SUBMISSION OF LABELING FOR HUMAN PRESCRIPTION DRUGS AND BIOLOGICS IN ELECTRONIC FORMAT

**Priority:** Other Significant

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

**Legal Authority:** 21 USC 321; 21 USC 331; 21 USC 351; 21 USC 353; 21 USC 355; 21 USC 360; 21 USC 371; 21 USC 374; 21 USC 379e; 42 USC 262; . . .

**CFR Citation:** 21 CFR 314; 21 CFR 601

**Legal Deadline:** None

**Abstract:** The Food and Drug Administration (FDA) is proposing to amend its regulations governing the format in which certain labeling in new drug applications, abbreviated new drug applications, certain biological license applications, supplements, and annual reports are required to be submitted. The rule would require that certain labeling content described under section 201.100(d)(3) be submitted to FDA in electronic format.

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**Small Entities Affected:** Businesses

**Government Levels Affected:** Federal

**Agency Contact:** Nicole K. Mueller, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Room 3037, (HFZ–7), 1451 Rockville Pike, Rockville, MD 20852

Phone: 301 594-2041

Fax: 301 594-6197

Email: muellern@cdr.fda.gov

**RIN:** 0910–AB91

### 1018. ADDITIONAL SAFEGUARDS FOR CHILDREN IN CLINICAL INVESTIGATIONS OF FDA-REGULATED PRODUCTS

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

**Unfunded Mandates:** Undetermined

**Legal Authority:** 21 USC 321; 21 USC 343; 21 USC 346; 21 USC 346a; 21 USC 348; 21 USC 350a; 21 USC 350b; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 360c to 360f; 21 USC 360h to 360j; 21 USC 371; 21 USC 379e; 21 USC 381; 41 USC 216; 41 USC 241; 41 USC 262; 41 USC 263b to 263n

**CFR Citation:** 21 CFR 50; 21 CFR 601

**Legal Deadline:** Other, Statutory, April 17, 2001, Other.

**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.

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**Regulatory Flexibility Analysis Required:** Undetermined

**Small Entities Affected:** None

**Government Levels Affected:** None

**Agency Contact:** Carol Drew, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Suite 3037 (HFZ–7), Center for Drug Evaluation and Research, 1451 Rockville Pike, Rockville, MD 20852

Phone: 301 594-2041

Fax: 301 827-5562

**RIN:** 0910–AC07

### 1019. BAR CODE LABEL REQUIREMENTS FOR HUMAN DRUG PRODUCTS AND BLOOD

**Regulatory Plan:** This entry is Seq. No. 51 in part II of this issue of the Federal Register.

**RIN:** 0910–AC26

### 1020. MEDICAL DEVICES; PATIENT EXAMINATION AND SURGEOUS’ GLOVES; ADULTERATION

**Priority:** Substantive, Nonsignificant

**Legal Authority:** 21 USC 321; 21 USC 331; 21 USC 351; 21 USC 352; 21 USC 371; 21 USC 374

**CFR Citation:** 21 CFR 800.20

**Legal Deadline:** None

**Abstract:** The Food and Drug Administration (FDA) is proposing to amend 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 proposal would clarify sampling plans and the scoring of defects, lower acceptance rates for leaking gloves, raise rejection rates for leaking gloves, and add tightened inspection schemes for reexamined glove lots. The rule is intended to facilitate industry compliance and enhance the safety and effectiveness of gloves.

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**Regulatory Flexibility Analysis Required:** No

**Government Levels Affected:** Undetermined

**Federalism:** Undetermined

**Agency Contact:** Joseph M. Sheehan, Chief, Regulations Staff, Department of Health and Human Services, Food and Drug Administration, HFZ–215, Center for Devices and Radiological Health, 1350 Piccard Drive, Rockville, MD 20850

Phone: 301 827-2974

Fax: 301 594-4795

Email: jms@cdrh.fda.gov

**RIN:** 0910–AC32

### 1021. AMENDMENTS TO THE PERFORMANCE STANDARD FOR DIAGNOSTIC X-RAY SYSTEMS AND THEIR MAJOR COMPONENTS

**Priority:** Substantive, Nonsignificant

**Legal Authority:** 21 USC 321; 21 USC 331; 21 USC 351; 21 USC 352; 21 USC 360e to 360j; 21 USC
1024. REGISTRATION OF FOOD AND ANIMAL FEED FACILITIES

Priority: Economically Significant. Major under 5 USC 801.

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

Legal Authority: PL 107–188, sec 305

 CFR Citation: 21 CFR 1


The Public Health Security and Bioterrorism Preparedness and Response Act of 2002, section 305, directs the Secretary, through FDA, to issue a final regulation establishing registration requirements by December 12, 2003. The statute is self-implementing on this date if FDA does not issue a final regulation that is effective by December 12, 2003.

Abstract: This rulemaking is one of a number of actions being taken to improve FDA’s ability to respond to threats of bioterrorism and other foodborne illness emergencies. Section 415 of the Federal Food, Drug, and Cosmetic Act (FFDCA), which was added by section 305 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), directs the Secretary to require any facility engaged in manufacturing, processing, packing, or holding of food for consumption by humans or animals in the United States to be registered with the Secretary through FDA. Section 415 directs the Secretary, through FDA, to promulgate final regulations implementing the requirements by December 12, 2003. The owner, operator, or agent in charge of the facility must submit the registration. Foreign facilities must include the name of the United States agent for the facility. The registration requirement are farms, restaurants, other retail food establishments, nonprofit food establishments in which food is prepared for or served directly to the consumer, and fishing vessels (except those engaged in processing as defined in 21 CFR 123.3(k)). Foreign facilities required to register include only those from which food is exported to the United States without further processing or packaging outside the United States. The Bioterrorism Act provides that if food from an unregistered foreign facility is offered for import into the United States without having registered, the food will be held at the port of entry or at a secure facility, until the foreign facility has registered.

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Regulatory Flexibility Analysis Required: Yes

Government Levels Affected: None
### 1025. PRIOR NOTICE OF IMPORTED FOOD UNDER THE PUBLIC HEALTH SECURITY AND BIOR TERRORISM PREPAREDNESS AND RESPONSE ACT OF 2002

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

**Legal Authority:** PL 107–188, sec 307

**CFR Citation:** 21 CFR 1.276 et seq

**Legal Deadline:** Final, Statutory, December 12, 2003, Final. 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, authorizes the Secretary, through FDA, to promulgate final regulations by December 12, 2003. Section 801(m) requires notification to FDA prior to the entry of imported food. The required prior notice would provide the identity of the article of food; the manufacturer; the shipper; the grower, if known at the time of notification; the originating country; the shipping country; and the anticipated port of entry. The regulation identifies the parties responsible for providing the notice and explains the information that the prior notice is required to contain, the method of submission of the notice, and the minimum and maximum period of advance notice required. Section 307 also states that if FDA does not receive prior notice or receives inadequate prior notice, the imported food shall be refused admission and held at the port of entry until proper notice is provided.

**Timetable:**

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**Government Levels Affected:** Federal

**Agency Contact:** Mary Ayling, Lead, Inspection and Compliance Team, Food Safety Staff, Department of Health and Human Services, Food and Drug Administration, HFS–32, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, College Park, MD 20740 Phone: 301 436–2131 Fax: 301 436–2605 Email: mary.ayling@cfsan.fda.gov

**RIN:** 0910–AC41

### 1026. REQUIREMENTS FOR LIQUID MEDICATED FEED AND FREE-CHOICE MEDICATED FEED

**Priority:** Substantive, Nonsignificant

**Legal Authority:** 21 USC 360b; 21 USC 371

**CFR Citation:** 21 CFR 558.5; 21 CFR 510.455

**Legal Deadline:** None

**Abstract:** In response to a citizen petition filed by the American Feed Industry Association, the Food and Drug Administration (FDA) is proposing to amend the requirements for liquid medicated animal feed to clarify what information and data are required to demonstrate chemical and positional stability. The amended regulations would also clarify the provisions for the submission of such data through a master file and the reference to master files by subsequent applicants. Additionally, FDA is proposing to amend the regulations for free-choice medicated feed to ensure consistency with the requirements for liquid medicated feed. Finally, FDA is proposing to amend the regulations for free-choice medicated feed and liquid medicated feed so that these provisions comply with the terms of the Animal Drug Availability Act of 1996.

**Timetable:**

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**Government Levels Affected:** None

**Agency Contact:** William D. Price, Special Assistant, Department of Health and Human Services, Food and Drug Administration, HFV–200, HFV–220, Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855 Phone: 301 827–6652 Fax: 301 594–4512

**RIN:** 0910–AC43

### 1027. PRESUBMISSION CONFERENCES

**Priority:** Substantive, Nonsignificant

**Legal Authority:** 21 USC 360b

**CFR Citation:** 21 CFR 514

**Legal Deadline:** None

**Abstract:** This rule will implement section 512(b)(3) of the Federal Food, Drug, and Cosmetic Act (the Act). This section of the Act states that any person intending to file a new animal drug application or supplemental new animal drug application, or to investigate a new animal drug is entitled to one or more conferences with the agency prior to submission to reach an agreement establishing a submission or investigational requirement. This rule would describe how to request a presubmission conference and describe the procedures for the conduct of presubmission conferences.

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**Government Levels Affected:** None

**Agency Contact:** Gail Schmerfeld, Special Assistant, Department of Health and Human Services, Food and Drug Administration, HFV–100, Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855 Phone: 301 827–0205

**RIN:** 0910–AC44
1028. 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 356; 21 USC 360; 21 USC 360g to 360h; 21 USC 360j; 21 USC 360k; 21 USC 360l; 21 USC 360g to 360ss; 21 USC 371; 21 USC 372; 21 USC 374; 21 USC 381; 42 USC 216; 42 USC 262; 42 USC 263; 42 USC 264

CFR Citation: 21 CFR 201.59; 21 CFR 610.21

Legal Deadline: None

Abstract: The final rule amends the FDA biologics regulations in response to the report and recommendations of the Panel on Review of Bacterial Vaccines and Toxoids with Standards of Potency (the Panel). The Panel reviewed the safety, efficacy, and labeling of bacterial vaccines and toxoids with standards of potency, bacterial antitoxins, and immune globulins. On the basis of the Panel’s findings and recommendations, FDA is classifying these products as Category I (safe, effective, and not misbranded), Category II (unsafe, ineffective, or misbranded), or Category III (off the market pending completion of studies permitting a determination of effectiveness).

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1029. CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PROCESSING, PACKING, OR HOLDING OF DRUGS; REVISION OF CERTAIN LABELING CONTROLS

Priority: Substantive, Nonsignificant.

Legal Authority: Not Yet Determined

CFR Citation: 21 CFR 211.122

Legal Deadline: None

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

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1030. ELIGIBILITY DETERMINATION FOR DONORS OF HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS

Priority: Other Significant

Legal Authority: 42 USC 216; 42 USC 243; 42 USC 263a; 42 USC 264; 42 USC 271

CFR Citation: 21 CFR 210.1(c); 21 CFR 210.2(a); 21 CFR 210.2(b); 21 CFR 211.1(b); 21 CFR 820.1(a)(1); 21 CFR 820.1(c); 21 CFR 1271

Legal Deadline: None

Abstract: The Food and Drug Administration is requiring certain manufacturers of human cells, tissues, and cellular and tissue-based products (HCT/Ps) to screen and test the donors of cells and tissues used in those products for evidence of, or risk factors for, relevant communicable disease. As part of this action, the agency is amending the current good manufacturing practice regulations that apply to HCT/Ps regulated as drugs, medical devices, and/or biological products to incorporate the new donor eligibility requirements into existing good manufacturing practice regulations for those products.

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and Drug Administration, Suite 200N (HFM–17), Center for Biologics Evaluation and Research, 1401 Rockville Pike, Rockville, MD 20852–1448
Phone: 301 827–6210
Fax: 301 827–9434

RIN: 0910–AB27

1031. CURRENT GOOD TISSUE PRACTICE FOR HUMAN CELL, TISSUE, AND CELLULAR AND TISSUE-BASED PRODUCTS ESTABLISHMENTS; INSPECTION AND ENFORCEMENT

Priority: Other Significant
Legal Authority: 42 USC 216; 42 USC 243; 42 USC 263a; 42 USC 264; 42 USC 271
CFR Citation: 21 CFR 1270; 21 CFR 1271
Legal Deadline: None
Abstract: The Food and Drug Administration (FDA) is proposing to amend its regulations on submission of bioequivalence (BE) data to require an abbreviated new drug application (ANDA) applicant to submit data from all BE studies the applicant conducts on a drug product formulation submitted for approval. In the past, ANDA applicants have submitted BE studies demonstrating that a generic product meets BE criteria for FDA to approve the ANDA but have not typically submitted additional BE studies conducted on the same drug product formulation. FDA is proposing to require ANDA applicants to submit information, in either a complete or summary report, from all additional passing and nonpassing BE studies conducted on the same drug product formulation submitted for approval.

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Next Action: Undetermined

Regulatory Flexibility Analysis Required: Yes
Government Levels Affected: None
Agency Contact: Aileen Ciampa, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, HFD–7, Center for Drug Evaluation and Research, 1451 Rockville Pike, Rockville, MD 20857
Phone: 301 594–2041
Fax: 301 827–5562

RIN: 0910–AC23

1032. REQUIREMENTS FOR SUBMISSION OF IN VIVO BIOEQUIVALENCE DATA

Priority: Substantive, Nonsignificant
Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 355a; 21 USC 356; 21 USC 356a to 356c; 21 USC 371; 21 USC 374; 21 USC 379
CFR Citation: 21 CFR 314.96(a)(1); 21 CFR 314.94(a)(7); 21 CFR 320.21(b)(1)
Legal Deadline: None
Abstract: The Food and Drug Administration (FDA) is proposing to amend its regulations on submission of bioequivalence (BE) data to require an abbreviated new drug application (ANDA) applicant to submit data from all BE studies the applicant conducts on a drug product formulation submitted for approval. In the past, ANDA applicants have submitted BE studies demonstrating that a generic product meets BE criteria for FDA to approve the ANDA but have not typically submitted additional BE studies conducted on the same drug product formulation. FDA is proposing to require ANDA applicants to submit information, in either a complete or summary report, from all additional passing and nonpassing BE studies conducted on the same drug product formulation submitted for approval.

