Monday,
June 28, 2004

Part VIII

Department of Health and Human Services

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

Office of the Secretary

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 by Federal departments and agencies. The purpose is to encourage public participation in the regulatory process by providing, at as early a stage as possible, summarized information about regulatory actions under consideration. Anyone wishing to communicate to the Department their views on the potential rulemakings outlined below is invited to do so.

When the Department publishes a regulatory proposal, information about it automatically becomes available to the public at www.regulations.gov, the Governmentwide Web site for submission of comments on proposed regulations. Citizens may submit comments by clicking the Submit a Comment on the Regulation link on this site, which will open a blank comment form that includes instructions on how to submit the comment and what information must be provided for the comment to be considered. Comments submitted via www.regulations.gov are transmitted to the Department daily, and, as legally required, all comments are reviewed and taken into account if a final regulation is developed.

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 notices of proposed rulemaking, or final rules within the next 12 months. (Also included, in several Long-Term Action sections, are summaries of actions that we will probably not take any earlier than 12 months after publication of this agenda.) We welcome the views of all concerned with regard to these planned rulemakings. Comments may be directed to the agency officials cited in each of the summaries. Or, if early attention at the Secretary’s level is seen as required, comments should be sent to: Ann C. Agnew, Executive Secretary to the Department, Room 603H, 200 Independence Avenue SW., Washington, DC 20201.


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 Identifier Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>813</td>
<td>Safe Harbor for Arrangements Involving Federally Qualified Health Centers</td>
<td>0991–AB06</td>
</tr>
<tr>
<td>814</td>
<td>Claims Collection</td>
<td>0991–AB18</td>
</tr>
<tr>
<td>815</td>
<td>Salary Offset</td>
<td>0991–AB19</td>
</tr>
<tr>
<td>816</td>
<td>Medicare and Federal Health Care Programs: Fraud and Abuse; Revisions to the Waiver Provisions of the OIG’s Exclusion Authorities</td>
<td>0991–AB33</td>
</tr>
</tbody>
</table>

Office of the Secretary—Final Rule Stage

<table>
<thead>
<tr>
<th>Sequence Number</th>
<th>Title</th>
<th>Regulation Identifier Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>817</td>
<td>Shared Risk Exception to the Safe Harbor Provisions</td>
<td>0991–AA91</td>
</tr>
<tr>
<td>818</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>
<tr>
<td>819</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>820</td>
<td>Clarification of Terms and Application of Program Exclusion Authority for Submitting Claims Containing Excessive Charges</td>
<td>0991–AB23</td>
</tr>
<tr>
<td>821</td>
<td>Technical Revisions to HIPDB Data Collection Activities</td>
<td>0991–AB31</td>
</tr>
</tbody>
</table>

Office of the Secretary—Long-Term Actions

<table>
<thead>
<tr>
<th>Sequence Number</th>
<th>Title</th>
<th>Regulation Identifier Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>822</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>823</td>
<td>Health Insurance Portability and Accountability Act—Enforcement</td>
<td>0991–AB29</td>
</tr>
</tbody>
</table>
**HHS**

**Office of the Secretary—Completed Actions**

<table>
<thead>
<tr>
<th>Sequence Number</th>
<th>Title</th>
<th>Regulation Identifier Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>824</td>
<td>Tax Refund Offset</td>
<td>0991–AB17</td>
</tr>
<tr>
<td>826</td>
<td>OIG Civil Money Penalties Under the Medicare Prescription Drug Discount Card Program</td>
<td>0991–AB30</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 Identifier Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>827</td>
<td>Requirements Governing the Use of Seclusion and Restraint in Certain Nonmedical Community-Based Facilities for Children and Youth</td>
<td>0930–AA10</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Sequence Number</th>
<th>Title</th>
<th>Regulation Identifier Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>828</td>
<td>Mandatory Guidelines for the Federal Workplace Drug Testing Program</td>
<td>0930–AA12</td>
</tr>
</tbody>
</table>

**Substance Abuse and Mental Health Services Administration—Completed Actions**

<table>
<thead>
<tr>
<th>Sequence Number</th>
<th>Title</th>
<th>Regulation Identifier Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>829</td>
<td>Substance Abuse and Mental Health Services Administration (SAMHSA) Charitable Choice</td>
<td>0930–AA11</td>
</tr>
<tr>
<td>830</td>
<td>Mandatory Guidelines for Federal Workplace Drug Testing Programs; Specimen Validity Testing</td>
<td>0930–AA13</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 Identifier Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>831</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—Completed Actions**

<table>
<thead>
<tr>
<th>Sequence Number</th>
<th>Title</th>
<th>Regulation Identifier Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>832</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 Identifier Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>833</td>
<td>Safety Reporting Requirements for Human Drug and Biological Products</td>
<td>0910–AA97</td>
</tr>
<tr>
<td>834</td>
<td>Food Labeling; Prominence of Calories</td>
<td>0910–AF22</td>
</tr>
<tr>
<td>835</td>
<td>Food Labeling; Serving Sizes</td>
<td>0910–AF23</td>
</tr>
<tr>
<td>836</td>
<td>Over-the-Counter (OTC) Drug Review—Sunscreen Products</td>
<td>0910–AF43</td>
</tr>
</tbody>
</table>
### Food and Drug Administration—Proposed Rule Stage

<table>
<thead>
<tr>
<th>Sequence Number</th>
<th>Title</th>
<th>Regulation Identifier Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>837</td>
<td>Foreign and Domestic Establishment Registration and Listing Requirements for Drugs and Biologics</td>
<td>0910–AA49</td>
</tr>
<tr>
<td>838</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>839</td>
<td>Prevention of Salmonella Enteritidis in Shell Eggs</td>
<td>0910–AC14</td>
</tr>
<tr>
<td>840</td>
<td>Exception From General Requirements for Informed Consent; Request for Comments and Information</td>
<td>0910–AC25</td>
</tr>
<tr>
<td>841</td>
<td>Medical Devices; Anesthesiology Devices; Proposed Reclassification of Pressure Regulators for Use With Medical Oxygen</td>
<td>0910–AC30</td>
</tr>
<tr>
<td>842</td>
<td>Food Standards: General Principles and Food Standards Modernization</td>
<td>0910–AC54</td>
</tr>
<tr>
<td>843</td>
<td>Positron Emission Tomography Drugs; Current Good Manufacturing Practices</td>
<td>0910–AC55</td>
</tr>
<tr>
<td>844</td>
<td>Reporting Information Regarding Falsification of Data</td>
<td>0910–AC59</td>
</tr>
<tr>
<td>845</td>
<td>Definition of “Serious Adverse Health Consequences” Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002</td>
<td>0910–AF06</td>
</tr>
<tr>
<td>846</td>
<td>Health Claims</td>
<td>0910–AF09</td>
</tr>
<tr>
<td>847</td>
<td>Quality Standard Regulation Establishing Allowable Level for Arsenic in Bottled Water</td>
<td>0910–AF10</td>
</tr>
<tr>
<td>848</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>849</td>
<td>Cochineal Extract and Carmine Label Declaration</td>
<td>0910–AF12</td>
</tr>
<tr>
<td>850</td>
<td>Charging for Investigational Drugs</td>
<td>0910–AF13</td>
</tr>
<tr>
<td>851</td>
<td>Treatment Use of Investigational Drugs</td>
<td>0910–AF14</td>
</tr>
<tr>
<td>852</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>
<tr>
<td>853</td>
<td>Use of Ozone-Depleting Substances: Removal of Essential Use Designation; Albuterol</td>
<td>0910–AF18</td>
</tr>
<tr>
<td>854</td>
<td>Revocation of the Status of Specific Products; Group A Streptococcus</td>
<td>0910–AF20</td>
</tr>
<tr>
<td>855</td>
<td>Latex Condoms: Special Controls</td>
<td>0910–AF21</td>
</tr>
<tr>
<td>856</td>
<td>Blood Initiative—Regulations for Human Blood and Blood Components Intended for Transfusion or for Further Manufacturing Use</td>
<td>0910–AF25</td>
</tr>
<tr>
<td>857</td>
<td>Over-the-Counter (OTC) Drug Review—Cough/Cold (Bronchodilator) Products</td>
<td>0910–AF32</td>
</tr>
<tr>
<td>858</td>
<td>Over-the-Counter (OTC) Drug Review—Cough/Cold (Combination) Products</td>
<td>0910–AF33</td>
</tr>
<tr>
<td>859</td>
<td>Over-the-Counter (OTC) Drug Review—Cough/Cold (Nasal Decongestant) Products</td>
<td>0910–AF34</td>
</tr>
<tr>
<td>860</td>
<td>Over-the-Counter (OTC) Drug Review—Internal Analgesics Products</td>
<td>0910–AF36</td>
</tr>
<tr>
<td>861</td>
<td>Over-the-Counter (OTC) Drug Review—Labeling of Drug Products for OTC Human Use</td>
<td>0910–AF37</td>
</tr>
<tr>
<td>862</td>
<td>Over-the-Counter (OTC) Drug Review—Weight Control Products</td>
<td>0910–AF45</td>
</tr>
</tbody>
</table>