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Next Action: Undetermined

Regulatory Flexibility Analysis Required: Yes
Government Levels Affected: None
Agency Contact: Aileen Ciampa, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, HFD–7, Center for Drug Evaluation and Research, 1451 Rockville Pike, Rockville, MD 20857
Phone: 301 594–2041
Fax: 301 827–5562

RIN: 0910–AC23

CFR Citation: 21 CFR 101
Legal Deadline: None
Abstract: The purpose of this rulemaking is to reduce mortality and morbidity by providing sensitive individuals with additional food allergen information to help them protect themselves from serious allergic reactions, including life-threatening anaphylactic shock. The common food allergens are: 1) peanuts; 2) soybeans; 3) milk; 4) eggs; 5) fish; 6) crustaceae (e.g., lobster, crab, shrimp); 7) tree nuts (e.g., almonds, chestnuts, macadamia nuts, pecans, walnuts, hazelnuts or filberts, cashews, brazil nuts, pistachios, pine nuts); and 8) wheat.

The rule would propose to require that foods that contain certain protein ingredients include information on the label in plain English terms that clearly identifies the presence of these ingredients.

The agency is also proposing to require food allergen labeling on spices, flavors, noncertified colors and incidental additives found in foods as ingredients that contain certain allergic proteins. Currently, section 403(i) of the Federal Food, Drug, and Cosmetic Act allows spices, flavors and noncertified colors used as ingredients of foods to be declared collectively on the label without naming each one. Federal regulations at 21 C.F.R. 101.100(a)(3) exempt incidental additives from ingredient declaration on the label if they are present in the food at an insignificant amount and do not have any technical or functional effect in the finished food.

1033. FOOD LABELING: FOOD ALLERGEN INGREDIENT LABELING

Priority: Other Significant. Major status under 5 USC 801 is undetermined.
Legal Authority: 21 USC 321 ; 21 USC 331; 21 USC 342; 21 USC 343; 21 USC 371

CFR Citation: 21 CFR 101
Legal Deadline: None
Abstract: The purpose of this rulemaking is to reduce mortality and morbidity by providing sensitive individuals with additional food allergen information to help them protect themselves from serious allergic reactions, including life-threatening anaphylactic shock. The common food allergens are: 1) peanuts; 2) soybeans; 3) milk; 4) eggs; 5) fish; 6) crustaceae (e.g., lobster, crab, shrimp); 7) tree nuts (e.g., almonds, chestnuts, macadamia nuts, pecans, walnuts, hazelnuts or filberts, cashews, brazil nuts, pistachios, pine nuts); and 8) wheat. The rule would propose to require that foods that contain certain protein ingredients include information on the label in plain English terms that clearly identifies the presence of these ingredients.

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Regulatory Flexibility Analysis Required: Yes
Government Levels Affected: None
Federalism: Undetermined
Agency Contact: Rhonda Rhoda Kane M.S., R.D., Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, HFS–820, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, College Park, MD 20740
Phone: 301 436–2371
Fax: 301 436–2636
Email: rkane2@cf腈an.fda.gov

RIN: 0910–AF07
## 1034. INVESTIGATIONAL USE NEW ANIMAL DRUG REGULATIONS

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

**Legal Authority:** 21 USC 321; 21 USC 351 to 353; 21 USC 360b; 21 USC 371

**CFR Citation:** 21 CFR 511

**Abstract:** FDA initiated a review of 21 C.F.R. 511.1 under section 610 of the Regulatory Flexibility Act. The purpose of the section 610 review was to determine if the rule should be amended to minimize adverse economic impacts on small entities. FDA solicited and considered comments on the following: 1) the continued need for the rule; 2) the nature of complaints or comments received concerning the rule; 3) the complexity of the rule; 4) the extent to which the rule overlaps, duplicates, or conflicts with other Federal, State, or local government rules; and 5) the degree to which technology, economic conditions, or other factors have changed in the area affected by the rule.

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**Regulatory Flexibility Analysis Required:** Undetermined

**Small Entities Affected:** Businesses

**Government Levels Affected:** None

**Agency Contact:** Marty Schoenemann, Department of Health and Human Services, Food and Drug Administration, HFV–126, HFV–100, Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855

Phone: 301 827–0220

**RIN:** 0910–AB02

## 1035. FOOD LABELING: TRANS FATTY ACIDS IN NUTRITION LABELING, NUTRIENT CONTENT CLAIMS, AND HEALTH CLAIMS

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

**CFR Citation:** 21 CFR 101

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**Regulatory Flexibility Analysis Required:** Yes

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

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

**Agency Contact:** Julie Schrimpf

Phone: 301 436–2373

Fax: 301 436–2639

Email: julie.schrimpf@cfsan.fda.gov

**RIN:** 0910–AB66

## 1036. ALUMINUM IN LARGE- AND SMALL-VOLUME PARENTERALS USED IN TOTAL PARENTERAL NUTRITION

**Priority:** Other Significant

**CFR Citation:** 21 CFR 201.323(c)

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**Regulatory Flexibility Analysis Required:** Undetermined

**Government Levels Affected:** None

**Agency Contact:** Christine F. Rogers

Phone: 301 594–2041

Fax: 301 827–5562

**RIN:** 0910–AC18

## 1037. REGULATION OF CARCINOGENIC COMPOUNDS USED IN FOOD-PRODUCING ANIMALS; DEFINITION OF “NO RESIDUE”

**Priority:** Substantive, Nonsignificant

**CFR Citation:** 21 CFR 500.80; 21 CFR 500.82; 21 CFR 500.84; 21 CFR 500.88

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**Regulatory Flexibility Analysis Required:** No

**Government Levels Affected:** None

**Agency Contact:** Steven Brynes

Phone: 301 827–6975

Email: sbrynes@cvm.fda.gov

**RIN:** 0910–AC45

## 1038. APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG: PATENT LISTING REQUIREMENTS AND APPLICATION OF 30-MONTH STAYS ON APPROVAL OF ABBREVIATED NEW DRUG APPLICATIONS

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

**CFR Citation:** 21 CFR 314.52(a)(3); 21 CFR 314.53(b); 21 CFR 314.53(c)(1); 21 CFR 314.53(c)(2); 21 CFR 314.95(a)(3)

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**Regulatory Flexibility Analysis Required:** No

**Government Levels Affected:** None

**Agency Contact:** Jarilyn Dupont

Phone: 301 827–3360

Fax: 301 594–6777

Email: jdupont@oc.fda.gov

**RIN:** 0910–AC48
### Proposed Rule Stage

**1039. 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.

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**Regulatory Flexibility Analysis Required:** No

**Government Levels Affected:** None

**Agency Contact:** John M. Heyob, Director, Division of Practitioner Data Banks, Department of Health and Human Services, Health Resources and Services Administration, Suite 300, 7519 Standish Place, Rockville, MD 20857

Phone: 301 443–2300
Fax: 301 443–6725

RIN: 0906–AA41

### Final Rule Stage

**1040. DESIGNATION OF MEDICALLY UNSERVED POPULATIONS AND HEALTH PROFESSIONAL SHORTAGE AREAS**

**Priority:** Substantive, Nonsignificant

**Legal Authority:** 42 USC 254b; 42 USC 254c

**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.

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**Regulatory Flexibility Analysis Required:** No

**Government Levels Affected:** None

**Agency Contact:** Andy Jordan, Acting Chief, Shortage Designation Branch, Department of Health and Human Services, Health Resources and Services Administration, Room 8C26, National Center for Health Workforce Analysis, Bureau of Health Professions, Parklawn Building, Rockville, MD 20857

Phone: 301 594–0197
Email: dsd@hrsa.gov

RIN: 0906–AA44

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### Proposed Rule Stage

**1041. • INTERIM FINAL RULE FOR THE SMALLPOX EMERGENCY PERSONNEL PROTECTION PROGRAM: SMALLPOX (VACCINIA) VACCINE INJURY TABLE**

**Priority:** Substantive, Nonsignificant

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

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

**CFR Citation:** 42 CFR 102

**Legal Deadline:** None

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

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<td>Interim Final Rule</td>
<td>08/27/03</td>
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**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** None

**Agency Contact:** Dr. Vito Caserta, Chief Medical Officer, Department of Health and Human Services, Health Resources and Services Administration, 10th Floor, 4350 East West Highway, Bethesda, MD 20814

Phone: 301 443–4956
Email: smallpox@hrsa.gov

RIN: 0906–AA60

### Final Rule Stage

**1042. • SMALLPOX VACCINE INJURY COMPENSATION PROGRAM: ADMINISTRATIVE IMPLEMENTATION**

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

**RIN:** 0906–AA61
### 1043. 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 1396e–2  
**CFR Citation:** 45 CFR 60  
**Legal Deadline:** None  
**Abstract:** Public Law 100–93 amended section 1921 of the Social Security Act to require that each State have in effect a system of reporting disciplinary licensure actions taken against all licensed health care practitioners and entities. It also requires States to report any negative action or finding that a peer review organization, private accreditation entity, or a State has concluded against a health care practitioner or entity. Section 1921 directs the Secretary to provide for maximum appropriate coordination in the implementation of these reporting requirements with those of the Health Care Quality Improvement Act of 1986 (title IV of Pub. L. 99–660). Section 1921 requirements will be incorporated into the National Practitioner Data Bank.

**Timetable:**  
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**Regulatory Flexibility Analysis Required:** No  
**Small Entities Affected:** No  
**Government Levels Affected:** State  
**Agency Contact:** John M. Heyob, Director, Division of Practitioner Data Banks, Department of Health and Human Services, Health Resources and Services Administration, Suite 300, 7519 Standish Place, Rockville, MD 20957  
**Phone:** 301 443–2300  
**Fax:** 301 443–6725  
**RIN:** 0906–AA57

---

### 1044. INDIAN CHILD PROTECTION AND FAMILY VIOLENCE PREVENTION ACT MINIMUM STANDARDS OF CHARACTER

**Priority:** Info./Admin./Other  
**CFR Citation:** 42 CFR 36  

**Completed:**  
**Reason:** Withdrawn  
**Date:** 11/18/03  
**FR Cite:** |

**Regulatory Flexibility Analysis Required:** No  
**RIN:** 0917–AA02

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### 1045. UNDERGRADUATE SCHOLARSHIP PROGRAM REGARDING PROFESSIONS NEEDED BY THE NATIONAL INSTITUTES OF HEALTH (NIH)

**Priority:** Substantive, Nonsignificant  
**Legal Authority:** 42 USC 216; 42 USC 288–4  
**CFR Citation:** 42 CFR 68b  
**Legal Deadline:** None  
**Abstract:** Section 487D of the Public Health Service Act, as added by the National Institutes of Health Revitalization Act of 1993, creates a program offering scholarships, in an amount not to exceed $20,000 per year of academic study, to individuals from disadvantaged backgrounds who are enrolled as full-time students at accredited institutions pursuing academic programs appropriate for careers in professions needed by NIH. For each year of scholarship support, the recipient agrees to service (employment) at NIH during which the individual is attending the educational institution and receiving the NIH scholarship. The proposed new regulations will cover this program.

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**Regulatory Flexibility Analysis Required:** No  
**Government Levels Affected:** Tribal  
**Agency Contact:** Ramona D. Williams  
**Phone:** 301 443–1589  
**RIN:** 0917–AA02

---

### 1046. 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 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.
1047. STANDARDS FOR A NATIONAL CHIMPANZEE SANCTUARY SYSTEM

Priority: Substantive, Nonsignificant
Legal Authority: 42 USC 287a–3a
CFR Citation: 42 CFR 9
Legal Deadline: NPRM, Statutory, June 18, 2001, NPRM.

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

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Regulatory Flexibility Analysis Required: No
Small Entities Affected: No
Government Levels Affected: None
Agency Contact: Jerry Moore, NIH Regulations Officer, Department of Health and Human Services, National Institutes of Health, Room 601 MSC 7669, 6011 Executive Boulevard, Rockville, MD 20852
Phone: 301 496–4606
Fax: 301 402–0169
Email: jm40z@nih.gov

RIN: 0925–AA28

1049. NATIONAL INSTITUTES OF HEALTH EXTRAMURAL LOAN REPAYMENT PROGRAM FOR CLINICAL RESEARCHERS

Priority: Substantive, Nonsignificant
Legal Authority: 42 USC 216; 42 USC 288–5a
CFR Citation: 42 CFR 68g
Legal Deadline: None

Abstract: NIH proposes to establish implementing regulations for the Extramural Loan Repayment Program for Clinical Researchers, authorized under section 487F of the Public Health Service Act. The program provides for the repayment of the existing educational loan debt of qualified health professionals who agree to conduct clinical research.

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Regulatory Flexibility Analysis Required: No
Small Entities Affected: No
Government Levels Affected: None
Agency Contact: Jerry Moore, NIH Regulations Officer, Department of Health and Human Services, National Institutes of Health, Room 601 MSC 7669, 6011 Executive Boulevard, Rockville, MD 20852
Phone: 301 496–4606
Fax: 301 402–0169
Email: jm40z@nih.gov

RIN: 0925–AA34

1051. NATIONAL INSTITUTES OF HEALTH LOAN REPAYMENT PROGRAM FOR HEALTH DISPARITIES RESEARCH

Priority: Substantive, Nonsignificant
Legal Authority: 42 USC 216; 42 USC 287c–33
CFR Citation: 42 CFR 68f
Legal Deadline: None
Abstract: NIH proposes to establish implementing regulations for the Loan Repayment Program for Health Disparities Research, authorized under section 485G of the Public Health Service Act. The program provides for the repayment of the existing educational loan debt of qualified health professionals who agree to conduct minority-health or other health-disparities research for a minimum of two years.

**Timetable:**

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Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Jerry Moore, NIH Regulations Officer, Department of Health and Human Services, National Institutes of Health, Room 601 MSC 7669, 6011 Executive Boulevard, Rockville, MD 20852
Phone: 301 496–4606
Fax: 301 402–0169
Email: jm40z@nih.gov
RIN: 0925–AA35

**1052. NATIONAL INSTITUTES OF HEALTH CLINICAL RESEARCH LOAN REPAYMENT PROGRAM FOR INDIVIDUALS FROM DISADVANTAGED BACKGROUNDS**

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 216; 42 USC 288–5

CFR Citation: 42 CFR 68a

**Legal Deadline:** None

**Abstract:** NIH proposes to amend the regulations governing the Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds to reflect the new maximum annual loan amount of $35,000 and a change in program eligibility to include qualified health professionals who are not NIH employees, as well as to amend the definition of “disadvantaged.”

**Timetable:**

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Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Jerry Moore, NIH Regulations Officer, Department of Health and Human Services, National Institutes of Health, Room 601 MSC 7669, 6011 Executive Boulevard, Rockville, MD 20852
Phone: 301 496–4606
Fax: 301 402–0169
Email: jm40z@nih.gov
RIN: 0925–AA36

**1053. NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT CONTRACEPTION AND INFERTILITY RESEARCH LOAN REPAYMENT PROGRAM**

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

Legal Authority: 42 USC 216; 42 USC 288–2

**CFR Citation:** 42 CFR 68a

**Legal Deadline:** None

**Abstract:** NIH proposes to amend its current regulations governing the National Institute of Child Health and Human Development Contraception and Infertility Research Loan Repayment Program to make the eligibility requirements of the Program consistent with the eligibility requirements of the other extramural loan repayment programs administered by NIH.

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Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Jerry Moore, NIH Regulations Officer, Department of Health and Human Services, National Institutes of Health, Room 601 MSC 7669, 6011 Executive Boulevard, Rockville, MD 20852
Phone: 301 496–4606
Fax: 301 402–0169
Email: jm40z@nih.gov
RIN: 0925–AA41

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

National Institutes of Health (NIH)

**1054. NATIONAL INSTITUTES OF HEALTH LOAN REPAYMENT PROGRAM FOR RESEARCH GENERALLY**

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 216; 42 USC 288–3

CFR Citation: 42 CFR 68d

**Legal Deadline:** None

**Abstract:** Regulations will be issued to govern the awarding of educational loan repayments to qualified health professionals who agree to conduct research as employees of the National Institutes of Health.

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Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Jerry Moore, NIH Regulations Officer, Department of Health and Human Services, National Institutes of Health, Room 601 MSC 7669, 6011 Executive Boulevard, Rockville, MD 20852
Phone: 301 496–4606
Fax: 301 402–0169
Email: jm40z@nih.gov
RIN: 0925–AA18

**Final Rule Stage**
1055. SCIENTIFIC PEER REVIEW OF RESEARCH GRANT APPLICATIONS AND RESEARCH AND DEVELOPMENT CONTRACT PROJECTS

Priority: Substantive, Nonsignificant
Legal Authority: 42 USC 216; 42 USC 282(b)(6); 42 USC 284(c)(3); 42 USC 289a; 42 USC 290aa–3
CFR Citation: 42 CFR 52h
Legal Deadline: None
Abstract: NIH staff have found ambiguities, misstatements, and voids in the existing peer review regulations. These regulations, which govern the first level of review, are being amended to reflect current policies and procedures.

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Regulatory Flexibility Analysis
Required: No

Government Levels Affected: None

Agency Contact: Jerry Moore, NIH Regulations Officer, Department of Health and Human Services, National Institutes of Health, Room 601 MSC 7669, 6011 Executive Boulevard, Rockville, MD 20852
Phone: 301 496–4606
Fax: 301 402–0169
Email: jm40z@nih.gov
RIN: 0925–AA20

1056. NATIONAL INSTITUTES OF HEALTH CENTER GRANTS

Priority: Substantive, Nonsignificant
Legal Authority: 42 USC 216; 42 USC 284g; 42 USC 285a–6(c)(1)(E); 42 USC 285a–7(c)(1)(G); 42 USC 285b–4; 42 USC 285c–5; 42 USC 285c–8; 42 USC 285d–6; 42 USC 285e–2; 42 USC 285e–3; 42 USC 285e–10a; ...
CFR Citation: 42 CFR 52a
Legal Deadline: None
Abstract: NIH proposes to amend the current center grants regulations to reflect new authorities set forth in sections 409C, 445I, 452E, and 485F of the Public Health Service Act. Section 409C concerns centers of excellence regarding research on autism; section 445I concerns centers of excellence in Alzheimer’s disease research and treatment; section 452E concerns centers regarding research on “fragile X;” and section 485F concerns centers of excellence for research education and training for individuals who are members of minority health disparity populations.

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Regulatory Flexibility Analysis
Required: No

Government Levels Affected: None

Agency Contact: Jerry Moore, NIH Regulations Officer, Department of Health and Human Services, National Institutes of Health, Room 601 MSC 7669, 6011 Executive Boulevard, Rockville, MD 20852
Phone: 301 496–4606
Fax: 301 402–0169
Email: jm40z@nih.gov
RIN: 0925–AA24

1057. PUBLIC HEALTH SERVICE POLICIES ON RESEARCH MISCONDUCT

Priority: Substantive, Nonsignificant
Legal Authority: 42 USC 216; 42 USC 241; 42 USC 289b
CFR Citation: 42 CFR 93
Legal Deadline: None
Abstract: This notice of proposed rulemaking proposes substantial revisions to the existing regulations at 42 CFR part 50, subpart A, “Responsibilities of Awardee and Applicant Institutions for Dealing With and Reporting Possible Misconduct in Science,” 54 FR 32449, August 8, 1989. The National Institutes of Health Revitalization Act of 1993 (NIH Act), Public Law 103–43, contains provisions that affect the current rule. For example, section 161 of the NIH Act established the Office of Research Integrity (ORI) as an independent entity reporting to the Secretary, and recent organizational changes have also affected the ORI’s operations. In addition, the Office of Science and Technology Policy (OSTP) published a Governmentwide policy that applies to federally-funded research and proposals submitted to the Federal agencies for research funding, 65 FR 76260, December 6, 2000. The proposed revised regulation will implement this OSTP policy, which contains a definition of research misconduct and basic guidelines for the response of Federal agencies and research institutions to allegations of research misconduct. The current regulation, which implemented section 493(e) of the Public Health Service Act, would be deleted, and a new part 93, subparts A, B, C, D, and E would be added.

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Regulatory Flexibility Analysis
Required: 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 Wootten Parkway, Rockville, MD 20852
Phone: 301 443–3400
Fax: 301 443–5351
Email: 0940–AA04

RIN: 0940–AA04

1058. HUMAN SUBJECTS PROTECTION REGULATIONS: INSTITUTIONAL REVIEW BOARDS REGISTRATION REQUIREMENTS

Priority: Substantive, Nonsignificant
Legal Authority: 5 USC 301; 42 USC 289
CFR Citation: 45 CFR 46
Legal Deadline: None
Abstract: This notice of proposed rulemaking proposes to add subpart F to Department of Health and Human Services (HHS) regulations for protection of human subjects, 45 CFR
part 46, to require registration of institutional review boards (IRBs) with HHS. The registration information would include contact information, approximate numbers of active protocols involving research conducted or supported by HHS, accreditation status, IRB membership, and staffing for the IRB. The proposed registration requirements will make it easier for the Office for Human Research Protections (OHRP) to convey information to IRBs, and will support the current IRB registration operated by OHRP. Under the current OHRP IRB registration system, the submission of certain registration information is required by human subjects protection regulations, and certain other information may be submitted voluntarily. This proposed information collection was submitted to the Office of Management and Budget under the Paperwork Reduction Act. Under the proposed rule, all registration information will be required, making the IRB registration system uniform with IRB registration requirements of the Food and Drug Administration (FDA), and creating a single, HHS IRB Registration system. FDA will simultaneously publish a proposed rule regarding FDA IRB registration requirements.

### Regulatory Flexibility Analysis

**Required:** No  
**Small Entities Affected:** No  
**Government Levels Affected:** None

### Agency Contact

Irene Stith-Coleman  
Ph.D, Department of Health and Human Services, Office of Public Health and Science, Suite 200, The Tower Building, 1101 Wooten Parkway, Rockville, MD 20852  
Phone: 301 496–7005  
Fax: 301 402–0527  
**RIN:** 0940–AA06

### 1059. HUMAN SUBJECTS PROTECTION REGULATIONS: TRAINING AND EDUCATION REQUIREMENTS FOR INSTITUTIONAL OFFICIALS, INSTITUTIONAL REVIEW BOARD MEMBERS AND STAFF, HUMAN PROTECTIONS ADMINISTRATORS, AND INVESTIGATOR

**Priority:** Other Significant  
**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 part 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.

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

**1060. 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.

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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: 301 443–3400
### Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS)

#### 1061. END STAGE RENAL DISEASE (ESRD) CONDITIONS FOR COVERAGE (CMS–3818–P)
**Regulatory Plan:**
This entry is Seq. No. 55 in part II of this issue of the Federal Register.
**RIN:** 0938–AG82

#### 1062. HOSPITAL CONDITIONS OF PARTICIPATION: REQUIREMENTS FOR APPROVAL AND REAPPROVAL OF TRANSPLANT CENTERS TO PERFORM ORGAN TRANSPLANTS (CMS–3835–P)
**Regulatory Plan:**
This entry is Seq. No. 56 in part II of this issue of the Federal Register.
**RIN:** 0938–AH17

#### 1063. HOSPICE CARE-CONDITIONS OF PARTICIPATION (CMS–3844–P)
**Priority:**
Other Significant
**Legal Authority:**
42 USC 1302; 42 USC 1395x(dd); 42 USC 1395hh
**CFR Citation:**
42 CFR 418
**Legal Deadline:**
None
**Abstract:**
This proposed rule revises existing conditions of participation that hospices must meet to participate in the Medicare program. The proposed requirements focus on the actual care delivered to patients and patients’ families by hospices and the results of that care, reflect an interdisciplinary view of patient care, allow hospices greater flexibility in meeting quality standards, and eliminate unnecessary procedural requirements.

**Timetable:**

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**Regulatory Flexibility Analysis Required:**
Undetermined
**Small Entities Affected:**
Businesses, Organizations
**Government Levels Affected:**
None
**Federalism:**
Undetermined
**Agency Contact:**
Mary Rossi Coajou, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of Clinical Standards and Quality, 7500 Security Boulevard, Baltimore, MD 21244 Phone: 410 786–6051

#### 1064. SUPPLIER STANDARDS FOR HOME OXYGEN, THERAPEUTIC SHOES, AND HOME NUTRITION THERAPY (CMS–6010–P)
**Priority:**
Substantive, Nonsignificant
**Legal Authority:**
Not Yet Determined
**CFR Citation:**
42 CFR 424.57
**Legal Deadline:**
None
**Abstract:**
This proposed rule would implement certain provisions in the statute relating to suppliers of durable medical equipment, prosthetics, orthotics, and supplies and establish service standards for suppliers of home oxygen equipment and therapeutic shoes home nutrition therapy. Establishing these standards would ensure that suppliers are qualified to provide the appropriate health care services and help safeguard the Medicare program and its beneficiaries from any instances of fraudulent or abusive billing practices.

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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:**
James Krall, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of Health Insurance Portability and Accountability, 7500 Security Boulevard, C3–02–16, Baltimore, MD 21244 Phone: 410 786–6999
**RIN:** 0938–AK62

#### 1065. HEALTH INSURANCE REFORM: CLAIMS ATTACHMENTS STANDARDS (CMS–0050–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–2[a](2)[B]
**CFR Citation:**
45 CFR 162
**Legal Deadline:**
**Abstract:**
This rule proposes an electronic standard for claims attachments. The standard is required by the Health Insurance Portability and Accountability Act of 1996. It would be used to transmit clinical data, in addition to those data contained in the claims standard, to help establish medical necessity for coverage.

**Timetable:**

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1066. ORGAN PROCUREMENT ORGANIZATION CONDITIONS FOR COVERAGE (CMS–3064–P)

Regulatory Plan: This entry is Seq. No. 57 in part II of this issue of the Federal Register.

RIN: 0938–AK81

1067. USE OF RESTRAINT AND SECLUSION IN MEDICARE AND MEDICAID PARTICIPATING FACILITIES THAT PROVIDE INPATIENT OR RESIDENTIAL CARE (CMS–2130–P)

Regulatory Plan: This entry is Seq. No. 58 in part II of this issue of the Federal Register.

RIN: 0938–AL26

1068. PROSPECTIVE PAYMENT SYSTEM FOR INPATIENT PSYCHIATRIC FACILITIES FY 2004 (CMS–1213–F)

Regulatory Plan: This entry is Seq. No. 59 in part II of this issue of the Federal Register.

RIN: 0938–AL50

1069. PROVIDER REIMBURSEMENT DETERMINATIONS AND APPEALS (CMS–1727–P)

Priority: Substantive, Nonsignificant

Legal Authority: Sec 1878 of the Social Security Act

CFR Citation: 42 CFR 405

Legal Deadline: None

Abstract: This proposed rule would redefine, clarify, and update the guidelines and procedures for Provider Reimbursement Review Board appeals, based on recent court decisions.

Timetable:

Action | Date | FR Cite
---|---|---
NPRM | 05/00/04 | None
Regulatory Flexibility Analysis Required: No
Small Entities Affected: No
Government Levels Affected: None
Agency Contact: David Mlawsky, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S3–16–26, Office of Clinical Standards and Quality, 7500 Security Boulevard, S3–16–26, Baltimore, MD 21244; Phone: 410 786–6851

RIN: 0938–AL64

1070. HEALTH COVERAGE PORTABILITY’S REQUEST FOR INFORMATION ON BENEFIT—SPECIFIC WAITING PERIODS (CMS–2150–NC)

Priority: Info./Admin./Other

Legal Authority: Not Yet Determined

CFR Citation: None

Legal Deadline: None

Abstract: This notice requests information on the use of benefit-specific waiting periods by group health plan and group health insurance issuers.

Timetable:

Action | Date | FR Cite
---|---|---
NPRM | 05/00/04 | None
Regulatory Flexibility Analysis Required: No
Small Entities Affected: No
Government Levels Affected: None
Agency Contact: Morton Marcus, Heal Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, C4–25–02, Baltimore, MD 21244; Phone: 410 786–4477

RIN: 0938–AL54

1071. DMERC SERVICE AREAS AND RELATED MATTERS (CMS–1219–P)

Priority: Substantive, Nonsignificant

Legal Authority: Sec 1842 of the Social Security Act; Sec 1834(j)(E) of the Social Security Act; Sec 1834(h)(3) of the Social Security Act; Sec 1834(a)(12) of the Social Security Act; Sec 1102; Social Security Act, sec 1832; Social Security Act, sec 1871

CFR Citation: 42 CFR 421.210

Legal Deadline: None

Abstract: This proposed rule would allow flexibility in making changes to the Durable Medical Equipment Regional Carrier contractor structure.