### Food and Drug Administration—Final Rule Stage

<table>
<thead>
<tr>
<th>Sequence Number</th>
<th>Title</th>
<th>Regulation Identifier Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>863</td>
<td>Investigational New Drugs: Export Requirements for Unapproved New Drug Products</td>
<td>0910–AA61</td>
</tr>
<tr>
<td>864</td>
<td>Labeling for Human Prescription Drugs; Revised Format</td>
<td>0910–AA94</td>
</tr>
<tr>
<td>865</td>
<td>Current Good Manufacturing Practice for Human Cell, Tissue, and Cellular and Tissue-Based Product Establishments; Inspection and Enforcement</td>
<td>0910–AB28</td>
</tr>
<tr>
<td>866</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)</td>
<td>0910–AB76</td>
</tr>
<tr>
<td>867</td>
<td>Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements</td>
<td>0910–AB88</td>
</tr>
<tr>
<td>868</td>
<td>Additional Safeguards for Children in Clinical Investigations of FDA-Regulated Products</td>
<td>0910–AC07</td>
</tr>
<tr>
<td>869</td>
<td>Medical Devices; Patient Examination and Surgeons’ Gloves; Adulteration</td>
<td>0910–AC32</td>
</tr>
<tr>
<td>870</td>
<td>Amendments to the Performance Standard for Diagnostic X-Ray Systems and Their Major Components</td>
<td>0910–AC34</td>
</tr>
<tr>
<td>871</td>
<td>Establishment and Maintenance of Records Pursuant to the Public Health Security and Bioterrorism Preparedness and Response Act of 2002</td>
<td>0910–AC39</td>
</tr>
<tr>
<td>872</td>
<td>Registration of Food and Animal Feed Facilities</td>
<td>0910–AC40</td>
</tr>
<tr>
<td>873</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>874</td>
<td>Presubmission Conferences</td>
<td>0910–AC44</td>
</tr>
<tr>
<td>875</td>
<td>Human Subject Protection; Foreign Clinical Studies Not Conducted Under an Investigational New Drug Application</td>
<td>0910–AF15</td>
</tr>
<tr>
<td>876</td>
<td>Blood Initiative—Revisions to Labeling and Storage Requirements for Blood and Blood Components, Including Source Plasma</td>
<td>0910–AF26</td>
</tr>
</tbody>
</table>
### Food and Drug Administration—Final Rule Stage (Continued)

<table>
<thead>
<tr>
<th>Sequence Number</th>
<th>Title</th>
<th>Regulation Identifier Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>877</td>
<td>Over-the-Counter (OTC) Drug Review—Antiperspirant Products</td>
<td>0910–AF30</td>
</tr>
<tr>
<td>878</td>
<td>Over-the-Counter (OTC) Drug Review—Cough/Cold (Antihistamine) Products</td>
<td>0910–AF31</td>
</tr>
<tr>
<td>879</td>
<td>Over-the-Counter (OTC) Drug Review—Ophthalmic Products</td>
<td>0910–AF39</td>
</tr>
<tr>
<td>880</td>
<td>Over-the-Counter (OTC) Drug Review—Skin Protectant Products</td>
<td>0910–AF42</td>
</tr>
<tr>
<td>881</td>
<td>Over-the-Counter (OTC) Drug Review—Vaginal Contraceptive Products</td>
<td>0910–AF44</td>
</tr>
</tbody>
</table>

### Food and Drug Administration—Long-Term Actions

<table>
<thead>
<tr>
<th>Sequence Number</th>
<th>Title</th>
<th>Regulation Identifier Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>882</td>
<td>Requirements Pertaining to Sampling Services and Private Laboratories Used in Connection With Imported Food</td>
<td>0910–AB96</td>
</tr>
<tr>
<td>883</td>
<td>Chronic Wasting Disease: Control of Food Products and Cosmetics Derived From Exposed Animal Populations</td>
<td>0910–AC21</td>
</tr>
<tr>
<td>884</td>
<td>Requirements for In Vivo Bioequivalence Data</td>
<td>0910–AC23</td>
</tr>
<tr>
<td>885</td>
<td>Toll-Free Number for Reporting Adverse Events on Labeling for Human Drugs</td>
<td>0910–AC35</td>
</tr>
<tr>
<td>886</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>887</td>
<td>Submission of Standardized Electronic Study Data From Clinical Studies Evaluating Human Drugs and Biologics</td>
<td>0910–AC52</td>
</tr>
<tr>
<td>888</td>
<td>Medical Gas Containers and Closures; Current Good Manufacturing Practice Requirements</td>
<td>0910–AC53</td>
</tr>
<tr>
<td>889</td>
<td>Food Labeling: Food Allergen Ingredient Labeling</td>
<td>0910–AF07</td>
</tr>
<tr>
<td>890</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>
<tr>
<td>891</td>
<td>Current Good Manufacturing Practices; Quality Control Procedures; Notification Requirements; Records and Reports</td>
<td>0910–AF27</td>
</tr>
<tr>
<td>892</td>
<td>Infant Formula Quality Factors</td>
<td>0910–AF28</td>
</tr>
<tr>
<td>893</td>
<td>Over-the-Counter (OTC) Drug Review—External Analgesic Products</td>
<td>0910–AF35</td>
</tr>
<tr>
<td>894</td>
<td>Over-the-Counter (OTC) Drug Review—Laxative Drug Products</td>
<td>0910–AF38</td>
</tr>
<tr>
<td>895</td>
<td>Over-the-Counter (OTC) Drug Review—Oral Health Care Products</td>
<td>0910–AF40</td>
</tr>
</tbody>
</table>

### Food and Drug Administration—Completed Actions

<table>
<thead>
<tr>
<th>Sequence Number</th>
<th>Title</th>
<th>Regulation Identifier Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>896</td>
<td>Over-the-Counter (OTC) Drug Review</td>
<td>0910–AA01</td>
</tr>
<tr>
<td>897</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>898</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>899</td>
<td>Blood Initiative</td>
<td>0910–AB26</td>
</tr>
<tr>
<td>900</td>
<td>Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products</td>
<td>0910–AB27</td>
</tr>
<tr>
<td>901</td>
<td>Supplements and Other Changes to an Approved Application</td>
<td>0910–AB61</td>
</tr>
<tr>
<td>902</td>
<td>Current Good Manufacturing Practice for Medicated Foods</td>
<td>0910–AB70</td>
</tr>
<tr>
<td>903</td>
<td>Requirements for Submission of Labeling for Human Prescription Drugs and Biologics in Electronic Format</td>
<td>0910–AB91</td>
</tr>
<tr>
<td>904</td>
<td>Use of Materials Derived From Bovine and Ovine Animals in FDA-Regulated Products</td>
<td>0910–AC19</td>
</tr>
<tr>
<td>905</td>
<td>Bar Code Label Requirements for Human Drug Products and Blood</td>
<td>0910–AC26</td>
</tr>
<tr>
<td>906</td>
<td>Administrative Detention of Food for Human or Animal Consumption Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002</td>
<td>0910–AC38</td>
</tr>
<tr>
<td>907</td>
<td>Requirements for Liquid Medicated Feed and Free-Choice Medicated Feed</td>
<td>0910–AC43</td>
</tr>
<tr>
<td>908</td>
<td>Biological Products; Bacterial Vaccines and Toxoids; Implementation of Efficacy Review</td>
<td>0910–AC56</td>
</tr>
<tr>
<td>909</td>
<td>Revision of the Requirements for Spore-Forming Microorganisms</td>
<td>0910–AC57</td>
</tr>
<tr>
<td>910</td>
<td>Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food (Part 110) (Completion of a Section 610 Review)</td>
<td>0910–AC58</td>
</tr>
<tr>
<td>911</td>
<td>Over-the-Counter (OTC) Drug Review—Antidiarrheal Products</td>
<td>0910–AF29</td>
</tr>
</tbody>
</table>
### Health Resources and Services Administration—Proposed Rule Stage

<table>
<thead>
<tr>
<th>Sequence Number</th>
<th>Title</th>
<th>Regulation Identifier Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>912</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>913</td>
<td>Designation of Medically Underserved Populations and Health Professional Shortage Areas</td>
<td>0906–AA44</td>
</tr>
<tr>
<td>914</td>
<td>Intestines Added to the Definition of Organs Covered by the Rules Governing the Operation of the Organ Procurement and Transplantation Network (OPTN)</td>
<td>0906–AA62</td>
</tr>
<tr>
<td>915</td>
<td>Notice of Proposed Rulemaking to Amend the Final Rule Governing the Operation of the Organ Procurement and Transplantation Network (OPTN)</td>
<td>0906–AA63</td>
</tr>
<tr>
<td>916</td>
<td>National Vaccine Injury Compensation Program; Revisions and Additions to the Vaccine Injury Table</td>
<td>0906–AA66</td>
</tr>
<tr>
<td>917</td>
<td>Liability Protection for Certain Free Clinic Health Professionals</td>
<td>0906–AA67</td>
</tr>
<tr>
<td>918</td>
<td>National Vaccine Injury Compensation Program: Calculation of Average Cost of a Health Insurance Policy</td>
<td>0906–AA68</td>
</tr>
</tbody>
</table>

### Health Resources and Services Administration—Final Rule Stage

<table>
<thead>
<tr>
<th>Sequence Number</th>
<th>Title</th>
<th>Regulation Identifier Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>919</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>920</td>
<td>Smallpox Vaccine Injury Compensation Program: Administrative Implementation</td>
<td>0906–AA61</td>
</tr>
<tr>
<td>921</td>
<td>Requirements Establishing a Limitation on Administrative Expenses; Ryan White CARE Act Title IV Grants for Coordinated Services and Access to Research</td>
<td>0906–AA65</td>
</tr>
</tbody>
</table>

### Health Resources and Services Administration—Long-Term Actions

<table>
<thead>
<tr>
<th>Sequence Number</th>
<th>Title</th>
<th>Regulation Identifier Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>922</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>

### National Institutes of Health—Proposed Rule Stage

<table>
<thead>
<tr>
<th>Sequence Number</th>
<th>Title</th>
<th>Regulation Identifier Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>923</td>
<td>Undergraduate Scholarship Program Regarding Professions Needed by the National Institutes of Health (NIH)</td>
<td>0925–AA10</td>
</tr>
<tr>
<td>924</td>
<td>National Institutes of Health Training Grants</td>
<td>0925–AA28</td>
</tr>
<tr>
<td>925</td>
<td>Standards for a National Chimpanzee Sanctuary System</td>
<td>0925–AA31</td>
</tr>
<tr>
<td>926</td>
<td>National Institutes of Health AIDS Research Loan Repayment Program</td>
<td>0925–AA32</td>
</tr>
<tr>
<td>927</td>
<td>National Institutes of Health Extramural Loan Repayment Program for Clinical Researchers</td>
<td>0925–AA33</td>
</tr>
<tr>
<td>928</td>
<td>National Institutes of Health Pediatric Research Loan Repayment Program</td>
<td>0925–AA34</td>
</tr>
<tr>
<td>929</td>
<td>National Institutes of Health Loan Repayment Program for Health Disparities Research</td>
<td>0925–AA35</td>
</tr>
<tr>
<td>930</td>
<td>National Institutes of Health Clinical Research Loan Repayment Program for Individuals From Disadvantaged Backgrounds</td>
<td>0925–AA36</td>
</tr>
<tr>
<td>931</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 Identifier Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>932</td>
<td>National Institutes of Health Loan Repayment Program for Research Generally</td>
<td>0925–AA18</td>
</tr>
<tr>
<td>933</td>
<td>National Institutes of Health Center Grants</td>
<td>0925–AA24</td>
</tr>
</tbody>
</table>
### National Institutes of Health—Completed Actions