Timetable:

Action | Date | FR Cite
---|---|---
NPRM | 09/00/04 | None
Regulatory Flexibility Analysis Required: No
Small Entities Affected: Businesses
Government Levels Affected: None
Agency Contact: Joan Brooks, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of Clinical Standards and Quality, 7500 Security Boulevard, Baltimore, MD 21244; Phone: 410 786–5526

RIN: 0938–AL76

1072. 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: Social Security Act, sec 1102; Social Security Act, sec 1832; Social Security Act, sec 1871

CFR Citation: 42 CFR 410; 42 CFR 424; 42 CFR 416; 42 CFR 408; 42 CFR 409

Legal Deadline: None

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

Timetable:

Action | Date | FR Cite
---|---|---
NPRM | 09/00/04 | None
Regulatory Flexibility Analysis Required: No
Small Entities Affected: Businesses
Government Levels Affected: State
Agency Contact: Jacqueline Morgan, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S3–02–01, Office of Clinical Standards and Quality, 7500 Security Boulevard, Baltimore, MD 21244; Phone: 410 786–4282

RIN: 0938–AL80
<table>
<thead>
<tr>
<th>Federal Register / Vol. 68, No. 245 / Monday, December 22, 2003 / Unified Agenda</th>
</tr>
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<tbody>
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<td><strong>HHS—CMS</strong></td>
</tr>
<tr>
<td><strong>Proposed Rule Stage</strong></td>
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</table>

| 1073. HEALTH COVERAGE PORTABILITY: TOLLING CERTAIN TIME PERIODS AND INTERACTIONS WITH FAMILY AND MEDICAL LEAVE ACT (CMS–2158–P) |
| Priority: Other Significant                    |
| Legal Authority: 42 USC 300 gg; PL 104–191     |
| CFR Citation: 45 CFR 146.113; 45 CFR 146.115; 45 CFR 146.120; 45 CFR 146.145 |
| Legal Deadline: None                           |
| Abstract: This proposed rule would determine whether a drug is considered usually self-administered and therefore, not covered under part B of Medicare. |
| **Timetable:**                                 |
| **Action** | **Date** | **FR Cite** |
| NPRM        | 08/00/04 |             |
| Regulatory Flexibility Analysis Required: No  |
| Small Entities Affected: Businesses, Organizations |
| Government Levels Affected: State, Local, Federal |
| Agency Contact: David Mlawsky, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S3–16–26, Center for Medicaid and State Operations, 7500 Security Boulevard, S3–16–26, Baltimore, MD 21244 Phone: 410 786–6851 |
| RIN: 0938–AM13 |

| 1075. PROCEDURES FOR MAINTAINING CODE LISTS IN THE NEGOTIATED NATIONAL COVERAGE DETERMINATIONS FOR CLINICAL DIAGNOSTIC LABORATORY SERVICES (CMS–3119–PN) |
| Priority: Other Significant                    |
| Legal Authority: 42 USC 1395h(a); 42 USC 1395e; 42 USC 1395u(a); 42 USC 1395x; 42 USC 1395y(a)(1)(A); 42 USC 1395y(a)(7) |
| CFR Citation: Not Yet Determined               |
| Legal Deadline: None                           |
| Abstract: This proposed notice would establish the procedures to be used for maintaining the lists of codes that were included in the national coverage determinations announced in the Federal Register on November 25, 2001 (66 FR 58788). It would also clarify the date of service provisions related to archived specimens from that final rule. |
| **Timetable:**                                 |
| **Action** | **Date** | **FR Cite** |
| NPRM        | 01/00/04 |             |
| Regulatory Flexibility Analysis Required: No  |
| Government Levels Affected: None               |
| Agency Contact: William Ullman, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C1–09–06, Baltimore, MD 21244 Phone: 410 786–4635 |
| RIN: 0938–AM39 |

| 1074. CRITERIA FOR DETERMINING WHETHER A DRUG IS CONSIDERED USUALLY SELF-ADMINISTERED (CMS–1228–P) |
| Priority: Economically Significant. Major status under 5 USC 801 is undetermined. |
| Legal Authority: Sec 1861(s)(2)(B) of the Social Security Act |
| CFR Citation: Not Yet Determined               |
| Legal Deadline: None                           |
| Abstract: This proposed rule would solicit comments on the criteria to determine whether a drug is considered usually self-administered and therefore, not covered under part B of Medicare. |
| **Timetable:**                                 |
| **Action** | **Date** | **FR Cite** |
| NPRM        | 08/00/04 |             |
| Regulatory Flexibility Analysis Required: No  |
| Government Levels Affected: None               |
| Agency Contact: Jacqueline Sheridan, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of Clinical Standards and Quality, 7500 Security Boulevard, C1–09–06, Baltimore, MD 21244 Phone: 410 786–6851 |
| RIN: 0938–AM13 |

| 1076. HOSPITAL PATIENTS’ RIGHTS COP–STANDARD SAFETY COMPLIANCE COMMITTEES (CMS–3120–P) |
| Priority: Other Significant. Major under 5 USC 801. |
| Legal Authority: Sec 1888(e) of the Social Security Act |
| CFR Citation: 42 CFR 413.330 to 413.350 |
| Legal Deadline: NPRM, Statutory, July 30, 2004, NPRM. |
| Abstract: This annual proposed rule updates the payment rates used under the skilled nursing facilities prospective payment system beginning October 1, 2004. |
| **Timetable:**                                 |
| **Action** | **Date** | **FR Cite** |
| Notice     | 06/00/04 |             |
| Regulatory Flexibility Analysis Required: Yes |
| Government Levels Affected: None               |
| Agency Contact: William Ullman, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C4–13–15, Center for Medicaid and State Operations, 7500 Security Boulevard, C5–07–08, Baltimore, MD 21244 Phone: 410 786–5067 |
| RIN: 0938–AM39 |

| 1077. PROSPECTIVE PAYMENT SYSTEM AND CONSOLIDATED BILLING FOR SKILLED NURSING FACILITIES—UPDATE FOR FY 2005 (CMS–1249–N) |
| Priority: Other Significant. Major under 5 USC 801. |
| Legal Authority: None                           |
| CFR Citation: None                              |
| Legal Deadline: None                            |
| Abstract: This entry is Seq. No. 60 in part II of this issue of the Federal Register. |
| **RIN:**                                       |
| RIN: 0938–AM39 |

| 1078. MODIFICATIONS TO ELECTRONIC TRANSACTIONS AND CODE SETS (CMS–0009–P) |
| Priority: Other Significant. Major status under 5 USC 801 is undetermined. |
| Unfunded Mandates: Undetermined                |

**Timetable:**
**Action** | **Date** | **FR Cite** |
| Notice     | 06/00/04 |             |
| Regulatory Flexibility Analysis Required: Yes |
| Government Levels Affected: None               |
| Agency Contact: Jacqueline Sheridan, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of Clinical Standards and Quality, 7500 Security Boulevard, C1–09–06, Baltimore, MD 21244 Phone: 410 786–6851 |
| RIN: 0938–AM13 |
Legal Authority: Social Security Act, sec 1171 to 1179
CFR Citation: 42 CFR 162.1002; 42 CFR 162.1802
Legal Deadline: None
Abstract: This proposed rule would revise the electronic transactions and code set standards mandated by the Health Insurance Portability and Accountability Act of 1996.

Timetable:

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<td>09/00/04</td>
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Regulatory Flexibility Analysis Required: No
Small Entities Affected: No
Government Levels Affected: None
Agency Contact: Joel Cohen, Office of Financial Management, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C3–04–06, 7500 Security Boulevard, Baltimore, MD 21244–1850 Phone: 410 786–3349
RIN: 0938–AM54

1080. REQUIREMENTS FOR NURSING HOMES TO IDENTIFY THE NUMBER OF LICENSED AND UNLICENSED NURSES (CMS–3121–P)

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: None

Abstract: This proposed rule will implement section 941 of the Benefits Improvement and Protection Act of 2000, which requires nursing homes to post daily, for each shift, the number of licensed and unlicensed nursing staff directly responsible for resident care.

Timetable:

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<th>Action</th>
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Regulatory Flexibility Analysis Required: No
Small Entities Affected: No
Government Levels Affected: None
Agency Contact: Cindy Read, Division Director, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare Mangement, 7500 Security Boulevard, C4–05–07, Baltimore, MD 21244 Phone: 410 786–1852
RIN: 0938–AM75

1081. CHANGES TO THE HOSPITAL OUTPATIENT PROSPECTIVE SYSTEM AND CALENDAR YEAR 2005 PAYMENT RATES (CMS–1427–P)

Priority: Other Significant. Major status under 5 USC 801 is undetermined.
Legal Authority: 42 USC 1935L; Balanced Budget Act of 1997; Medicare, Medicaid and SCHIP Balanced Budget Refinement Act of 1999; Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000
CFR Citation: Not Yet Determined
Legal Deadline: NPRM, Statutory, January 1, 2004, NPRM.

Abstract: The proposed rule would revise the Medicare hospital outpatient prospective payment system beginning January 1, 2005. (The statute requires that this proposed rule and subsequent final rule be published by November 1, 2004.)

Timetable:

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<tr>
<th>Action</th>
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Regulatory Flexibility Analysis Required: Yes
Government Levels Affected: Federal
Agency Contact: Nancy Archer, Office of Clinical Standards and Quality, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S3–05–27, 7500 Security Boulevard, Baltimore, MD 21244–1850 Phone: 410 786–0596
RIN: 0938–AM56

1082. CHANGES TO THE HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEM AND FY 2005 RATES (CMS–1428–P)

Priority: Economically Significant. Major status under 5 USC 801 is undetermined.
Legal Authority: Sec 1886(d) of the Social Security Act
CFR Citation: 42 CFR 412; 42 CFR 413; 42 CFR 485; 42 CFR 489

Abstract: We would revise the Medicare acute hospital inpatient prospective payment system for operating and capital-related costs to
implement changes arising from our continuing experience with these systems. In addition, in the Addendum, we describe changes to the amounts and factors used to determine the rates for Medicare hospital inpatient services for operating costs and capital-related costs. These changes apply to discharges on or after October 1, 2004. We also set forth proposed rate-of-increase limits as well as proposed policy changes for hospitals and hospital units excluded from the prospective payments systems. (The statute requires that this proposed and subsequent final rule be published by August 1, 2004.)

**Timetable:**

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**Agency Contact:** Tzvi Hefter, Director, Division of Acute Care, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C4–07–07, Center for Medicare Management, 7500 Security Boulevard, C4–07–07, Baltimore, MD 21244 Phone: 410 786–4487

**RIN:** 0938–AM80

**Abstract:** This proposed rule would update rates for the prospective payment system for inpatient rehabilitation facilities for FY 2005. (The statute requires that the subsequent final rule be published by August 1, 2004.)

**Timetable:**

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<th>Action</th>
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</table>

**Agency Contact:** Tzvi Hefter, Director, Division of Acute Care, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C4–07–07, Center for Medicare Management, 7500 Security Boulevard, C4–07–07, Baltimore, MD 21244 Phone: 410 786–4487

**RIN:** 0938–AM84

**Abstract:** This proposed rule would update rates for the prospective payment system for inpatient rehabilitation facilities for FY 2005. (The statute requires that the subsequent final rule be published by August 1, 2004.)

**Timetable:**

<table>
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<th>Action</th>
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</table>

**Agency Contact:** Robert Kuhl, Division Director, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C4–11–06, Center for Medicare Management, 7500 Security Boulevard, C5–06–24, Baltimore, MD 21244 Phone: 410 786–4597

**RIN:** 0938–AM82
Medicaid and SCHIP, respectively, require States to provide to the Secretary information to monitor program performance. This rule would require States under the current statutory provisions and the IPIA and through this regulation to estimate improper payments using the CMS PERM methodology for the reporting year in the Medicaid and SCHIP programs. The States are further required to submit payment error rates to CMS for the purpose of calculating a national level payment error rate as required by the IPIA.

### Timetable:

**Action** | **Date** | **FR Cite**
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NPRM | 05/00/04 | |

**Regulatory Flexibility Analysis**

**Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** State

**Federalism:** Undetermined

**Agency Contact:** Wayne Alden Slaughter, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, S3–13–15, Baltimore, MD 21244

Phone: 410 786–0038

**RIN:** 0938–AM86

### 1087. • REQUIREMENTS FOR long-term CARE FACILITIES: HOSPICE SERVICES (CMS–3140–P)

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

**Unfunded Mandates:** Undetermined

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

**CFR Citation:** 42 CFR 483

**Legal Deadline:** None

**Abstract:** This proposed rule will clarify the hospice care of residents in long-term care facilities. This rule will reflect the changes in the hospice proposed rule (CMS–3844–P, 42 CFR 418) that is to reflect the interdisciplinary view of resident care and improve the quality of healthcare furnished through the Medicare and Medicaid programs reflect the interdisciplinary view of resident care and improve the quality of health care furnished through the Medicare and Medicaid programs.

### Timetable:

**Action** | **Date** | **FR Cite**
--- | --- | ---
NPRM | 06/00/04 | |

**Regulatory Flexibility Analysis**

**Required:** Yes

**Government Levels Affected:** Federal

**Agency Contact:** Latesha Walker, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786–1101

**RIN:** 0938–AM90

### 1089. • HOME HEALTH PROSPECTIVE PAYMENT SYSTEM RATE UPDATE FY 2005 (CMS–1265–P)

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

**Legal Authority:** 42 USC 1395ff

**CFR Citation:** None

**Legal Deadline:** None

**Abstract:** This 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. As part of this proposed rule, we are proposing to rebase and revise the home health market basket to reflect total cost and modifying certain variables for some of the cost categories. (The proposed and final rules must be published by July 1, 2004, to allow three months for systems changes.)

### Timetable:

**Action** | **Date** | **FR Cite**
--- | --- | ---
NPRM | 09/00/04 | |

**Regulatory Flexibility Analysis**

**Required:** Yes

**Government Levels Affected:** None

**Agency Contact:** Randy Throndset, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786–0131

**RIN:** 0938–AM93

### 1090. • REVISIONS TO COST SHARING REGULATIONS (CMS–2144–P)

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

**Unfunded Mandates:** Undetermined

**Legal Authority:** Social Security Act, sec 1916; Social Security Act, sec 1902(a)(4)

**CFR Citation:** 42 CFR 447.51 to 447.56

**Legal Deadline:** None

**Abstract:** This proposed rule would revise the cost sharing requirements in our current regulation to allow for the imposition of higher levels of cost sharing and more flexibility in the way in which cost sharing is imposed and administered under current statutory requirements. (The cost sharing requirements have remained unchanged since 1974. States have requested that we update the cost sharing requirements.)