<table>
<thead>
<tr>
<th>Sequence Number</th>
<th>Title</th>
<th>Regulation Identifier Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>934</td>
<td>Scientific Peer Review of Research Grant Applications and Research and Development Contract Projects</td>
<td>0925–AA20</td>
</tr>
</tbody>
</table>

### Office of Public Health and Science—Prerule Stage

<table>
<thead>
<tr>
<th>Sequence Number</th>
<th>Title</th>
<th>Regulation Identifier Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>935</td>
<td>Human Subjects Protection Regulations: Additional Protections for Adult Individuals with Impaired Decisionmaking Capacity</td>
<td>0940–AA11</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 Identifier Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>936</td>
<td>Public Health Service Policies on Research Misconduct</td>
<td>0940–AA04</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 Identifier Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>937</td>
<td>Public Health Service Standards for the Protection of Research Misconduct Whistleblowers</td>
<td>0940–AA01</td>
</tr>
<tr>
<td>938</td>
<td>Human Subjects Protection Regulations: Institutional Review Boards Registration Requirements</td>
<td>0940–AA06</td>
</tr>
<tr>
<td>939</td>
<td>Federal Policy for the Protection of Human Subjects Technical Amendment</td>
<td>0940–AA10</td>
</tr>
</tbody>
</table>

### Office of Public Health and Science—Long-Term Actions

<table>
<thead>
<tr>
<th>Sequence Number</th>
<th>Title</th>
<th>Regulation Identifier Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>940</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>

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

<table>
<thead>
<tr>
<th>Sequence Number</th>
<th>Title</th>
<th>Regulation Identifier Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>941</td>
<td>Home Health Agency (HHA) Conditions of Participation (CoPs) (CMS-3819-P)</td>
<td>0938–AG81</td>
</tr>
<tr>
<td>942</td>
<td>End Stage Renal Disease (ESRD) Conditions for Coverage (CMS-3818-P) (Section 610 Review)</td>
<td>0938–AG82</td>
</tr>
<tr>
<td>943</td>
<td>Hospital Conditions of Participation: Requirements for Approval and Reapproval of Transplant Centers To Perform Organ Transplants (CMS-3835-P)</td>
<td>0938–AH17</td>
</tr>
<tr>
<td>944</td>
<td>Hospice Care—Conditions of Participation (CMS-3844-P)</td>
<td>0938–AH27</td>
</tr>
<tr>
<td>945</td>
<td>Standard Unique National Health Plan Identifiers (CMS-6017-P)</td>
<td>0938–AH87</td>
</tr>
<tr>
<td>946</td>
<td>Appeals of Carrier Determination that a Supplier Fails to Meet the Requirements for Medicare Billing Privileges (CMS-6003-P2)</td>
<td>0938–AI49</td>
</tr>
<tr>
<td>947</td>
<td>Rural Health Clinics: Amendments to Participation Requirements and Payment Provisions and Establishment of a Quality Assessment and Improvement Program (CMS-1910-P2)</td>
<td>0938–AJ17</td>
</tr>
<tr>
<td>948</td>
<td>Supplier Standards for Home Oxygen, Therapeutic Shoes, and Home Nutrition Therapy (CMS-6010-P)</td>
<td>0938–AJ88</td>
</tr>
<tr>
<td>949</td>
<td>Health Insurance Reform: Claims Attachments Standards (CMS-0050-P)</td>
<td>0938–AK62</td>
</tr>
<tr>
<td>950</td>
<td>Organ Procurement Organization Conditions for Coverage (CMS-3064-P)</td>
<td>0938–AK81</td>
</tr>
<tr>
<td>951</td>
<td>Use of Restraint and Seclusion in Medicare and Medicaid Participating Facilities That Provide Inpatient or Residential Care (CMS-2130-P)</td>
<td>0938–AL26</td>
</tr>
</tbody>
</table>
## Centers for Medicare & Medicaid Services—Proposed Rule Stage (Continued)