### Timetable:

**Action** | **Date** | **FR Cite**
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NPRM | 09/00/04 | |
Department of Health and Human Services (HHS) Centers for Medicare & Medicaid Services (CMS)

<table>
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<tr>
<th>1091. HOME HEALTH AGENCY (HHA) CONDITIONS OF PARTICIPATION (COPS) (CMS–3819–FC)</th>
<th>1092. REQUIREMENTS FOR ESTABLISHING AND MAINTAINING MEDICARE BILLING PRIVILEGES (CMS–6002–F)</th>
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<tbody>
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<td>Legal Authority: 42 USC 1302; 42 USC 1395x; 42 USC 1395cc(a); 42 USC 1395hh; 42 USC 1395bb</td>
<td>Legal Authority: 42 USC 1302; 42 USC 1395hh</td>
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<tr>
<td>CFR Citation: 42 CFR 484</td>
<td>CFR Citation: 42 CFR 424</td>
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<tr>
<td>Legal Deadline: None</td>
<td>Legal Deadline: None</td>
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<tr>
<td>Abstract: This final rule revises the existing CoPs that 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.</td>
<td>Abstract: This final rule is needed as part of the Administration’s anti-fraud and abuse efforts. It would give us the authority to enroll and re-enroll providers with time frames for re-enrollment.</td>
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<td>Small Entities Affected: Businesses, Organizations</td>
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<td>Agency Contact:</td>
<td>Agency Contact:</td>
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<tr>
<td>Scott Cooper, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare &amp; Medicaid Services, Office of Clinical Standards and Quality, 7500 Security Boulevard, Baltimore, MD 21244 Phone: 410 786–5716</td>
<td>Patricia Peyton, Office of Information Services, Department of Health and Human Services, Centers for Medicare &amp; Medicaid Services, N3–20–05, 7500 Security Boulevard, Baltimore, MD 21224–1850 Phone: 410 786–1812</td>
</tr>
</tbody>
</table>

Federalism: This action may have federalism implications as defined in EO 13132.
Agency Contact: Alissa Deboy, Special Assistant, Department of Health and Human Services, Centers for Medicare & Medicaid Services, CMSO, S2–14–26, 7500 Security Boulevard, Baltimore, MD 21244 Phone: 410 786–6041
RIN: 0938–AM94

1093. HEALTH INSURANCE REFORM: STANDARD UNIQUE HEALTH CARE PROVIDER IDENTIFIER (CMS–0045–F)

Priority: Other Significant. Major under 5 USC 801.
Legal Authority: 42 USC 1320D–2(b)(1)
CFR Citation: 42 CFR 160; 42 CFR 162
Abstract: This final rule establishes a standard unique identifier for all health care providers under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 (Pub. L. 104–191). The rule implements administrative simplification initiatives that have a national scope beyond Medicare and Medicaid.
Timetable:
<table>
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<td>NPRM</td>
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<td>63 FR 25320</td>
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<td>07/06/98</td>
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Regulatory Flexibility Analysis Required: Yes
Government Levels Affected: Federal, Local, State, Tribal
Federalism: This action may have federalism implications as defined in EO 13132.
Additional Information: None
Agency Contact: Patricia Peyton, Office of Information Services, Department of Health and Human Services, Centers for Medicare & Medicaid Services, N3–20–05, 7500 Security Boulevard, Baltimore, MD 21224–1850 Phone: 410 786–1812
RIN: 0938–AH99

1094. APPEALS OF CARRIER DETERMINATION THAT A SUPPLIER FAILS TO MEET THE REQUIREMENTS FOR MEDICARE BILLING PRIVILEGES (CMS–6003–F)

Priority: Substantive, Nonsignificant
Legal Authority: 42 USC 1302; 42 USC 1395u(b)(3)(C); 42 USC 1395ff(b)
CFR Citation: 42 CFR 405.874
Legal Deadline: None
Abstract: This final rule will extend appeal rights to all suppliers whose enrollment applications for Medicare billing privileges are disallowed by a carrier or whose Medicare billing privileges are revoked, except for those suppliers covered under other existing appeals provisions of our regulations. In addition, we will revise certain appeal provisions to correspond with the existing appeal provisions in those other sections of our regulations. CMS will also extend appeal rights to all suppliers not covered by existing regulations to ensure they have a full and fair opportunity to be heard. **Timetable:**

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<td>10/25/99</td>
<td>64 FR 57431</td>
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<td>04/00/04</td>
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Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Jean Marie Moore, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, C5–05–05, Baltimore, MD 21244

Phone: 410 786–3508

RIN: 0938–AI93

1096. MEDICARE OUTCOME AND ASSESSMENT INFORMATION SET (OASIS) DATA REPORTING REQUIREMENTS (CMS–3006–F)

Priority: Other Significant

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

Legal Deadline: None

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

**Timetable:**

<table>
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<th>Action</th>
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<td>01/25/99</td>
<td>64 FR 3748</td>
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<td>06/00/04</td>
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Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses

Government Levels Affected: State, Local, Tribal

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

Agency Contact: Aucha Prachanronarong, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of Clinical Standards and Quality, 7500 Security Blvd, Baltimore, MD 21244

Phone: 410 786–9614

RIN: 0938–AJ10

1097. RURAL HEALTH CLINICS: AMENDMENTS TO PARTICIPATION REQUIREMENTS AND PAYMENT PROVISIONS AND ESTABLISHMENT OF A QUALITY ASSESSMENT AND IMPROVEMENT PROGRAM (CMS–1910–F)

Priority: Other Significant

Legal Authority: 42 USC 1302; 42 USC 1395hh

CFR Citation: 42 CFR 405; 42 CFR 491

Legal Deadline: None

Abstract: This rule amends the Medicare certification and payment requirements for rural health clinics (RHCs), as required by section 4205 of the Balanced Budget Act of 1997 (BBA 1997). It changes the definition of a qualifying rural shortage area in which a Medicare RHC must be located; establishes criteria for identifying RHCs essential to delivery of primary care services that we can continue to approve as Medicare RHCs in areas no longer designated as medically underserved; and limits nonphysician practitioner staffing requirements. This rule imposes payment limits on provider-based RHCs and prohibits the use of RHC space, professional staff, equipment, and other RHC resources by another Medicare entity. The rule also requires RHCs to establish a quality assessment and performance improvement program. (The statute required that this rule be published by January 1, 1999.)

**Timetable:**

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<th>Action</th>
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<td>NPRM</td>
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<td>65 FR 10450</td>
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<td>12/00/03</td>
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Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: Federal

Agency Contact: David Worgo, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 4–15–18, Center for Medicare Management, 7500 Security Boulevard, C4–15–18, Baltimore, MD 21244

Phone: 410 786–5919

RIN: 0938–AJ17
### 1098. HOSPITAL CONDITIONS OF PARTICIPATION: LABORATORY SERVICES (CMS–3014–F)

**Priority:** Substantive, Nonsignificant  
**Legal Authority:** 42 USC 1302; 42 USC 1395hh  
**CFR Citation:** 42 CFR 482.27  
**Legal Deadline:** None  
**Abstract:** This rule 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 HCV; quarantine prior collections from a donor who is at increased risk for transmitting HCF infection; notify transfusion recipients, as appropriate, of the need for HCV testing and counseling; and maintain records for at least 10 years.

#### Timetable:

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<th>Action</th>
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<tr>
<td>NPRM</td>
<td>11/22/02</td>
<td>67 FR 70363</td>
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**Regulatory Flexibility Analysis Required:** No  
**Small Entities Affected:** Businesses  
**Government Levels Affected:** None  
**Agency Contact:** Thomas Saltz, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Centers for Medicare Management, 7500 Security Boulevard, C4–05–27, Baltimore, MD 21244  
Phone: 410 786–4480  
**RIN:** 0938–AJ96

### 1100. USE OF RESTRAINT AND SECLUSION IN RESIDENTIAL TREATMENT FACILITIES PROVIDING INPATIENT PSYCHIATRIC SERVICES TO INDIVIDUALS UNDER AGE 21 (CMS–2065–F)

**Regulatory Plan:** This entry is Seq. No. 61 in part II of this issue of the Federal Register.  
**RIN:** 0938–AJ36

### 1101. ALL PROVIDER BAD DEBT PAYMENT (CMS–1126–F)

**Priority:** Other Significant. Major under 5 USC 801.  
**Legal Authority:** 42 USC 1302; 42 USC 1395ff(b); 42 USC 1395g; 42 USC 1395[a]; 42 USC 1395[f]; 42 USC 1395[n]; 42 USC 1395x(v); 42 USC 1395cc; 42 USC 1395hh; 42 USC 1395rr; 42 USC 1395tt  
**CFR Citation:** 42 CFR 413.80; 42 CFR 413.178  
**Legal Deadline:** None  
**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:

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<tr>
<td>NPRM</td>
<td>02/10/03</td>
<td>68 FR 6682</td>
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### 1099. 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 to 4449; PL 106–113, sec 131; PL 106–534, sec 321 to 322  
**CFR Citation:** 42 CFR 418  
**Legal Deadline:** None  
**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.

### 1102. REVIEW OF NATIONAL COVERAGE DETERMINATIONS AND LOCAL COVERAGE DETERMINATIONS (CMS–3063–F)

**Priority:** Other Significant  
**Legal Authority:** Sec 522 of the BIPA 2000  
**CFR Citation:** 42 CFR 405  
**Legal Deadline:** NPRM, Statutory, October 1, 2001, NPRM.  
**Abstract:** This final rule would announce a new process for beneficiaries to appeal national and local coverage determinations (LCDs), including the role that the Department Appeals Board and, in the case of LCDs, Administrative Law Judges, will have in reviewing the decisions. It implements section 522 of the Benefits Improvement and Protection Act of 2000 (BIPA).

#### Timetable:

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**Regulatory Flexibility Analysis Required:** No  
**Small Entities Affected:** No  
**Government Levels Affected:** None  
**Agency Contact:** James Bossemeyer, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C5–16–26, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786–9317
Email: jbossemeyer@hcfa.gov

RIN: 0938–AK60

1103. PHYSICIANS' REFERRALS TO HEALTH CARE ENTITIES WITH WHICH THEY HAVE FINANCIAL RELATIONSHIPS—PHASE II (CMS–1810–FC)

Priority: Other Significant
Legal Authority: 42 USC 1877
CFR Citation: 42 CFR 411

Abstract: This final rule incorporates into regulation certain statutory provisions that preclude payment for services under Medicare if a physician makes a referral to a facility in which he/she has a financial interest. It addresses comments from the January 9, 1998, proposed rule concerning the ownership, investment, and compensation exceptions. It also addresses comments from the January 4, 2001, final rule with comment period.

Timetable:

Action Date FR Cite
Final Action 12/00/03

Regulatory Flexibility Analysis Required: Yes
Government Levels Affected: None
Agency Contact: Joanne Sinsheimer, Technical Advisor, CMM, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicaid and State Operations, 7500 Security Boulevard, C4–25–02, Baltimore, MD 21244
Phone: 410 786–4620
RIN: 0938–AK67

1104. RATE OF REIMBURSEMENT OF PHOTOCOPY EXPENSES FOR QUALITY IMPROVEMENT ORGANIZATIONS (CMS–3055–F)

Priority: Substantive, Nonsignificant
Legal Authority: Social Security Act, sec 1102; Social Security Act, sec 1154; Social Security Act, sec 1159; Social Security Act, sec 1866; Social Security Act, sec 1871
CFR Citation: 42 CFR 476.78
Legal Deadline: None

Abstract: This rule increases the rate of reimbursement of photocopy expenses as required by the regulations governing utilization and quality control quality improvement organizations. CMS' current regulations identify the photocopying reimbursement methodology for prospective payment system hospitals.

Timetable:

Action Date FR Cite
NPRM 07/25/03 68 FR 44000
Final Action 07/00/04

Regulatory Flexibility Analysis Required: No
Small Entities Affected: No
Government Levels Affected: Not yet determined
Agency Contact: David Walczak, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, C4–25–02, Baltimore, MD 21244
Phone: 410 786–4475
RIN: 0938–AK79

1105. ELIMINATION OF STATEMENT OF INTENT PROCEDURES FOR FILING MEDICARE CLAIMS (CMS–1185–F)

Priority: Other Significant. Major status under 5 USC 801 is undetermined.
Legal Authority: Not Yet Determined
CFR Citation: 42 CFR 442

Abstract: The final rule would eliminate the written statement of intent procedures for filing Medicare claims from the current Medicare regulation. Providers, suppliers, and other qualified claimants would still have 15 to 27 months to submit valid claims to Medicare.

Timetable:

Action Date FR Cite
NPRM 07/25/03 68 FR 43998
Final Action 07/00/04

Regulatory Flexibility Analysis Required: No
Small Entities Affected: No
Government Levels Affected: None
Agency Contact: Denise Cox, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Health Insurance Specialist, 7500 Security Boulevard, S1–05–06, Baltimore, MD 21244
Phone: 410 786–3195
RIN: 0938–AK79

1106. EXTENDING MEDICARE ENTITLEMENT WHEN DISABILITY BENEFIT ENTITLEMENT ENDS BECAUSE OF SUBSTANTIAL GAINFUL ACTIVITY (CMS–4018–F)

Priority: Substantive, Nonsignificant
Legal Authority: Sec 202 of the TWWIA of 1999; PL 106–170
CFR Citation: 42 CFR 406.12
Legal Deadline: None

Abstract: This final rule implements the Ticket to Work and Work Incentives Improvement Act of 1999. It provides working disabled individuals with continued Medicare entitlement for an additional 54 months beyond the current limit, for a total of 78 months of Medicare coverage following the 15th month of the extended period of eligibility.

1107. MEDICARE PROGRAM; INTEREST CALCULATION (CMS–6014–F)

Priority: Other Significant
Legal Authority: Sec 1815(d) of the Social Security Act; Sec 1833 (j) of the Social Security Act
CFR Citation: 42 CFR 405.378
Legal Deadline: None

Abstract: This final rule will change the formula for computing interest on provider and supplier overpayments.
and underpayments to make it consistent with the new CMS accounting system, Healthcare Integrated General Ledger Accounting System.

**Timetable:**

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<th>Action</th>
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<td>68 FR 43995</td>
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**Regulatory Flexibility Analysis**

Required: No

Small Entities Affected: None

Government Levels Affected: Federal, Local, State

Agency Contact: David Mlawsky, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S3–16–26, Center for Medicaid and State Operations, 7500 Security Boulevard, S3–16–26, Baltimore, MD 21244

Phone: 410 786–6851

RIN: 0938–AL43

1109. PERMITTING PREMIUM REDUCTIONS AS ADDITIONAL BENEFITS UNDER MEDICARE+CHOICE PLANS (CMS–6016–F)

Priority: Substantive, Nonsignificant

Legal Authority: 606 of BIPA

CFR Citation: 42 CFR 408


Abstract: This final rule implements section 606 of the Benefits Improvement and Protection Act of 2000 to allow Medicare+Choice organizations to elect a reduction in capitation payments so that these organizations could offer Medicare part B premium reductions to enrollees.

**Timetable:**

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<th>Action</th>
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**Regulatory Flexibility Analysis**

Required: No

Small Entities Affected: No

Government Levels Affected: Federal, Local, State

Agency Contact: Michele Sanders, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of Financing Management, 7500 Security Boulevard, S1–06–27, Baltimore, MD 21244

Phone: 410 786–0808

RIN: 0938–AL91

1111. CHANGES TO THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM AND CALENDAR YEAR 2004 PAYMENT RATES (CMS–1471–F)

Priority: Other Significant. Major under 5 USC 801.