<table>
<thead>
<tr>
<th>Sequence Number</th>
<th>Title</th>
<th>Regulation Identifier Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>952</td>
<td>Provider Reimbursement Determinations and Appeals (CMS-1727-P)</td>
<td>0938–AL54</td>
</tr>
<tr>
<td>953</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>954</td>
<td>Revisions to Conditions for Coverage for Ambulatory Surgical Centers (CMS-3887-P)</td>
<td>0938–AL80</td>
</tr>
<tr>
<td>955</td>
<td>Health Coverage Portability: Tolling Certain Time Periods and Interactions With Family and Medical Leave Act (CMS-2158-P)</td>
<td>0938–AL88</td>
</tr>
<tr>
<td>956</td>
<td>Modifications to Electronic Transactions and Code Sets (CMS-0009-P)</td>
<td>0938–AM50</td>
</tr>
<tr>
<td>957</td>
<td>Changes to the Hospital Outpatient Prospective System and Calendar Year 2005 Payment Rates (CMS-1427-P)</td>
<td>0938–AM75</td>
</tr>
<tr>
<td>958</td>
<td>Ticket to Work: Defining Individuals with Potentially Severe Disabilities and Providing a Work Threshold (CMS-2172-P)</td>
<td>0938–AM79</td>
</tr>
<tr>
<td>959</td>
<td>Payment Error Rate Measurement (PERM) Program (CMS-2186-P)</td>
<td>0938–AM86</td>
</tr>
<tr>
<td>960</td>
<td>Requirements for Long-Term Care Facilities: Hospice Services (CMS-3140-P)</td>
<td>0938–AM87</td>
</tr>
<tr>
<td>961</td>
<td>Hospital Conditions of Participation: Requirements For History and Physical Examinations; Authentication of Verbal Orders, Securing Medications and Post-Anesthesia Evaluations (CMS-3122-P)</td>
<td>0938–AM88</td>
</tr>
<tr>
<td>962</td>
<td>Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005 (CMS-1429-P)</td>
<td>0938–AM90</td>
</tr>
<tr>
<td>963</td>
<td>Revised Civil Money Penalties, Assessments, Exclusions, and Related Appeals Processes (CMS-3146-P)</td>
<td>0938–AM98</td>
</tr>
<tr>
<td>964</td>
<td>Physician Referral for Nuclear Medicine Services and Supplies (CMS-1261-P)</td>
<td>0938–AN04</td>
</tr>
<tr>
<td>965</td>
<td>Medicare Advantage Program Title II (CMS-4069-P)</td>
<td>0938–AN06</td>
</tr>
<tr>
<td>966</td>
<td>Special Rules for Employer-Sponsored Drug Programs: Subsidies to Encourage Retention (Title I) (CMS-2199-P)</td>
<td>0938–AN07</td>
</tr>
<tr>
<td>967</td>
<td>Medicare Drug Benefit Effective Calendar Year 2006 (Title I) (CMS-4068-P)</td>
<td>0938–AN08</td>
</tr>
<tr>
<td>968</td>
<td>Enhanced DSH Treatment for Certain Hospitals (CMS-1988-P)</td>
<td>0938–AN09</td>
</tr>
<tr>
<td>969</td>
<td>Prior Determination Process (CMS-6024-P)</td>
<td>0938–AN10</td>
</tr>
<tr>
<td>970</td>
<td>Competitive Acquisition for Certain Durable Medical Equipment (DME), Prosthetics, Orthotics, and Supplies (CMS-1270-P)</td>
<td>0938–AN14</td>
</tr>
<tr>
<td>971</td>
<td>Update of the List of Covered Procedures for Ambulatory Surgical Centers for 2005 (CMS-1478-P)</td>
<td>0938–AN23</td>
</tr>
<tr>
<td>972</td>
<td>Revisions to HIPAA Code Sets (CMS-0013-P)</td>
<td>0938–AN25</td>
</tr>
<tr>
<td>973</td>
<td>Payment for Clinical Laboratory Tests (CMS-1494-P)</td>
<td>0938–AN26</td>
</tr>
<tr>
<td>974</td>
<td>Prospective Payment System for Long Term Care Hospitals: Annual Payment Rate Updates and Policy Changes for 2006 (CMS-1483-P)</td>
<td>0938–AN28</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Sequence Number</th>
<th>Title</th>
<th>Regulation Identifier Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>975</td>
<td>Use of Restraint and Seclusion in Residential Treatment Facilities Providing Inpatient Psychiatric Services to Individuals Under Age 21 (CMS-2065-F)</td>
<td>0938–AJ96</td>
</tr>
<tr>
<td>976</td>
<td>Revisions to the Medicare Appeals Process (CMS-4004-FC)</td>
<td>0938–AL67</td>
</tr>
<tr>
<td>977</td>
<td>Electronic Medicare Claims Submission (CMS-0008-F)</td>
<td>0938–AM22</td>
</tr>
<tr>
<td>978</td>
<td>Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities—Update for FY 2005 (CMS-1249-N)</td>
<td>0938–AM46</td>
</tr>
<tr>
<td>979</td>
<td>Title I: Non-Federal Governmental Plans Exempt From HIPAA (CMS-2033-F)</td>
<td>0938–AM71</td>
</tr>
<tr>
<td>980</td>
<td>Revisions to the Appeals Process for Initial Claim Determinations (CMS-4064-FC)</td>
<td>0938–AM73</td>
</tr>
<tr>
<td>981</td>
<td>Conditions for Coverage of Power Mobility Devices, Including Powered Wheelchairs and Power-Operated Vehicles Scooter(CMS-3017-IFC)</td>
<td>0938–AM74</td>
</tr>
<tr>
<td>982</td>
<td>Hospice Wage Index FY 2005 (CMS-1264-N)</td>
<td>0938–AM78</td>
</tr>
<tr>
<td>983</td>
<td>Changes to the Hospital Inpatient Prospective Payment System and FY 2005 Rates (CMS-1428-F)</td>
<td>0938–AM80</td>
</tr>
<tr>
<td>984</td>
<td>Prospective Payment System for Inpatient Rehabilitation Facilities for FY 2005 (CMS-1360-N)</td>
<td>0938–AM82</td>
</tr>
<tr>
<td>985</td>
<td>Home Health Prospective Payment System Rate Update FY 2005 (CMS-1265-P)</td>
<td>0938–AM93</td>
</tr>
<tr>
<td>986</td>
<td>Changes to Medicare Payment for Drugs and Physician Fee Schedule Payments for Calendar Year 2004—Correction Notice CMS-1372-IFC)</td>
<td>0938–AM97</td>
</tr>
<tr>
<td>987</td>
<td>Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships: Extension of Partial Delay of Effective Date (CMS-1809-F5)</td>
<td>0938–AM99</td>
</tr>
<tr>
<td>988</td>
<td>Time Limitation on Record keeping Requirements Under the Drug Rebate Program (CMS-2188-P)</td>
<td>0938–AN01</td>
</tr>
<tr>
<td>989</td>
<td>Extended Availability of Unexpended SCHIP Funds From the Appropriation for FYs 1998 Through 2004; Authority To Use a Portion of SCHIP Funds for Medicaid Expenditures (CMS-2187-N)</td>
<td>0938–AN03</td>
</tr>
<tr>
<td>990</td>
<td>FY 2005 SCHIP Allotments (CMS-2201-N)</td>
<td>0938–AN11</td>
</tr>
<tr>
<td>991</td>
<td>Schedule for Publishing Medicare Final Regulations After a Proposed or Interim Final Regulation (CMS-9026-N)</td>
<td>0938–AN12</td>
</tr>
<tr>
<td>992</td>
<td>Evaluation Criteria and Standards for Quality Improvement Program Contracts (CMS-3142-NC)</td>
<td>0938–AN13</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 Identifier Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>993</td>
<td>Part A Premiums for Calendar Year 2005 for the Uninsured Aged and for Certain Disabled Individuals Who Have Exhausted Other Entitlement (CMS-8022-N)</td>
<td>0938–AN15</td>
</tr>
<tr>
<td>994</td>
<td>Inpatient Hospital Deductible and Hospital and Extended Care Services Coinsurance Amounts for Calendar Year 2005 (CMS-8021-N)</td>
<td>0938–AN16</td>
</tr>
<tr>
<td>995</td>
<td>Medicare Part B Monthly Actuarial Rates and Premium Rate Beginning January 1, 2005 (CMS-8020-N)</td>
<td>0938–AN18</td>
</tr>
<tr>
<td>996</td>
<td>Fee Schedule for Payment of Ambulance Services-Update for Calendar Year 2005 (CMS-1267-N)</td>
<td>0938–AN20</td>
</tr>
<tr>
<td>997</td>
<td>Procedure for Producing Guidance Documents Describing Medicare’s Coverage Process (CMS-3141-N)</td>
<td>0938–AN21</td>
</tr>
<tr>
<td>998</td>
<td>Amendment to the Interim Final Regulation for Mental Health Parity (CMS-2152-F2)</td>
<td>0938–AN22</td>
</tr>
<tr>
<td>999</td>
<td>Medicare Ambulance Fee Schedule Update (CMS-1492-IFC)</td>
<td>0938–AN24</td>
</tr>
<tr>
<td>1000</td>
<td>Medicare Secondary Payer (MSP): Workmen’s Compensation (CMS-1272-FC)</td>
<td>0938–AN27</td>
</tr>
<tr>
<td>1001</td>
<td>Random Prepayment Review (CMS-6022-IFC)</td>
<td>0938–AN31</td>
</tr>
<tr>
<td>1002</td>
<td>Additional Payments for Certain Medicare Part B Drugs (CMS-1280-FC)</td>
<td>0938–AN34</td>
</tr>
<tr>
<td>1004</td>
<td>Fire Safety Requirements for Certain Health Care Facilities, Amendment (CMS-3047-F2)</td>
<td>0938–AN36</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Sequence Number</th>
<th>Title</th>
<th>Regulation Identifier Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>1005</td>
<td>Requirements for Establishing and Maintaining Medicare Billing Privileges (CMS-6002-F)</td>
<td>0938–AH73</td>
</tr>
<tr>
<td>1006</td>
<td>Medicare Outcome and Assessment Information Set (OASIS) Data Reporting Requirements (CMS-3006-F)</td>
<td>0938–AJ10</td>
</tr>
<tr>
<td>1007</td>
<td>Hospital Conditions of Participation: Laboratory Services (CMS-3014-F)</td>
<td>0938–AJ29</td>
</tr>
<tr>
<td>1008</td>
<td>Medicare Hospice Care Amendments (CMS-1022-F)</td>
<td>0938–AJ36</td>
</tr>
<tr>
<td>1009</td>
<td>Physicians’ Referrals to Health Care Entities With Which They Have Financial Relationships—Phase II (CMS-1810-IFC)</td>
<td>0938–AK67</td>
</tr>
<tr>
<td>1010</td>
<td>Continuation of Medicare Entitlement When Disability Benefit Ends Because of Substantial Gainful Activity (CMS-4018-F)</td>
<td>0938–AK94</td>
</tr>
<tr>
<td>1011</td>
<td>Medicare Program: Interest Calculation (CMS-6014-F)</td>
<td>0938–AL14</td>
</tr>
<tr>
<td>1012</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>1013</td>
<td>Prospective Payment System for Inpatient Psychiatric Facilities FY 2004 (CMS-1213-F)</td>
<td>0938–AL50</td>
</tr>
<tr>
<td>1014</td>
<td>DMCER Service Areas and Related Matters (CMS-1219-F)</td>
<td>0938–AL76</td>
</tr>
<tr>
<td>1015</td>
<td>Procedures for Maintaining Code Lists in the Negotiated National Coverage Determinations for Clinical Diagnostic Laboratory Services (CMS-3119-F)</td>
<td>0938–AM36</td>
</tr>
<tr>
<td>1016</td>
<td>Hospital Patients’ Rights CoP—Standard Safety Compliance Committees (CMS-3120-P)</td>
<td>0938–AM39</td>
</tr>
<tr>
<td>1017</td>
<td>Requirements for Nursing Homes To Identify the Number of Licensed and Unlicensed Nurses (CMS-3121-F)</td>
<td>0938–AM55</td>
</tr>
<tr>
<td>1018</td>
<td>Covered Outpatient Drugs Under the Medicaid Drug Rebate Program (CMS-2174-P)</td>
<td>0938–AM81</td>
</tr>
<tr>
<td>1019</td>
<td>Revisions to Cost Sharing Regulations (CMS-2144-P)</td>
<td>0938–AM94</td>
</tr>
<tr>
<td>1020</td>
<td>Medicare Program; Hospital Outpatient Prospective Payment System Payment Reform for Calendar Year 2004 CMS-1371-IFC</td>
<td>0938–AM96</td>
</tr>
<tr>
<td>1021</td>
<td>Payment for Respiratory Assist Devices with Bi-level Capability and a Back-up Rate (CMS-1167-F)</td>
<td>0938–AN02</td>
</tr>
<tr>
<td>1022</td>
<td>Manufacturers’ Submission of Average Sales Price Data for Medicare Part B Drugs and Biologicals (CMS-1380-IFC)</td>
<td>0938–AN05</td>
</tr>
<tr>
<td>1023</td>
<td>Nondiscrimination In Post-Hospital Referral to Home Health Agencies and Other Entities (CMS-1224-F)</td>
<td>0938–AN19</td>
</tr>
<tr>
<td>1024</td>
<td>Nondiscrimination in Health Coverage and Bonafide Wellness Plans in the Group Market (CMS-2022-F)</td>
<td>0938–AN29</td>
</tr>
<tr>
<td>1025</td>
<td>Hospital Conditions of Participation: Patients’ Rights (CMS-3018-F)</td>
<td>0938–AN30</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Sequence Number</th>
<th>Title</th>
<th>Regulation Identifier Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>1026</td>
<td>Health Insurance Reform: Standard Unique Health Care Provider Identifier (CMS-0045-F)</td>
<td>0938–AH99</td>
</tr>
<tr>
<td>1027</td>
<td>Coverage of Religious Nonmedical Health Care Institutions (CMS-1909-F)</td>
<td>0938–AJ83</td>
</tr>
<tr>
<td>1028</td>
<td>All Provider Bad Debt Payment (CMS-1126-F)</td>
<td>0938–AK02</td>
</tr>
<tr>
<td>1029</td>
<td>Review of National Coverage Determinations and Local Coverage Determinations (CMS-3063-F)</td>
<td>0938–AK60</td>
</tr>
<tr>
<td>1030</td>
<td>Rate of Reimbursement of Photocopy Expenses for Quality Improvement Organizations (CMS-3055-F)</td>
<td>0938–AK68</td>
</tr>
</tbody>
</table>
### Centers for Medicare & Medicaid Services—Completed Actions (Continued)