Legal Authority: 42 USC 1395L; Balanced Budget Act of 1997; Medicare, Medicaid, and SCHIP; Balanced Budget Refinement Act of 1999; Medicare, Medicaid, and SCHIP; Benefits Improvement and Protection Act of 2000

CFR Citation: Not Yet Determined

Legal Deadline: None

Abstract: This final rule adjusts payments under the Medicare hospital outpatient payment system beginning January 1, 2004.

**Timetable:**

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<td>68 FR 47966</td>
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**Regulatory Flexibility Analysis**

Required: Yes

Government Levels Affected: Federal

Agency Contact: Cindy Read, Division Director, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare Management, C4–05–07, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786–1852

RIN: 0938–AL91

1112. ELECTRONIC MEDICARE CLAIMS SUBMISSION (CMS–0008–F)

Priority: Other Significant

Legal Authority: PL 107–105

CFR Citation: Not Yet Determined

Legal Deadline: None

Abstract: This final rule implements the requirements for electronic submission of Medicare claims, submitted on or after October 16, 2003. In addition, this rule also implements the conditions upon which a waiver could be granted for these requirements.

**Timetable:**

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<th>Action</th>
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<td>08/15/03</td>
<td>68 FR 48805</td>
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1114. MONTHLY ACTUARIAL RATES AND MONTHLY SUPPLEMENTARY MEDICAL INSURANCE PREMIUM RATE BEGINNING JANUARY 1, 2004 (CMS–8017–N)

Priority: Other Significant
Legal Authority: 42 USC 1395r; Sec 1839 of the Social Security Act
CFR Citation: None
Legal Deadline: NPRM, Statutory, September 30, 2003, NPRM.
Abstract: This notice announces the monthly actuarial rates for aged (age 65 and over) and disabled (under age 65) enrollees in the Medicare Supplementary Medical Insurance (SMI) program for 2004. It announces the monthly SMI premium to be paid by all enrollees during 2004.

Timetable:
Action | Date | FR Cite
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Notice | 12/00/03 | None

Regulatory Flexibility Analysis
Required: Yes
Small Entities Affected: No
Government Levels Affected: None
Agency Contact: Carter S. Warfield, Deputy Director, Medicare and Medicaid Cost Estimates Group, OACT, Department of Health and Human Services, Centers for Medicaid and State Operations, 7500 Security Boulevard, Baltimore, MD 21244 Phone: 410 786–6396
RIN: 0938–AM32

1115. PART A PREMIUMS FOR CALENDAR YEAR 2004 FOR THE UNINSURED AGED AND FOR CERTAIN DISABLED INDIVIDUALS WHO HAVE EXHAUSTED OTHER ENTITLEMENT (CMS–8018–N)

Priority: Other Significant
Legal Authority: 42 USC 1395i–2(d)(2); 42 USC 1395i–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 30, 2003, NPRM.
Abstract: This notice announces the hospital insurance premium for calendar year 2004 under Medicare’s Hospital Insurance Program (Part A) for the uninsured aged and for certain disabled individuals who have exhausted other entitlement.

Timetable:
Action | Date | FR Cite
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Final Rule with Comment | 05/02/03 | 68 FR 23410
Final Rule Comment | 07/01/03 | None
Final Rule Effective | 06/02/03 | None
Final Action | 03/00/04 | None

Regulatory Flexibility Analysis
Required: No
Small Entities Affected: None
Government Levels Affected: State
Agency Contact: James Mayhew, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicaid and State Operations, 7500 Security Boulevard, Baltimore, MD 21244 Phone: 410 786–9244
RIN: 0938–AM42
1117. FEE SCHEDULE FOR PAYMENT OF AMBULANCE SERVICES UPDATE FOR CALENDAR YEAR 2004 (CMS–1232–FC)

Priority: Other Significant
Legal Authority: 42 USC 1395m(1)(1)
CFR Citation: None
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.

Regulatory Flexibility Analysis
Required: No
Small Entities Affected: No
Government Levels Affected: Local, State
Agency Contact: Dave Holstein, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Insurance Standards Team, S3–16–16, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–1564
RIN: 0938–AM71

Timetable:

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1118. • NON–FEDERAL GOVERNMENTAL PLANS EXEMPT FROM HIPAA TITLE I REQUIREMENTS (CMS–2033–F)

Priority: Substantive, Nonsignificant. Major status under 5 USC 801 is undetermined.
Legal Authority: Sec 2721(b)(2) of the Public Health Service Act
CFR Citation: 45 CFR 146.180
Legal Deadline: None

Abstract: This final rule adopts as final the exemption election requirements that apply to self-funded non-Federal governmental plans. Since we received no public comments on the July 26, 2002, interim final with comment period, this rule finalizes the circumstances under which plan sponsors may exempt these plans from most of the requirements of title XXVII of the Public Health Service Act and provides guidance on the procedures, limitations, and documentation associated with exemption elections.

Regulatory Flexibility Analysis
Required: No
Small Entities Affected: None
Government Levels Affected: None
Agency Contact: Anne Tayloe, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicaid and State Operations, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–4546
RIN: 0938–AM44

1119. • REVISES TO THE APPEALS PROCESS FOR INITIAL CLAIM DETERMINATIONS (CMS–4064–F)

Regulatory Plan: This entry is Seq. No. 63 in part II of this issue of the Federal Register.
RIN: 0938–AM73

1120. • MORE FLEXIBLE REQUIREMENTS FOR POWERED-OPERATED VEHICLES (CMS–3017–FC)

Priority: Substantive, Nonsignificant. Major status under 5 USC 801 is undetermined.
Legal Authority: Sec 1102 of the Social Security Act; Sec 1871 of the Social Security Act
CFR Citation: 42 CFR ch IV, sec 410, subpart B; 42 CFR 410.38
Legal Deadline: None

Abstract: This rule will make the requirements to purchase power operated vehicles, functioning as wheelchairs, less stringent.

Regulatory Flexibility Analysis
Required: No
Small Entities Affected: No
Government Levels Affected: None
Agency Contact: Terri Deutseh, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 55–08–28, 7500 Security Blvd, Baltimore, MD 21244
Phone: 410 786–9462
RIN: 0938–AM78

1121. • HOSPICE WAGE INDEX FY 2005 (CMS–1264–N)

Priority: Routine and Frequent. Major status under 5 USC 801 is undetermined.
Legal Authority: 1814(i)(A)
CFR Citation: 42 CFR 418.306(d)
Legal Deadline: Final, Statutory, October 1, 2004, Final.
Wage Index update is effective October 1, of each year.

Abstract: This notice will announce the annual update to the hospice wage index for FY 2005. 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 August 8, 1997.

Regulatory Flexibility Analysis
Required: No
Small Entities Affected: None
Government Levels Affected: None
Agency Contact: Terri Deutseh, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 55–08–28, 7500 Security Blvd, Baltimore, MD 21244
Phone: 410 786–9462
RIN: 0938–AM78

1122. • TICKET TO WORK: DEFINING INDIVIDUALS WITH POTENTIALLY SEVERE DISABILITIES (CMS–2172–N)

Priority: Other Significant. Major status under 5 USC 801 is undetermined.
Legal Authority: Ticket to Work and Work Incentives Improvement Act of 1999
CFR Citation: None
Legal Deadline: None

Abstract: This proposed rule would provide a definition of “medically determinable severe impairment” under the Ticket to Work and Work Incentives Improvement Act of 1999.

Regulatory Flexibility Analysis
Required: No
1123. • HOSPITAL CONDITIONS OF PARTICIPATION: REQUIREMENTS FOR HISTORY AND PHYSICAL EXAMINATIONS; AUTHENTICATION OF VERBAL ORDERS, SECURING MEDICATIONS AND POST-ANESTHESIA EVALUATIONS (CMS–3122–F)

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

Legal Authority: 42 USC 1395 x; 42 USC 1396 d; 42 USC 1395 bb

CFR Citation: 42 CFR 482

Legal Deadline: None

Abstract: This final rule will change the existing requirements to decrease the burden on hospitals to conform to current standards of practice. Hospitals must meet these final requirements to participate in the Medicare and Medicaid programs. They must establish and maintain policies and procedures that will ensure their hospital will meet these requirements by using standard practices with regards to history and physical examinations, and completion of the post-anesthesia evaluation.

Timetable:

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Regulatory Flexibility Analysis Required: Yes

Agency Contact: Carey O'Connor, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare and State Operations, 7500 Security Boulevard, S2–14–26, Baltimore, MD 21224

Phone: 410 786–2117

RIN: 0938–AM79

1124. • DISPROPORTIONATE SHARE HOSPITAL (DSH) PAYMENTS INSTITUTIONS FOR MENTAL DISEASE (IMDS) (CMS–2062–N)

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

Legal Authority: Not Yet Determined

CFR Citation: None

Abstract: This notice announces the preliminary Federal share disproportionate share hospital (DSH) allotments for Federal fiscal year (FFY) 2002 in accordance with the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000. It also announces the FFY 1999, 2000, and 2001 limitations on aggregate DSH payments that States may make to institutions for mental disease and other mental health facilities. In addition, it specifies a format to be used by States when submitting the annual DSH report mandated by the statute.

Timetable:

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Regulatory Flexibility Analysis Required: No

Agency Contact: Patricia Chmielewski, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786–6899

RIN: 0938–AM88

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

1125. STANDARD UNIQUE NATIONAL HEALTH PLAN IDENTIFIERS (CMS–6017–P)

Priority: Substantive, Nonsignificant. Major under 5 USC 801.

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

Legal Authority: 42 USC 1320d to 1320d–8

CFR Citation: 45 CFR 160; 45 CFR 162


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 in section 262 of the Health Insurance Portability & Accountability Act of 1996.

Timetable:

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Regulatory Flexibility Analysis Required: Yes

Agency Contact: Helen Dietrick, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S1–07–17, Office of Information Services, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786–7448

RIN: 0938–AH87

1126. EXCLUSION OF MEDICARE BENEFITS FOR ALIENS NOT LAWFULLY PRESENT IN THE UNITED STATES (CMS–1222–FC)

Priority: Other Significant

Legal Authority: Sec 5561 of BBA 1997; Sec 401(b) of the Personal Responsibility and Work Opportunity Act of 1996; 42 USC 1611(b)

CFR Citation: 42 CFR 411.11

Legal Deadline: None

Abstract: This final rule with comment period amends our regulations to prohibit Medicare benefits to an alien who is not lawfully present in the United States. Section 5561 of the Balanced Budget Act amended section 401(b) of the Personal Responsibility and Work Opportunity Act of 1996 to prohibit Medicare payments for services furnished to an alien who is
HHS—CMS

Long-Term Actions

not “lawfully present in the United States” and meets certain other conditions.

Timetable:

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

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Frederick William Grabau, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center of Medicaid and State Operations, 7500 Security Boulevard, C4–25–02, Baltimore, MD 21244

Phone: 410 786–0206

RIN: 0938–AM47

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1127. ● CHANGES TO THE CRITERIA FOR BEING CLASSIFIED AS AN INPATIENT REHABILITATION FACILITY (CMS–1262–F)

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

Legal Authority: Sec 1886 of the Social Security Act; 42 USC 1395cc

CFR Citation: 42 CFR 412

Legal Deadline: None

Abstract: This final rule would revise classification criteria, commonly known as the “75 percent rule,” for a hospital to be classified as an inpatient rehabilitation facility (IRF). It would also modify and expand the medical conditions listed in the 75 percent rule regulatory requirements. We are proposing these changes to ensure that patients in IRF settings receive appropriate intensive inpatient rehabilitation services.

Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>09/09/03</td>
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<td>10/00/04</td>
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Regulatory Flexibility Analysis Required: No

Small Entities Affected: Undetermined

Government Levels Affected: None

Agency Contact: Robert Kuhl, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Centers for Medicare Management, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786–4597

RIN: 0938–AM72

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Department of Health and Human Services (HHS)

Centers for Medicare & Medicaid Services (CMS)

1128. CONDITIONS OF PARTICIPATION OF INTERMEDIATE CARE FACILITIES FOR PERSONS WITH MENTAL RETARDATION (CMS–3046–P)

Priority: Other Significant

CFR Citation: 42 CFR 400; 42 CFR 435; 42 CFR 440; 42 CFR 441; 42 CFR 483

Completed:

Reason Date FR Cite
Withdrawn 08/19/03

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Anita Panicker

Phone: 410 786–5646

RIN: 0938–AK23

1130. FIRE SAFETY REQUIREMENTS FOR CERTAIN HEALTH CARE FACILITIES (CMS–3047–F)

Priority: Other Significant

CFR Citation: 42 CFR 403; 42 CFR 416; 42 CFR 418; 42 CFR 460; 42 CFR 482; 42 CFR 483

Completed:

Reason Date FR Cite
Final Action 01/10/03 68 FR 1374

Regulatory Flexibility Analysis Required: Yes

Government Levels Affected: State

Agency Contact: Nancy Archer

Phone: 410 786–0596

RIN: 0938–AK40

1132. REVISED PROCESS FOR MAKING MEDICARE NATIONAL COVERAGE DETERMINATIONS (CMS–3062–N)

Priority: Other Significant

CFR Citation: None

Completed:

Reason Date FR Cite
Notice 09/26/03 68 FR 187

Regulatory Flexibility Analysis Required: No

Government Levels Affected: Federal

Agency Contact: Vadim Lubarsky

Phone: 410 786–0840

RIN: 0938–AK61

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1129. LABORATORY REQUIREMENTS RELATING TO QUALITY SYSTEMS AND CERTAIN PERSONNEL QUALIFICATIONS (CMS–2226–CN)

Priority: Other Significant

CFR Citation: 42 CFR 493

Completed:

Reason Date FR Cite
Correction Notice 08/22/03 68 FR 50722

Regulatory Flexibility Analysis Required: No

---

1131. HOSPITAL CONDITIONS OF PARTICIPATION: QUALITY ASSESSMENT AND PERFORMANCE IMPROVEMENTS (GAPI) (CMS–3050–F)

Priority: Other Significant

CFR Citation: 42 CFR 482.21

Completed:

Reason Date FR Cite
Notice 09/26/03 68 FR 187

Regulatory Flexibility Analysis Required: No

Government Levels Affected: Federal

Agency Contact: Vadim Lubarsky

Phone: 410 786–0840

RIN: 0938–AK61
### HHS—CMS

#### Completed Actions

<table>
<thead>
<tr>
<th>Number</th>
<th>Title</th>
<th>Priority</th>
<th>CFR Citation</th>
<th>Completed</th>
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<tr>
<td>1133</td>
<td>MODIFICATIONS TO MEDICARE MANAGED CARE RULES (CMS–4041–F)</td>
<td>Other Significant</td>
<td>42 CFR 409; 42 CFR 417; 42 CFR 422</td>
<td>Final Rule 08/22/03 68 FR 50839</td>
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<td>1134</td>
<td>INPATIENT DISPROPORTIONATE SHARE HOSPITAL (DSH) ADJUSTMENT: CALCULATION OF MEDICAID PATIENT AND TOTAL PATIENT DAYS IN THE MEDICARE DSH ADJUSTMENT (CMS–1171–P)</td>
<td>Other Significant</td>
<td>Merged With 0938–AL89</td>
<td>No</td>
<td>Federal, State</td>
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<td>1135</td>
<td>MODIFICATIONS TO THE STATE CHILDREN’S HEALTH INSURANCE PROGRAM (SCHIP) (CMS–2006–F)</td>
<td>Substantive, Nonsignificant</td>
<td>42 CFR 435; 42 CFR 436; 42 CFR 457</td>
<td>Withdrew 11/18/03</td>
<td>No</td>
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<td>1136</td>
<td>REQUIREMENTS FOR PAID FEEDING ASSISTANTS IN LONG-TERM CARE FACILITIES (CMS–2131–F)</td>
<td>Other Significant</td>
<td>42 CFR 483.73; 42 CFR 483.75(c)</td>
<td>Final Rule 09/26/03 68 FR 55528</td>
<td>No</td>
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<td>1137</td>
<td>CHANGES TO THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM AND CALENDAR YEAR 2003 PAYMENT RATES; CHANGES TO PAYMENT SUSPENSION FOR UNFILED COST REPORTS; CORRECTION TO FINAL RULE (CMS–1206–CN2)</td>
<td>Other Significant</td>
<td>42 CFR 405; 42 CFR 419</td>
<td>Final Action 08/22/03 68 FR 50717</td>
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<td>PAYMENT FOR RESPIRATORY ASSIST DEVICES WITH BI-LEVEL CAPABILITY AND A BACK-UP RATE (CMS–1167–F)</td>
<td>Other Significant</td>
<td>42 CFR 414</td>
<td>Withdrew 11/18/03</td>
<td>No</td>
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</table>

#### Agency Contact Information
- **Tony Hausner**: Phone: 410 786–1093
- **Stephen Phillips**: Phone: 410 786–4548
- **Nola Petrovich**: Phone: 410 786–4671
- **Cindy Read**: Phone: 410 786–1852
- **Carol Blackford**: Phone: 410 786–5909
- **Cheryl Auestein-Casnoff**: Phone: 410 786–4196
- **Joel Kaiser**: Phone: 410 786–4499
- **David Mlawsky**: Phone: 410 786–6851
<table>
<thead>
<tr>
<th>HHS—CMS</th>
<th>Completed Actions</th>
</tr>
</thead>
</table>

**1142. STATE ALLOTMENTS FOR PAYMENT OF MEDICARE PART B PREMIUMS FOR QUALIFYING INDIVIDUALS; FEDERAL FY 2002 (CMS–2136–FN)**

- **Government Levels Affected:** None
- **Agency Contact:** Stacey Bush
  - Phone: 410 786–6102
- **RIN:** 0938–AL62

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

**CFR Citation:** None

**Completed:**
- Reason: Final Action
  - Date: 08/22/03
  - FR Cite: 68 FR 50790

**Regulatory Flexibility Analysis Required:** No

**Government Levels Affected:** None

**Agency Contact:** Robert Nakielny
- Phone: 410 786–4466
- RIN: 0938–AL79

**1143. MEDICAID COVERAGE RULES FOR INMATES OF PUBLIC INSTITUTIONS (CMS–2077–P)**

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

**CFR Citation:** 42 CFR 435.1008; 42 CFR 435.1009; 42 CFR 435.1012; 42 CFR 436.1004

**Completed:**
- Reason: Withdrawn
  - Date: 08/08/03

**Regulatory Flexibility Analysis Required:** No

**Government Levels Affected:** Local, State

**Agency Contact:** Tom Shenk
- Phone: 410 786–3295
- RIN: 0938–AL85

**1144. TARGETED CASE MANAGEMENT (CMS–2061–P)**

- **Priority:** Substantive, Nonsignificant

**CFR Citation:** 42 CFR 431; 42 CFR 440; 42 CFR 441

**Completed:**
- Reason: Withdrawn
  - Date: 08/08/03

**Regulatory Flexibility Analysis Required:** No

**Government Levels Affected:** None

**Agency Contact:** Kathy Poisal
- Phone: 410 786–5940
- RIN: 0938–AL87

**1145. CHANGES TO THE HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEM AND FY 2004 RATES (CMS–1470–F)**

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

**CFR Citation:** 42 CFR 412; 42 CFR 413; 42 CFR 485; 42 CFR 489

**Completed:**
- Reason: Final Action
  - Date: 08/01/03
  - FR Cite: 68 FR 45346

**Regulatory Flexibility Analysis Required:** Yes

**Government Levels Affected:** None

**Agency Contact:** Tzvi Hefter
- Phone: 410 786–4487
- Scott Cooper
  - Phone: 410 786–4487
- RIN: 0938–AL89

**1146. PROSPECTIVE PAYMENT SYSTEM AND CONSOLIDATED BILLING FOR SKILLED NURSING FACILITIES—UPDATE FOR FY 2004 (CMS–1473–NC)**

- **Priority:** Other Significant

**CFR Citation:** None

**Completed:**
- Reason: NPRM
  - Date: 05/16/03
  - FR Cite: 68 FR 26758
- Final Rule
  - Date: 08/04/03
  - FR Cite: 68 FR 46036

**Regulatory Flexibility Analysis Required:** No

**Government Levels Affected:** None

**Agency Contact:** Randy Throendset
- Phone: 410 786–0131
- RIN: 0938–AL94

**1147. PROSPECTIVE PAYMENT SYSTEM FOR INPATIENT REHABILITATION HOSPITALS FOR FY 2004 (CMS–1474–F)**

- **Priority:** Substantive, Nonsignificant

**CFR Citation:** 42 CFR 412; 42 CFR 413

**Completed:**
- Reason: NPRM
  - Date: 05/16/03
  - FR Cite: 68 FR 26758
- Final Rule
  - Date: 08/04/03
  - FR Cite: 68 FR 46036

**Regulatory Flexibility Analysis Required:** No

**Government Levels Affected:** None

**Agency Contact:** Robert Kuhl
- Phone: 410 786–4597
- RIN: 0938–AL95

**1148. HOME HEALTH PROSPECTIVE PAYMENT SYSTEM RATE UPDATE FOR FY 2004 (CMS–1475–NC)**

- **Priority:** Other Significant

**CFR Citation:** None

**Completed:**
- Reason: Notice
  - Date: 07/02/03
  - FR Cite: 68 FR 39763

**Regulatory Flexibility Analysis Required:** Yes

**Government Levels Affected:** None

**Agency Contact:** Randy Throendset
- Phone: 410 786–0131
- RIN: 0938–AL94

**1149. PROSPECTIVE PAYMENT SYSTEM FOR INPATIENT REHABILITATION HOSPITALS FOR FY 2004 (CMS–1474–F)**

- **Priority:** Substantive, Nonsignificant

**CFR Citation:** 42 CFR 412; 42 CFR 413

**Completed:**
- Reason: NPRM
  - Date: 05/16/03
  - FR Cite: 68 FR 26758
- Final Rule
  - Date: 08/04/03
  - FR Cite: 68 FR 46036

**Regulatory Flexibility Analysis Required:** No

**Government Levels Affected:** None

**Agency Contact:** Robert Kuhl
- Phone: 410 786–4597
- RIN: 0938–AL95

**1150. REVISIONS TO PAYMENT POLICIES UNDER THE PHYSICIAN FEE SCHEDULE FOR CALENDAR YEAR 2004 (CMS–1476–P)**

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

**CFR Citation:** None

**Completed:**
- Reason: NPRM
  - Date: 05/16/03
  - FR Cite: 68 FR 26786
- Final Rule
  - Date: 08/04/03
  - FR Cite: 68 FR 46036

**Regulatory Flexibility Analysis Required:** No

**Government Levels Affected:** None

**Agency Contact:** Robert Kuhl
- Phone: 410 786–4597
- RIN: 0938–AL95

**1151. PROSPECTIVE PAYMENT SYSTEM FOR INPATIENT REHABILITATION HOSPITALS FOR FY 2004 (CMS–1474–F)**

- **Priority:** Substantive, Nonsignificant

**CFR Citation:** 42 CFR 412; 42 CFR 413

**Completed:**
- Reason: NPRM
  - Date: 05/16/03
  - FR Cite: 68 FR 26758
- Final Rule
  - Date: 08/04/03
  - FR Cite: 68 FR 46036

**Regulatory Flexibility Analysis Required:** No

**Government Levels Affected:** None

**Agency Contact:** Robert Kuhl
- Phone: 410 786–4597
- RIN: 0938–AL95
### HHS—CMS

#### Completed Actions

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<th>Reason</th>
<th>Date</th>
<th>FR Cite</th>
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#### Regulatory Flexibility Analysis
- **Required:** Yes
- **Government Levels Affected:** Federal
- **Agency Contact:** Diane Milstead
  - Phone: 410 786–3355
- **RIN:** 0938–AL96

#### 1151. NONDISCRIMINATION IN POST-HOSPITAL REFERRAL TO HOME HEALTH AGENCIES AND OTHER ENTITIES (CMS–1224–F)
- **Priority:** Substantive, Nonsignificant
- **CFR Citation:** 42 CFR 482
- **Completed:**
  - **Reason:** Withdrawn
  - Date: 11/18/03

#### Regulatory Flexibility Analysis
- **Required:** No
- **Government Levels Affected:** None
- **Agency Contact:** Elizabeth Carmody
  - Phone: 410 786–7533
- **RIN:** 0938–AM01

#### 1152. UPDATE OF THE LIST OF COVERED PROCEDURES FOR AMBULATORY SURGICAL CENTERS (CMS–1885–FC)
- **Priority:** Other Significant
- **CFR Citation:** 42 CFR 416
- **Completed:**
  - **Reason:** Withdrawn
  - Date: 11/18/03

#### Regulatory Flexibility Analysis
- **Required:** No
- **Government Levels Affected:** None
- **Agency Contact:** Bob Cereghino
  - Phone: 410 786–4645
- **RIN:** 0938–AM02

#### 1153. MEDICAID HOME AND COMMUNITY BASED SERVICES WAIVERS (CMS–2162–P)
- **Priority:** Substantive, Nonsignificant
- **CFR Citation:** 42 CFR 441.300
- **Completed:**
  - **Reason:** Withdrawn
  - Date: 10/30/03

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

#### Government Levels Affected:
- **State, Local**
  - **Agency Contact:** David Mlawsky
    - Phone: 410 786–6851
  - **RIN:** 0938–AM15

#### 1154. PAYMENT REFORM FOR PART B DRUGS (CMS–1229–F)
- **Priority:** Economically Significant. Major status under 5 USC 801 is undetermined.
- **CFR Citation:** 42 CFR 405
- **Completed:**
  - **Reason:** Merged With
  - **Date:** 08/20/03
  - **FR Cite:** 68 FR 50428

#### Regulatory Flexibility Analysis
- **Required:** No
- **Government Levels Affected:** None
- **Agency Contact:** Marjorie Baldo
  - Phone: 410 786–4617
- **RIN:** 0938–AM12

#### 1155. NONDISCRIMINATION IN HEALTH COVERAGE IN THE GROUP MARKET (CMS–2022–F)
- **Priority:** Substantive, Nonsignificant. Major status under 5 USC 801 is undetermined.
- **CFR Citation:** 45 CFR 146.121
- **Completed:**
  - **Reason:** Withdrawn
  - Date: 11/18/03

#### Regulatory Flexibility Analysis
- **Required:** No
- **Government Levels Affected:** Local, State
- **Agency Contact:** David Mlawsky
  - Phone: 410 786–6851
- **RIN:** 0938–AM14

#### 1156. BONA FIDE WELLNESS PROGRAMS (CMS–2078–F)
- **Priority:** Substantive, Nonsignificant. Major status under 5 USC 801 is undetermined.
- **CFR Citation:** 45 CFR 146.121(f)
- **Completed:**
  - **Reason:** Withdrawn
  - Date: 08/27/03

#### Regulatory Flexibility Analysis
- **Required:** Yes
- **Government Levels Affected:** State, Local
  - **Agency Contact:** David Mlawsky
    - Phone: 410 786–6851
  - **RIN:** 0938–AM15

#### 1157. TIME LIMITATION ON RECALCULATIONS AND DISPUTES UNDER THE DRUG REBATE PROGRAM (CMS–2175–FC)
- **Priority:** Economically Significant. Major status under 5 USC 801 is undetermined.
- **CFR Citation:** 42 CFR 447.534
- **Completed:**
  - **Reason:** Final Rule with Comment
  - **Date:** 08/29/03
  - **FR Cite:** 68 FR 51912
  - **Comment Period End:** 10/28/03

#### Regulatory Flexibility Analysis
- **Required:** Yes
- **Government Levels Affected:** Federal, Local, State
- **Agency Contact:** Marge Lee Watchorn
  - Phone: 410 786–4361
- **RIN:** 0938–AM20

#### 1158. MEDICAID ESTATE RECOVERIES (CMS–2083–P)
- **Priority:** Other Significant. Major status under 5 USC 801 is undetermined.
- **CFR Citation:** None
- **Completed:**
  - **Reason:** Withdrawn
  - Date: 08/27/03

#### Regulatory Flexibility Analysis
- **Required:** No
- **Government Levels Affected:** None
- **Agency Contact:** Ingrid Osborne
  - Phone: 410 786–4461
- **RIN:** 0938–AM30

#### 1159. APPLICATION OF THE EMERGENCY MEDICAL TREATMENT AND LABOR ACT (EMTALA) (CMS–1063–F)
- **Priority:** Other Significant. Major status under 5 USC 801 is undetermined.
- **CFR Citation:** Not Yet Determined
- **Completed:**
  - **Reason:** Final Rule
  - **Date:** 09/09/03
  - **FR Cite:** 68 FR 53222