<table>
<thead>
<tr>
<th>Sequence Number</th>
<th>Title</th>
<th>Regulation Identifier Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>1031</td>
<td>Elimination of Statement of Intent Procedures for Filing Medicare Claims (CMS-1185-F)</td>
<td>0938–AK79</td>
</tr>
<tr>
<td>1032</td>
<td>Permitting Premium Reductions as Additional Benefits Under Medicare+Choice Plans (CMS-6016-F)</td>
<td>0938–AL49</td>
</tr>
<tr>
<td>1033</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>1034</td>
<td>Criteria for Determining Whether a Drug is Considered Usually Self-Administered (CMS-1228-P)</td>
<td>0938–AM13</td>
</tr>
<tr>
<td>1035</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>1036</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>1037</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>1038</td>
<td>Grants to States for Operation of Qualified High Risk Pools (CMS-2179-FC)</td>
<td>0938–AM42</td>
</tr>
<tr>
<td>1039</td>
<td>Fee Schedule for Payment of Ambulance Services Update for Calendar Year 2004 (CMS-1232-FCC)</td>
<td>0938–AM44</td>
</tr>
<tr>
<td>1040</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>1041</td>
<td>Revised Civil Money Penalties, Assessments, Exclusions, and Related Appeals Procedures (CMS-6146-P)</td>
<td>0938–AM54</td>
</tr>
<tr>
<td>1042</td>
<td>Changes to the Criteria for Being Classified as an Inpatient Rehabilitation Facility (CMS-1262-F)</td>
<td>0938–AM72</td>
</tr>
<tr>
<td>1043</td>
<td>Prospective Payment System for Long-Term Care Hospitals: Annual Payment Rate Updates and Policy Changes Effective 7/1/04 (CMS-1263-F)</td>
<td>0938–AM84</td>
</tr>
<tr>
<td>1044</td>
<td>Disproportionate Share Hospital (DSH) Payments Institutions for Mental Disease (IMDs) (CMS-2062-N)</td>
<td>0938–AM89</td>
</tr>
<tr>
<td>1045</td>
<td>Physicians’ Referrals to Health Care Entities With Which They Have Financial Relationships: Extension of Partial Delay of Effective Date (CMS-1809-F4)</td>
<td>0938–AM95</td>
</tr>
<tr>
<td>1046</td>
<td>Notice of One-Time Appeal Process for Hospital Wage Index Classification (CMS-1373-N)</td>
<td>0938–AN00</td>
</tr>
</tbody>
</table>

### Administration for Children and Families—Proposed Rule Stage

<table>
<thead>
<tr>
<th>Sequence Number</th>
<th>Title</th>
<th>Regulation Identifier Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>1047</td>
<td>Safeguarding Child Support and Expanded Federal Parent Locator Services (FPLS) Information</td>
<td>0970–AC01</td>
</tr>
<tr>
<td>1048</td>
<td>Developmental Disabilities and Bill of Rights Act</td>
<td>0970–AC07</td>
</tr>
<tr>
<td>1049</td>
<td>Administrative Costs for Children in Title IV-E Foster Care</td>
<td>0970–AC14</td>
</tr>
<tr>
<td>1050</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 Identifier Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>1051</td>
<td>Child Support Enforcement Program; Federal Tax Refund Offset</td>
<td>0970–AC09</td>
</tr>
<tr>
<td>1052</td>
<td>Head Start Transportation</td>
<td>0970–AC16</td>
</tr>
</tbody>
</table>

### Administration for Children and Families—Completed Actions

<table>
<thead>
<tr>
<th>Sequence Number</th>
<th>Title</th>
<th>Regulation Identifier Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>1053</td>
<td>Child Support Enforcement for Indian Tribes</td>
<td>0970–AB73</td>
</tr>
<tr>
<td>1054</td>
<td>Charitable Choice Provisions Applicable to the Temporary Assistance for Needy Families Program</td>
<td>0970–AC12</td>
</tr>
<tr>
<td>1055</td>
<td>Community Services Block Grant Charitable Choice</td>
<td>0970–AC13</td>
</tr>
</tbody>
</table>
Department of Health and Human Services (HHS)
Office of the Secretary (OS)

813. 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

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:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>07/00/04</td>
<td></td>
</tr>
<tr>
<td>NPRM Comment Period End</td>
<td>09/00/04</td>
<td></td>
</tr>
<tr>
<td>Final Rule</td>
<td>11/00/04</td>
<td></td>
</tr>
</tbody>
</table>

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
Related RIN: Related to 0991-AB18
RIN: 0991-AB18

814. CLAIMS COLLECTION

Priority: Substantive, Nonsignificant
Legal Authority: 31 USC 3711; 31 CFR 900 to 904
CFR Citation: 45 CFR 30

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:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>07/00/04</td>
<td></td>
</tr>
<tr>
<td>NPRM Comment Period End</td>
<td>09/00/04</td>
<td></td>
</tr>
<tr>
<td>Final Rule</td>
<td>11/00/04</td>
<td></td>
</tr>
</tbody>
</table>

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

815. SALARY OFFSET

Priority: Substantive, Nonsignificant
Unfunded Mandates: Undetermined
Legal Authority: 5 USC 5514; 5 CFR 550
CFR Citation: 45 CFR 33

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

Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>07/00/04</td>
<td></td>
</tr>
<tr>
<td>NPRM Comment Period End</td>
<td>09/00/04</td>
<td></td>
</tr>
<tr>
<td>Final Rule</td>
<td>11/00/04</td>
<td></td>
</tr>
</tbody>
</table>

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-AB19
of 2003, this rule would revise the OIG’s exclusion authority to permit any Federal healthcare program to request a waiver of an OIG exclusion imposed under sections 1128(a)(1), (a)(3), or (a)(4) of the Social Security Act.

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANPRM</td>
<td>05/23/97</td>
<td>62 FR 28410</td>
</tr>
<tr>
<td>ANPRM Comment</td>
<td>06/09/97</td>
<td>64 FR 65304</td>
</tr>
<tr>
<td>Interim Final Rule</td>
<td>11/19/99</td>
<td>64 FR 63504</td>
</tr>
<tr>
<td>Final Rule</td>
<td>12/00/04</td>
<td>65 FR 76460</td>
</tr>
</tbody>
</table>

**Regulatory Flexibility Analysis**

**Required:** No

**Government Levels Affected:** None

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

**Related RIN:** Related to 0991–AB06

**RIN:** 0991–AA91

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

**Legal Authority:** PL 100–259, Civil Rights Restoration Act of 1987

**CFR Citation:** 45 CFR 80; 45 CFR 84; 45 CFR 86; 45 CFR 84; 45 CFR 90; 45 CFR 91

**Legal Deadline:** None

**Abstract:** This final rule amends 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.

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANPRM</td>
<td>09/25/02</td>
<td>67 FR 60202</td>
</tr>
<tr>
<td>ANPRM Comment</td>
<td>10/25/02</td>
<td>67 FR 78360</td>
</tr>
<tr>
<td>Period End</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Final Rule</td>
<td>04/00/05</td>
<td></td>
</tr>
</tbody>
</table>

**Regulatory Flexibility Analysis**

**Required:** No

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

**Small Entities Affected:** No

**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

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

**Priority:** Substantive, Nonsignificant

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

**CFR Citation:** 42 CFR 1001

**Legal Deadline:** None

**Abstract:** This final rule will expand the existing safe harbor for certain waivers of beneficiary coinsurance and deductible amounts to benefit the policyholders of Medicare SELECT supplemental insurance. Specifically, the amended safe harbor will protect waivers of coinsurance and deductible amounts under part A or part B of the Medicare program owed by beneficiaries covered by a Medicare SELECT policy issued in accordance with section 1882(t)(1) of the Social Security Act, if the waiver is in accordance with a price reduction agreement covering such policyholders between the Medicare SELECT issuer and the provider or supplier offering the waiver.
820. CLARIFICATION OF TERMS AND APPLICATION OF PROGRAM EXCLUSION AUTHORITY FOR SUBMITTING CLAIMS CONTAINING EXCESSIVE CHARGES

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1320a–7b; 42 USC 1395mm; 42 USC 1395w–27; 42 USC 1396d; 42 USC 1396u–2; 42 USC 1395d–5; 42 USC 1395f–5; 42 USC 1395w–50; 42 USC 1395w–55; 42 USC 1395w–56; 42 USC 1396a; 42 USC 1396b; 42 USC 1396c; 42 USC 1396d; 42 USC 1396f.

CFR Citation: 42 CFR 1003

Legal Deadline: None

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

Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>09/15/03</td>
<td>68 FR 53939</td>
</tr>
<tr>
<td>NPRM Comment</td>
<td>11/14/03</td>
<td></td>
</tr>
<tr>
<td>Period End</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Final Action</td>
<td>01/05/05</td>
<td></td>
</tr>
</tbody>
</table>

Regulatory Flexibility Analysis

Required: No

Government Levels Affected: None

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

RIN: 0991–AB23

821. TECHNICAL REVISIONS TO HIPDB DATA COLLECTION ACTIVITIES

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

Legal Authority: 42 USC 1320d–5; Sec 1128E(b)(2), Social Security Act

CFR Citation: 45 CFR 61

Legal Deadline: None

Abstract: This rule makes technical changes to the Healthcare Integrity and Protection Data Bank data collection reporting requirements by clarifying the types of personal numeric identifiers that may be reported to the data bank in connection with adverse actions. The rule classifies that in lieu of a Social Security Number (SSN), an individual taxpayer identification number (ITIN) may be reported to the data bank when, in those limited situations, an individual does not have a SSN.

Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interim Final Rule</td>
<td>10/00/04</td>
<td></td>
</tr>
<tr>
<td>Interim Final Rule</td>
<td>11/00/04</td>
<td></td>
</tr>
</tbody>
</table>

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–AB31

822. 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:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>To Be Determined</td>
<td></td>
</tr>
</tbody>
</table>

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–AB03

823. HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT—ENFORCEMENT

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

Legal Authority: Subtitle F of title II of PL 104–191; 42 USC 1320d–5

CFR Citation: Not Yet Determined

Legal Deadline: None

Abstract: This rulemaking would seek to establish a framework for enforcing compliance with the “administrative simplification” provisions of the Health Insurance Portability and Accountability Act (HIPAA) of 1996 — subtitle F of title II of Public Law 104–191, through the imposition of civil money penalties.
### HHS—OS

**Timetable:**

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>To Be Determined</td>
<td></td>
</tr>
</tbody>
</table>

**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** Businesses

**Government Levels Affected:** None

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

Phone: 202 690–1840

RIN: 0991–AB29

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

#### Office of the Secretary (OS)

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

**CFR Citation:** 45 CFR 31

**Completed:**

<table>
<thead>
<tr>
<th>Reason</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>Final Rule</td>
<td>12/18/03</td>
<td>68 FR 70444</td>
</tr>
</tbody>
</table>

**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** None

**Agency Contact:** Katherine M. Drews

Phone: 202 619–0150

RIN: 0991–AB17

#### 825. IMPLEMENTATION OF THE EQUAL ACCESS TO JUSTICE ACT IN AGENCY PROCEEDINGS

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

**CFR Citation:** 45 CFR 13

**Completed:**

<table>
<thead>
<tr>
<th>Reason</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>Final Rule</td>
<td>01/21/04</td>
<td>69 FR 2843</td>
</tr>
</tbody>
</table>

**Regulatory Flexibility Analysis Required:** Yes

**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–AB30

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

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

**Priority:** Substantive, Nonsignificant

**Legal Authority:** Sec 101, PL 108–173; Sec 1860D–31, Social Security Act

**CFR Citation:** 42 CFR 1003

---

**Abstract:** This rule sets forth the OIG's new authority for imposing civil money penalties against endorsed sponsors under the medicare prescription drug discount card program that knowingly engage in false or misleading marketing practices; overcharge program enrollees; or misuse transitional assistance funds.

---

**Regulatory Flexibility Analysis Required:** Yes

**Small Entities Affected:** Businesses

**Government Levels Affected:** State

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

**Agency Contact:** Paolo Del Vecchio, Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, Room 13–103, Parklawn, Rockville, MD 20857

Phone: 301 443–2619

RIN: 0930–AA10

---

**Regulatory Flexibility Analysis Required:** Yes

**Small Entities Affected:** Businesses

**Government Levels Affected:** State

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

**Agency Contact:** Paolo Del Vecchio, Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, Room 13–103, Parklawn, Rockville, MD 20857

Phone: 301 443–2619

RIN: 0930–AA10
Department of Health and Human Services (HHS)
Substance Abuse and Mental Health Services Administration (SAMHSA)

828. MANDATORY GUIDELINES FOR THE FEDERAL WORKPLACE DRUG TESTING PROGRAM

Priority: Other Significant
Legal Authority: PL 100–71; 5 USC 7301
CFR Citation: None

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

Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>Notice</td>
<td>04/13/04</td>
<td>69 FR 19673</td>
</tr>
<tr>
<td>Final Action</td>
<td>04/00/05</td>
<td></td>
</tr>
</tbody>
</table>

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

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

829. SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION (SAMHSA)
CHARITABLE CHOICE

Priority: Other Significant. Major status under 5 USC 801 is undetermined.
CFR Citation: 42 CFR 54, sec 54.1—13; 42 CFR 54a, sec 54a.1—14
Completed: None

Reason: Final Rule
Date: 09/30/03
FR Cite: 68 FR 56429

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
Phone: 301 443–2324
Fax: 301 443–0247
RIN: 0930-AA11

830. MANDATORY GUIDELINES FOR FEDERAL WORKPLACE DRUG TESTING PROGRAMS; SPECIMEN VALIDITY TESTING

Priority: Other Significant
Legal Authority: PL 100-71, sec 503
CFR Citation: None
Legal Deadline: None

Abstract: HHS is establishing standards for determining the validity of urine specimens collected under the Mandatory Guidelines for Federal Workplace Drug Testing Programs. These standards ensure that specimen validity testing (SVT) and reporting procedures are uniformly applied to all Federal agency urine specimens when a validity test is conducted.

Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>Notice</td>
<td>04/13/04</td>
<td>69 FR 19644</td>
</tr>
</tbody>
</table>

Regulatory Flexibility Analysis
Required: No

Small Entities Affected: Businesses

Government Levels Affected: Local, State

Agency Contact: Walter F. Vogel, CSAP, Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, CSAP, Suite 815, Rockville II, Rockville, MD 20857
Phone: 301 443–6014
RIN: 0930-AA13

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

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

Priority: Other Significant. Major status under 5 USC 801 is undetermined.
Legal Authority: 29 USC 651 et seq; 30 USC 4; 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:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>10/00/04</td>
<td></td>
</tr>
</tbody>
</table>

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
### 832. 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  
**CFR Citation:** 42 CFR 83

<table>
<thead>
<tr>
<th>Reason</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>Final Action</td>
<td>05/28/04</td>
<td>69 FR 30763</td>
</tr>
</tbody>
</table>

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

---

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

**Priority:** Other Significant. Major status under 5 USC 801 is undetermined.  
**Unfunded Mandates:** Undetermined  
**Legal Authority:** 42 USC 216; 42 USC 241; 42 USC 242a; 42 USC 262; 42 USC 263; 42 USC 263a to 263–n; 42 USC 264; 42 USC 300aa; 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 360b to 360j; 21 USC 361a; 21 USC 371; 21 USC 374; 21 USC 375; 21 USC 379e; 21 USC 381

**Legal Deadline:** None

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

**Timetable:**

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>03/14/03</td>
<td>68 FR 12406</td>
</tr>
<tr>
<td>NPRM Comment Period Extended</td>
<td>06/18/03</td>
<td></td>
</tr>
<tr>
<td>NPRM Comment Period End</td>
<td>07/14/03</td>
<td></td>
</tr>
<tr>
<td>NPRM Comment Period Extension End</td>
<td>10/14/03</td>
<td></td>
</tr>
<tr>
<td>Comment Review End</td>
<td>09/00/04</td>
<td></td>
</tr>
</tbody>
</table>

---

### 834. • FOOD LABELING; PROMINENCE OF CALORIES

**Priority:** Other Significant. Major status under 5 USC 801 is undetermined.  
**Unfunded Mandates:** Undetermined  
**Legal Authority:** 21 USC 321; 21 USC 343; 21 USC 371

**Legal Deadline:** None

**Abstract:** In response to the Report of the Working Group on Obesity (OWG) that FDA issued on March 12, 2004, the agency will issue an advance notice of proposed rulemaking (ANPRM) in its efforts to combat the nation's obesity problem. The ANPRM will request comments on ways to give more prominence to “calories” on the food label.

**Timetable:**

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANPRM</td>
<td>10/00/04</td>
<td></td>
</tr>
</tbody>
</table>

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

---

### 835. • FOOD LABELING; SERVING SIZES

**Priority:** Other Significant. Major status under 5 USC 801 is undetermined.  
**Unfunded Mandates:** Undetermined  
**Legal Authority:** 21 USC 321; 21 USC 343; 21 USC 371

**Legal Deadline:** None

**Abstract:** In response to the Report of the Working Group on Nutrition (OWG) that FDA issued on March 12, 2004, the agency will issue an advance notice of proposed rulemaking (ANPRM) in its efforts to combat the nation’s obesity problem. The ANPRM will request comments on changes to the agency’s labeling regulations on serving size and comments on allowance of truthful, nonmisleading and useful approaches for promoting consumption of smaller portion sizes.

**Timetable:**

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANPRM</td>
<td>10/00/04</td>
<td></td>
</tr>
</tbody>
</table>

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

---

### Department of Health and Human Services (HHS)  
Centers for Disease Control and Prevention (CDC)
Federalism: Undetermined
Agency Contact: Lori LeGault, Nutritionist, Department of Health and Human Services, Food and Drug Administration, HFS–840, 5100 Paint Branch Parkway, College Park, MD 20740
Phone: 301–436–1791
Fax: 301–436–2635
Email: ilegault@cfsan.fda.gov
RIN: 0910–AF23

836. • OVER–THE–COUNTER (OTC) DRUG REVIEW—SUNSCREEN PRODUCTS

Priority: Routine and Frequent
Legal Authority: 21 USC 321p; 21 USC 351 to 353; 21 USC 355; 21 USC 360a; 21 USC 371a; 21 USC 331; 21 USC 360; 21 USC 360b; 21 USC 361; 21 USC 371
CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358
Legal Deadline: None
Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e. final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed.

Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANPRM (Sunscreen and Insect Repellent)</td>
<td>11/00/04</td>
<td></td>
</tr>
<tr>
<td>NPRM (UVA/UVB)</td>
<td>11/00/04</td>
<td></td>
</tr>
</tbody>
</table>

Related RIN: Split from 0910–AA01
RIN: 0910–AF43

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

837. FOREIGN AND DOMESTIC ESTABLISHMENT REGISTRATION AND LISTING REQUIREMENTS FOR DRUGS AND BIOLOGICS

Priority: Other Significant
Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351; 21 USC 352; 21 USC 355; 21 USC 360; 21 USC 360b; 21 USC 371; 21 USC 374; 42 USC 262; 42 USC 264; 42 USC 271
Legal Deadline: None
Abstract: The proposed rule would amend FDA regulations on the registration of producers of drugs and the listing of drugs in commercial distribution. The proposed revisions would reorganize, consolidate, clarify, and modify current regulations concerning who must register establishments and list drugs 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:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>11/00/04</td>
<td></td>
</tr>
</tbody>
</table>

Regulatory Flexibility Analysis Required: Yes
Small Entities Affected: Businesses
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, 5515 Security Lane, Suite 1101 (HFD–7), Rockville, MD 20852
Phone: 301 594–2041
Fax: 301 827–5562
Email: mullerh@cder.fda.gov
RIN: 0910–AA49

838. 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 379e
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.

Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>07/00/04</td>
<td></td>
</tr>
</tbody>
</table>

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, 5515 Security Lane, Suite 1101 (HFD–7), Rockville, MD 20852
Phone: 301 594–2041
Fax: 301 827–5562
Email: pendletonb@cder.fda.gov
RIN: 0910–AB34
839. PREVENTION OF SALMONELLA ENTERITIDIS IN SHELL EGGS

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

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

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

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

**Legal Deadline:** None

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

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

In accordance with discussions at the public meetings, FDA intends to publish a proposed rule to require that shell eggs be produced under a plan that is designed to prevent transovarian SE from contaminating eggs at the farm during production.

FDA intends to discuss in its proposal certain provisions of the 1999 Food Code that are relevant to how eggs are handled, prepared, and served at certain retail establishments. In addition, the agency plans to consider whether it should require provisions for certain retail establishments that serve populations most at risk of egg-related illness (i.e., the elderly, children, and the immunocompromised).

**Timetable:**

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>09/00/04</td>
<td></td>
</tr>
</tbody>
</table>

**Regulatory Flexibility Analysis Required:** Yes

**Small Entities Affected:** Businesses

**Government Levels Affected:** Undetermined

**Federalism:** Undetermined

**Agency Contact:** Rebecca Buckner, Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, HFS–306, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, College Park, MD 20740

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

RIN: 0910–AC14

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

**Priority:** Other Significant

**Legal Authority:** 21 USC 321; 21 USC 351; 21 USC 352; 21 USC 353; 21 USC 354; 21 USC 355; 21 USC 356; 21 USC 360; 21 USC 360a; 21 USC 360b; 21 USC 360c; 21 USC 360d; 21 USC 360e; 21 USC 360f; 21 USC 360g; 21 USC 360h; 21 USC 360i; 21 USC 360j; 21 USC 371; 21 USC 381

**CFR Citation:** 21 CFR 50.23

**Legal Deadline:** None

**Abstract:** FDA is proposing an amendment to the exception from the general requirement for informed consent in certain circumstances involving the use of investigational in vitro diagnostic devices to identify chemical, biological, radiological, or nuclear agents in a potential terrorist event or other public health emergency.

**Timetable:**

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>12/00/04</td>
<td></td>
</tr>
</tbody>
</table>

**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** None

**Agency Contact:** Catherine Lorraine, Director, Policy Development and Coordination Group, Department of Health and Human Services, Food and Drug Administration, 14–101–11, 5600 Fishers Lane, Rockville, MD 20857

Phone: 301 827–3360
Fax: 301 827–6777
Email: joseph.sheehan@fda.hhs.gov

RIN: 0910–AC30

841. 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)).

**Timetable:**

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>12/00/04</td>
<td></td>
</tr>
</tbody>
</table>

**Regulatory Flexibility Analysis Required:** Undetermined

**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, HFZ–215, 1350 Piccard Drive, Rockville, MD 20850

Phone: 301 827–2974
Fax: 301 594–4765
Email: joseph.sheehan@fda.hhs.gov

RIN: 0910–AC25
842. FOOD STANDARDS: GENERAL PRINCIPLES AND FOOD STANDARDS MODERNIZATION

Priority: Other Significant

Legal Authority: 21 USC 321; 21 USC 336; 21 USC 341; 21 USC 343; 21 USC 371

CFR Citation: 21 CFR 130.5

Legal Deadline: None

Abstract: In 1995, the FDA and FSIS reviewed their regulatory procedures and requirements for food standards to determine whether any were still needed, and if so, which ones should be modified or streamlined. To request public comment to assist them in their review of the need for food standards, both agencies published advance notices of proposed rulemaking (ANPRMs) on food standards in December, 1995 (60 FR 47453 and 60 FR 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. 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.

Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANPRM</td>
<td>12/29/95</td>
<td>60 FR 67492</td>
</tr>
<tr>
<td>ANPRM Comment</td>
<td>04/29/96</td>
<td></td>
</tr>
<tr>
<td>Period End</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NPRM</td>
<td>09/00/04</td>
<td></td>
</tr>
</tbody>
</table>

843. POSITRON EMISSION TOMOGRAPHY DRUGS; CURRENT GOOD MANUFACTURING PRACTICES

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

Unfunded Mandates: Undetermined

Legal Authority: PL 105–115, sec 121

CFR Citation: 21 CFR 220


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

Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>01/00/05</td>
<td>FR Cite</td>
</tr>
</tbody>
</table>

844. REPORTING INFORMATION REGARDING FALSIFICATION OF DATA

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

Unfunded Mandates: Undetermined

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

CFR Citation: 21 CFR 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:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>02/00/05</td>
<td></td>
</tr>
</tbody>
</table>

Regulatory Flexibility Analysis

Required: Undetermined

Government Levels Affected: None

Agency Contact: Brian L. Pendleton, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Suite 3037 (HFD–7), Center for Drug Evaluation and Research, 5515 Security Lane, Suite 1101 (HFD–7), Rockville, MD 20852 Phone: 301 594–2041 Fax: 301 827–5562 Email: pendletonb@cder.fda.gov

Related RIN: Previously reported as 0910–AC63

RIN: 0910–AC55

RIN: 0910–AC59
845. DEFINITION OF “SERIOUS ADVERSE HEALTH CONSEQUENCES” UNDER THE PUBLIC HEALTH SECURITY AND BIOTERRORISM PREPAREDNESS AND RESPONSE ACT OF 2002

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

Legal Authority: 21 USC 334(h)(1)(A); 21 USC 335a(b)(3); 21 USC 343(v); 21 USC 350c(a) and (b); 21 USC 371; 21 USC 374(a)(1); 21 USC 381(j)(1) and (m)(2)(B)(ii); 21 USC 398(a)

CFR Citation: 21 CFR 1.3(c)

Legal Deadline: None

Abstract: The proposed rule would define the term “serious adverse health consequences” for purposes of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) and any implementing regulations. The term is used to describe part of the standard that is the basis for FDA to exercise certain authorities provided in sections 303, 304, 306, 307, 308, and 310 of title III (Protecting Safety and Security of the Food and Drug Supply), subtitle A (Protection of Food Supply), of the Bioterrorism Act.

Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>07/00/04</td>
<td></td>
</tr>
</tbody>
</table>

Regulatory Flexibility Analysis

Required: Undetermined

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Ms. Karen Carson, Deputy Director, Office of Plant and Dairy Foods and Beverages, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, Rm 3 A-001, College Park, MD 20740
Phone: 301 436–1664
Fax: 301 436–2632
Email: karen.carson@cfsan.fda.gov

John E. Kvenberg, Deputy Director, Office of Compliance (HFS–600), Department of Health and Human Services, Food and Drug Administration, HFS–10, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, Rm 3B064, College Park, MD 20740
Phone: 301 436–5359
Fax: 301 436–2717
Email: john.kvenberg@cfsan.fda.gov

846. HEALTH CLAIMS

Priority: Other Significant

Unfunded Mandates: Undetermined

Legal Authority: 21 USC 343; 21 USC 371

CFR Citation: Not Yet Determined

Legal Deadline: None

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

Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANPRM</td>
<td>11/25/03</td>
<td>68 FR 66040</td>
</tr>
<tr>
<td>ANPRM Comment Period Extended</td>
<td>01/27/04</td>
<td>69 FR 3868</td>
</tr>
<tr>
<td>ANPRM Comment Period End</td>
<td>02/25/04</td>
<td></td>
</tr>
<tr>
<td>NPRM</td>
<td>01/00/05</td>
<td></td>
</tr>
</tbody>
</table>

Regulatory Flexibility Analysis

Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Federalism: Undetermined

Agency Contact: Nancy Crane, Department of Health and Human Services, Food and Drug Administration, HFS–830, 5100 Paint Branch Parkway, Rm 3, College Park, MD 20740
Phone: 301 436–2632
Fax: 301 436–2636
Email: nancy.crane@cfsan.fda.gov

RIN: 0910–AF09

847. 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; 21 USC 343; 21 USC 343–1; 21 USC 348; 21 USC 349; 21 USC 371; 21 USC 379e

CFR Citation: 21 CFR 165.110(b)


Abstract: Under section 410 of the Federal Food, Drug, and Cosmetic Act (the Act), not later than 180 days before the effective date of a National Primary Drinking Water Regulation (NPDRW) issued by the Environmental Protection Agency (EPA) for a contaminant under section 1412 of the Safe Drinking Water Act, the Food and Drug Administration (FDA) is required to issue a standard of quality regulation for that contaminant in bottled water or make a finding that such a regulation is not necessary to protect the public health because the contaminant is contained in water in public water systems but not in water used for bottled water. The effective date for any such standard of quality regulation is to be the same as the effective date of the NPDRW. On January 22, 2001, EPA published a final rule revising the existing 0.05 mg/L maximum contaminant level (MCL) for arsenic in public drinking water to 0.01 mg/L (10 ppb). The effective date for this rule was temporarily delayed for 60 days from March 23, 2001, to a new effective date of May 22, 2001, in accordance with the memorandum of January 20, 2001, from the Assistant to the President and Chief of Staff, entitled “Regulatory Review Plan” (66 FR 7701; January 24, 2001). On May 22, 2001, EPA announced that it would further delay the effective date for the rule until February 22, 2002, to allow time to complete a reassessment of the information on which the revised arsenic standard is based. On February 22, 2002, the arsenic MCL of 0.01 mg/L in public drinking water rule became effective and water systems must comply with the new standard for arsenic in public drinking water by January 23, 2006. In accordance with section 410 of the Act, FDA is required to issue a standard of quality regulation for arsenic in bottled drinking water by July 27, 2005, with an effective date of January 23, 2006, or make a finding
that such a regulation is not necessary to protect the public health.