#### Regulatory Flexibility Analysis
- **Required:** No
### HHS—CMS

| 1160. PHYSICIAN OWNERSHIP IN SPECIALTY HOSPITALS (CMS–1240–P) |
|------------------|------------------|
| **Priority:** Substantive, Nonsignificant | **CFR Citation:** 42 CFR 411 |
| **Completed:** | **Completed:** |
| Reason | Date | FR Cite |
| Withdrawn | 08/19/03 | 68 FR 34494 |
| Regulatory Flexibility Analysis Required: Yes | Government Levels Affected: None |
| **Agency Contact:** Rebecca Hirshorn Phone: 410 786–3411 | **Agency Contact:** Stephen Phillips Phone: 410 786–4548 |
| **RIN:** 0938–AM34 | **RIN:** 0938–AM41 |

| 1161. APPROVAL OF THE JOINT COMMISSION ON ACCREDITATION OF HEALTHCARE ORGANIZATIONS (JCAHO) FOR DEEMING AUTHORITY FOR HOSPICES (CMS–2177–FN) |
|------------------|------------------|
| **Priority:** Routine and Frequent | **CFR Citation:** Not Yet Determined |
| **Completed:** | **Completed:** |
| Reason | Date | FR Cite |
| Withdrawn | 11/18/03 | |
| Regulatory Flexibility Analysis Required: Undetermined | Government Levels Affected: None |
| Federalism: Undetermined | **Agency Contact:** Jackie Proctor Phone: 410 786–8852 |
| **RIN:** 0938–AM35 | **RIN:** 0938–AM45 |

| 1162. HOSPITAL COST-TO-CHARGE RATIOS USED TO CALCULATE COST OUTLIER PAYMENTS UNDER THE MEDICARE SHORT-TERM INPATIENT PROSPECTIVE PAYMENT SYSTEM (CMS–1243–F) |
|------------------|------------------|
| **Priority:** Economically Significant. Major under 5 USC 801. | **CFR Citation:** 42 CFR 412.84; 42 CFR 412.116 |
| **Completed:** | **Completed:** |
| Reason | Date | FR Cite |
| Final Action | 06/09/03 | 68 FR 34494 |
| Regulatory Flexibility Analysis Required: Yes | Government Levels Affected: None |
| **Agency Contact:** Stephen Phillips Phone: 410 786–4548 | **Agency Contact:** Cathaleen Ahern Phone: 410 786–4515 |
| **RIN:** 0938–AM41 | **RIN:** 0938–AM56 |

| 1163. AMBULANCE FEE SCHEDULE CONDITION CODES (CMS–1247–P) |
|------------------|------------------|
| **Priority:** Substantive, Nonsignificant. Major status under 5 USC 801 is undetermined. | **CFR Citation:** Not Yet Determined |
| **Completed:** | **Completed:** |
| Reason | Date | FR Cite |
| Withdrawn | 11/18/03 | |
| Regulatory Flexibility Analysis Required: Undetermined | Government Levels Affected: None |
| **Agency Contact:** Anne Tayloe Phone: 410 786–4546 | **Agency Contact:** Mark Horney Phone: 410 786–4554 |
| **RIN:** 0938–AM45 | **RIN:** 0938–AM59 |

| 1164. HOSPICE WAGE INDEX FOR FY 2004 (CMS–1233–N) |
|------------------|------------------|
| **Priority:** Routine and Frequent | **CFR Citation:** 42 CFR 418.306(C) |
| **Completed:** | **Completed:** |
| Reason | Date | FR Cite |
| Notice | 09/30/03 | 68 FR 56478 |
| Regulatory Flexibility Analysis Required: No | Government Levels Affected: None |
| **Agency Contact:** Carol Blackford Phone: 410 786–5909 | **Agency Contact:** Suzanne Ripley, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C4–25–02, 7500 Security Blvd, Baltimore, MD 21244 Phone: 410 786–0970 |
| **RIN:** 0938–AM56 | **RIN:** 0938–AM64 |

| 1165. ANNOUNCEMENT OF APPLICATIONS FROM HOSPITALS REQUESTING WAIVERS FOR ORGAN PROCUREMENT SERVICE AREAS IN CALENDAR YEAR 2003 (CMS–1246–NC) |
|------------------|------------------|
| **Priority:** Routine and Frequent | **CFR Citation:** 42 CFR 486.306 |
| **Completed:** | **Completed:** |
| Reason | Date | FR Cite |
| Withdrawn | 09/04/03 | |
| Regulatory Flexibility Analysis Required: No | Government Levels Affected: None |
| **Agency Contact:** Rebecca Hirshorn Phone: 410 786–3411 | **Agency Contact:** Suzanne Ripley, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C4–25–02, 7500 Security Blvd, Baltimore, MD 21244 Phone: 410 786–0970 |
| **RIN:** 0938–AM64 | **RIN:** 0938–AM59 |
### Proposed Rules

#### 1167. SAFEGUARDING CHILD SUPPORT AND EXPANDED FEDERAL PARENT LOCATOR SERVICES (FPLS) INFORMATION

**Priority:** Substantive, Nonsignificant  
**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, offset of Federal payments for purposes of collecting child support, and safeguarding of information. This regulation would update various sections in 45 CFR chapter III to reflect the statutory changes.

**Timetable:**

<table>
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<th>Action</th>
<th>Date</th>
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</tr>
</thead>
<tbody>
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<td>03/00/04</td>
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**Regulatory Flexibility Analysis**  
**Required:** No

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

**Agency Contact:** Eileen C. Brooks, Deputy Director, Policy Division, Department of Health and Human Services, Administration for Children and Families, 4th Floor East, OCSE, DPP, 370 L'Enfant Promenade SW., Washington, DC 20447  
Phone: 202 401–5369  
TDD Phone: 800 877–8339  
Fax: 202 401–4054  
Email: ebrooks@acf.hhs.gov  
RIN: 0970–AC01

#### 1168. DEVELOPMENTAL DISABILITIES AND BILL OF RIGHTS ACT

**Priority:** Substantive, Nonsignificant  
**Legal Authority:** PL 106–402; USC 15001 et seq  
**CFR Citation:** 45 CFR 1385 to 1388  
**Legal Deadline:** Final, Statutory, October 30, 2001, Final.  

**Abstract:** A notice of proposed rulemaking will be published in the Federal Register to amend current regulations and to implement changes made by the Developmental Disabilities Assistance and Bill of Rights Act of 2000.

**Timetable:**

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

**Small Entities Affected:** No

**Government Levels Affected:** State

**Agency Contact:** Kathleen McHugh, Division Director, Children’s Bureau Policy, Department of Health and Human Services, Administration for Children and Families, Room 2411, 330 C Street SW., Washington, DC 20447  
Phone: 202 401–5789  
Fax: 202 205–8221  
Email: kmchugh@acf.hhs.gov  
RIN: 0970–AC14

#### 1169. ADMINISTRATIVE COST SHARING UNDER TANF

**Priority:** Substantive, Nonsignificant  
**Legal Authority:** 42 USC 672; 42 USC 674; 42 USC 1302  
**CFR Citation:** 45 CFR 1356.60(c)  
**Legal Deadline:** None

**Abstract:** This proposed rule will enable States (including the District of Columbia) and territories to use either the “primary program” cost allocation methodology previously allowed under the Aid to Families with Dependent Children (AFDC) program to allocate the common administrative costs of determining eligibility in the Temporary Assistance for Needy Families (TANF) program, the Medicaid program, and the Food Stamp programs or to continue to use a “benefiting” cost allocation methodology. Pursuant to a determination by Secretary Thompson, States and territories would be able to elect to use their Federal TANF funds to pay for costs that are common to the administration of the TANF, Medicaid, and Food Stamps Programs, in accordance with the primary program cost allocation methodology previously allowed under the former AFDC program.

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<table>
<thead>
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### 1171. CHILD SUPPORT ENFORCEMENT FOR INDIAN TRIES

**Priority:** Other Significant  
**Legal Authority:** 42 USC 655(f)  
**CFR Citation:** 45 CFR 309  
**Legal Deadline:** None  
**Abstract:** This rule specifies how tribes can obtain direct payments from the Department of Health and Human Services for provision of child support enforcement services if they submit a plan meeting the objectives of title IV-D, including establishment of paternity, modification and enforcement of support orders, and location of absent parents.  
**Timetable:**  
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**Regulatory Flexibility Analysis Required:** No  
**Small Entities Affected:** No  
**Government Levels Affected:** State, Tribal  
**Agency Contact:** Paige Biava, Division of Policy and Planning, Department of Health and Human Services, Administration for Children and Families, 5th Floor East, OCSE, DPP, 370 L’Enfant Promenade SW., Washington, DC 20447  
Phone: 202 401–9386  
Email: ebiava@acf.hhs.gov  
**RIN:** 0970–AC09

### 1172. CHILD SUPPORT ENFORCEMENT PROGRAM; FEDERAL TAX REFUND OFFSET

**Priority:** Substantive, Nonsignificant  
**Legal Authority:** 42 USC 664; 42 USC 1302  
**CFR Citation:** 45 CFR 303.72  
**Legal Deadline:** None  
**Abstract:** This interim final rule will revise existing regulations on collecting child support arrears through the Federal Tax Refund Offset process. The revisions are needed to reflect changes in data processing protocols with the Department of the Treasury. We are also updating the regulation to reflect current business practices and requests from the state child support agencies.  
**Timetable:**  
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**Regulatory Flexibility Analysis Required:** No  
**Small Entities Affected:** No  
**Government Levels Affected:** State  
**Agency Contact:** Paige Biava, Division of Policy and Planning, Department of Health and Human Services, Administration for Children and Families, 5th Floor East, OCSE, DPP, 370 L’Enfant Promenade SW., Washington, DC 20447  
Phone: 202 401–9386  
Email: ebiava@acf.hhs.gov  
**RIN:** 0970–AB73

### 1173. CHARITABLE CHOICE PROVISIONS APPLICABLE TO THE TEMPORARY ASSISTANCE FOR NEEDY FAMILIES PROGRAM

**Priority:** Other Significant  
**Legal Authority:** 42 USC 1302; 42 USC 604(a)  
**CFR Citation:** 45 CFR 260.30; 45 CFR 260.34  
**Legal Deadline:** None  
**Abstract:** This proposed rule would implement the Charitable Choice statutory provisions at section 104 of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 as amended. It is the policy of the Administration for Children and Families that, within constitutional church-state guidelines, faith-based organizations should be able to compete on an equal footing for funding under the Temporary Assistance for Needy Families (TANF) program. In addition to giving families a greater choice of TANF-funded providers, these rules ensure that the character of religious providers is not impaired and that the religious freedom of TANF beneficiaries is not impaired.  
**Timetable:**  
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**Regulatory Flexibility Analysis Required:** No  
**Small Entities Affected:** No  
**Government Levels Affected:** State  
**Agency Contact:** April Kaplan, Deputy Director, Office of Family Assistance, Department of Health and Human Services, Administration for Children and Families, 5th Floor East, 370 L’Enfant Promenade SW., Washington, DC 20447  
Phone: 202 401–5138  
Email: akaplan@acf.hhs.gov  
**RIN:** 0970–AC12

### 1174. COMMUNITY SERVICES BLOCK GRANT CHARITABLE CHOICE

**Priority:** Substantive, Nonsignificant  
**Legal Authority:** 42 USC 9901; PL 105–285, sec 672; 42 USC 9902; PL 105–285, sec 673  
**CFR Citation:** 45 CFR 1050  
**Legal Deadline:** None  
**Abstract:** This proposed rule would implement the Charitable Choice statutory provisions at section 679 of the Community Services Block Grant Act. These provisions apply to
programs authorized under the Act, including the Community Services Block grant program, Training, Technical Assistance and Capacity Building program, Community Food and Nutrition Program, National Youth Sports program, and discretionary grants for economic development, rural community development, and neighborhood innovation, which are all administered by the Administration for Children and Families (ACF). It is ACF’s policy that, within the framework of constitutional church-state guidelines, faith-based organizations should be able to compete on an equal footing for funding, and ACF supports the participation of faith-based organizations in these programs.

**Timetable:**

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**Regulatory Flexibility Analysis Required:** No

**Government Levels Affected:** Federal

**Agency Contact:** Clarence Carter, Director, Office of Community Services, Department of Health and Human Services, Administration for Children and Families, 5th Floor East, 370 L’Enfant Promenade SW., Washington, DC 20447

Phone: 202 401–9333

Email: ccarter@acf.hhs.gov

RIN: 0970–AC13

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

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

**1175. CONSTRUCTION AND MAJOR RENOVATION OF HEAD START AND EARLY HEAD START FACILITIES**

**Priority:** Other Significant

**CFR Citation:** 45 CFR 1309

**Completed:**

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**Regulatory Flexibility Analysis Required:** No

**Government Levels Affected:** Local, Tribal

**Agency Contact:** Douglas Klafehn

Phone: 202 205–8569

Email: dklafehn@acf.dhhs.gov

RIN: 0970–AB54

**1176. CHILD SUPPORT ENFORCEMENT PROGRAM OMNIBUS CONFORMING REGULATION**

**Priority:** Substantive, Nonsignificant

**CFR Citation:** 45 CFR 301 to 305

**Completed:**

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<td>68 FR 25293</td>
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**Regulatory Flexibility Analysis Required:** No

**Government Levels Affected:** State

**Agency Contact:** Eileen C. Brooks

Phone: 202 401–5369

TDD Phone: 800 877–8339

Fax: 202 401–4054

Email: ebrooks@acf.hhs.gov

RIN: 0970–AB81

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**1177. TECHNICAL REVISION OF HEAD START REGULATIONS TO MAKE THEM CONFORM TO RECENT STATUTORY REVISIONS**

**Priority:** Substantive, Nonsignificant

**CFR Citation:** 45 CFR 1301 to 1303; 45 CFR 1305; 45 CFR 1308

**Completed:**

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**Regulatory Flexibility Analysis Required:** No

**Government Levels Affected:** State

**Agency Contact:** Sheck Chin

Phone: 202 260–5830

TDD Phone: 800 877–8339

Fax: 202 401–4054

Email: schin@acf.hhs.gov

RIN: 0970–AC11
1179. GRANTS FOR STATE AND COMMUNITY PROGRAMS ON AGING, TRAINING, RESEARCH, AND DISCRETIONARY PROGRAMS; VULNERABLE ELDER RIGHTS; GRANTS TO INDIANS AND NATIVE HAWAI’ANS

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 3001 et seq

CFR Citation: 45 CFR 1321; 45 CFR 1326; 45 CFR 1328

Legal Deadline: None

Abstract: In response to the reauthorization of the Older Americans Act, Public Law 106–501, the Administration on Aging (AoA) proposes to issue a notice of proposed rulemaking by spring of 2004.

Timetable:

<table>
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Regulatory Flexibility Analysis Required: Yes

Government Levels Affected: State, Tribal

Federalism: Undetermined

Agency Contact: Edwin Walker, Deputy Assistant Secretary for Policy and Programs, Department of Health and Human Services, Administration on Aging, Washington, DC 20201
Phone: 202 401–4634

RIN: 0985–AA00

[FR Doc. 03–27071 Filed 12–19–03; 8:45 am]

BILLING CODE 4150–24–S