**Timetable:**

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>10/00/04</td>
<td></td>
</tr>
<tr>
<td>NPRM Comment</td>
<td>12/00/04</td>
<td></td>
</tr>
</tbody>
</table>

**Regulatory Flexibility Analysis**

- **Required:** Undetermined
- **Small Entities Affected:** Businesses
- **Government Levels Affected:** Undetermined
- **Federalism:** Undetermined
- **Agency Contact:** Christine F. Rogers, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Suite 3059 (HFD-7), Center for Drug Evaluation and Research, 5515 Security Lane, Suite 1101 (HFD-7), Rockville, MD 20852
  - Phone: 301 594–2041
  - Fax: 301 827–5562
  - RIN: 0910–AF11

**849. COCHINEAL EXTRACT AND CARMINE LABEL DECLARATION**

- **Priority:** Other Significant. Major status under 5 USC 801 is undetermined.
- **Legal Authority:** 21 USC 379(e)(b)
- **CFR Citation:** 21 CFR 73.100 (d); 21 CFR 73.1100 (c); 21 CFR 73.2087 (c); 21 CFR 101.22 (k); 21 CFR 701.3; 21 CFR 740.20
- **Legal Deadline:** None

**Abstract:** The purpose of this proposed rule is to protect consumers who have allergies to the color additives carmine and cochineal extract by requiring label declaration on products under FDA jurisdiction. This action responds to adverse event reports received by FDA and to a citizen petition submitted to FDA.

**Timetable:**

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>12/00/04</td>
<td></td>
</tr>
</tbody>
</table>

**850. CHARGING FOR INVESTIGATIONAL DRUGS**

- **Priority:** Substantive, Nonsignificant. Major status under 5 USC 801 is undetermined.
- **Legal Authority:** 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 371; 42 USC 262
- **CFR Citation:** 21 CFR 312.7; 21 CFR 312.8
- **Legal Deadline:** None

**Abstract:** The proposed rule would amend FDA’s investigational new drug exemption regulations concerning charging for investigational drugs. The proposed rule describes the types of investigational uses for which a sponsor may be able to charge, including uses for which charging was not previously expressly permitted, and the criteria for allowing charging for the identified investigational uses. The proposed rule would also describe the types of costs that can be recovered when charging for an investigational drug.

**Timetable:**

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>09/00/04</td>
<td></td>
</tr>
</tbody>
</table>

**851. TREATMENT USE OF INVESTIGATIONAL DRUGS**

- **Priority:** Substantive, Nonsignificant. Major status under 5 USC 801 is undetermined.
- **Legal Authority:** 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 371; 42 USC 262
- **CFR Citation:** 21 CFR 312.40; 21 CFR 312.42; 21 CFR 312.400; 21 CFR 312.425; 21 CFR 312.410; 21 CFR 312.415; 21 CFR
Abstract: The proposed rule would amend FDA regulations governing investigational new drug exemptions (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.

Timetable:

### Action | Date | FR Cite
--- | --- | ---
NPRM | 12/00/04 | |
Standard of Potency.” The vaccines had been licensed by the National Institutes of Health prior to 1972, when regulatory authority over these vaccines was transferred to FDA. The regulation prohibits the use of Group A streptococcus organisms and derivatives of Group A streptococcus as ingredients in Bacterial Vaccines and Bacterial Antigens with “No U.S. Standard of Potency.” The regulation was never intended to refer to purified streptococcus vaccines, which were not developed at that time. Therefore, the regulation is being revoked.

Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM – Companion to Direct Final Rule</td>
<td>04/00/05</td>
<td></td>
</tr>
<tr>
<td>Direct Final Rule</td>
<td>04/00/05</td>
<td></td>
</tr>
</tbody>
</table>

Regulatory Flexibility Analysis Required: No
Small Entities Affected: No
Government Levels Affected: None
Agency Contact: Valerie Butler, Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, Suite 200N (HFM–17), 1401 Rockville Pike, Rockville, MD 20852
Phone: 301 827–6210
Fax: 301 827–9434
Email: joseph.sheehan@fda.hhs.gov
RIN: 0910–AF21

856. • BLOOD INITIATIVE—REGULATIONS FOR HUMAN BLOOD AND BLOOD COMPONENTS INTENDED FOR TRANSFUSION OR FOR FURTHER MANUFACTURING USE

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; …
CFR Citation: 21 CFR 600; 21 CFR 601; 21 CFR 606; 21 CFR 607; 21 CFR 610; …
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 Subcommittee on House Resources and Intergovernmental Relations, the General Accounting Office, and the Institute of Medicine, as well as on public comments. The other remaining subject intended to be addressed in the rulemakings include labeling of blood and blood components (0910-AF26). These actions are intended to help ensure the continued safety of the Nation’s blood supply.

Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>06/00/05</td>
<td></td>
</tr>
</tbody>
</table>

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 20852–1448
Phone: 301 827–6210
Fax: 301 827–9434
Related RIN: Split from 0910–AB26
RIN: 0910–AF25

857. • OVER-THE-COUNTER (OTC) DRUG REVIEW—COUGH/COLD (BRONCHODILATOR) PRODUCTS

Priority: Routine and Frequent
Legal Authority: 21 USC 321p; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 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 358
Legal Deadline: None
Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e. final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed.

Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM (Amendment)</td>
<td>09/00/04</td>
<td></td>
</tr>
</tbody>
</table>
858. • OVER-THE-COUNTER (OTC) DRUG REVIEW—COUGH/COLD (COMBINATION) PRODUCTS

Priority: Routine and Frequent

Legal Authority: 21 USC 321p; 21 USC 351 to 353; 21 USC 355; 21 USC 360a; 21 USC 371a; 21 USC 331; 21 USC 360; 21 USC 360b; 21 USC 361; 21 USC 371

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

Legal Deadline: None

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

Timetable:

Action Date FR Cite
NPRM (Phenytoin) 09/00/04
NPRM (Propoxyphene) 09/00/04

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

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

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

860. • OVER-THE-COUNTER (OTC) DRUG REVIEW—INTERNAL ANALGESIC PRODUCTS

Priority: Routine and Frequent

Legal Authority: 21 USC 321p; 21 USC 351 to 353; 21 USC 355; 21 USC 360a; 21 USC 371a; 21 USC 331; 21 USC 360; 21 USC 360b; 21 USC 361; 21 USC 371

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

Legal Deadline: None

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

Timetable:

Action Date FR Cite
NPRM (Amendment) 08/00/04

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: None

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

Related RIN: Split from 0910–AA01
RIN: 0910–AF36
862. OVER-THE-COUNTER (OTC) DRUG REVIEW—WEIGHT CONTROL PRODUCTS

Priority: Routine and Frequent
Legal Authority: 21 USC 321p; 21 USC 351 to 353; 21 USC 360a; 21 USC 371a; 21 USC 331; 21 USC 360b; 21 USC 360b; 21 USC 361; 21 USC 371
CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358
Legal Deadline: None

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

863. 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.
establishments to follow current good tissue-based products (HCT/P) human cell, tissue, and cellular and Administration (FDA) is requiring Abstract:

CFR Citation: 243; 42 USC 263a; 42 USC 264; 42 USC 865. CURRENT GOOD TISSUE, AND CELLULAR AND PRACTICE FOR HUMAN CELL,組織 and Research, 5515 Security Lane, HHS—FDA Final Rule Stage

Regulatory Flexibility Analysis Required: Yes
Small Entities Affected: Businesses Government Levels Affected: Undetermined
Federalism: Undetermined
Agency Contact: Audrey Thomas, Regulatory Policy Analyst, Office of Regulatory Policy, Department of Health and Human Services, Food and Drug Administration, Suite 1101 (HFD–7), Rockville, MD 20852
Phone: 301 827–6241
Fax: 301 827–9434
RIN: 0910–AB28

865. CURRENT GOOD TISSUE PRACTICE FOR HUMAN CELL, TISSUE, AND CELLULAR AND TISSUE–BASED PRODUCT 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 requiring human cell, tissue, and cellular and tissue-based products (HCT/P) establishments to follow current good tissue practice (CGTP), which governs the methods used in, and the facilities and controls used for, the manufacture of HCT/Ps, recordkeeping, and the establishment of a quality program. FDA is also issuing regulations pertaining to labeling, reporting, inspections, and enforcement. 

Timetable:

Action Date FR Cite
NPRM 12/22/00 65 FR 81082
NPRM Comment 03/22/01
Period End
NPRM Comment 03/30/01
Period Reopened
NPRM Comment 06/22/01
Period Reopening
End
Final Action 10/00/04

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

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 20852–1448
Phone: 301 827–6210
Fax: 301 827–9434
RIN: 0910–AB28


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 263a; 42 USC 264

CFR Citation: 21 CFR 606; 21 CFR 610

Legal Deadline: None

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

Timetable:

Action Date FR Cite
NPRM 01/08/01 66 FR 1508
NPRM Comment 05/08/01
Period End
Final Action 12/00/04

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

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 20852–1448
Phone: 301 827–6210
Fax: 301 827–9434
RIN: 0910–AB28

Related RIN: Related to 0910–AB26
RIN: 0910–AB76

867. CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKING, OR HOLDING DIETARY INGREDIENTS AND DIETARY SUPPLEMENTS Priority: Economically Significant. Major under 5 USC 801.

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

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

CFR Citation: 21 CFR 111

Legal Deadline: None

Abstract: The Food and Drug Administration proposed in the Federal Register of March 13, 2003 (68 FR
868. 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 360e; 21 USC 360h to 360j; 21 USC 371; 21 USC 379e; 21 USC 381; 41 USC 216; 41 USC 241; 41 USC 262; 41 USC 263b to 263n

CFR Citation: 21 CFR 50; 21 CFR 56


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

Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>02/06/97</td>
<td>62 FR 5700</td>
</tr>
<tr>
<td>ANPRM Comment</td>
<td>06/06/97</td>
<td></td>
</tr>
<tr>
<td>NPRM Comment</td>
<td>03/13/03</td>
<td>68 FR 12157</td>
</tr>
<tr>
<td>Period End</td>
<td>08/11/03</td>
<td></td>
</tr>
<tr>
<td>Final Action</td>
<td>11/00/04</td>
<td></td>
</tr>
</tbody>
</table>

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Carol Drew, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Suite 3037 (HFD–7), Center for Drug Evaluation and Research, 5515 Security Lane, Suite 1101 (HFD–7), Rockville, MD 20852

Phone: 301 827–2974

Fax: 301 594–4765

Email: joseph.sheehan@fda.hhs.gov

RIN: 0910–AC07

869. MEDICAL DEVICES; PATIENT EXAMINATION AND SURGEONS' GLOVES; ADULTERATION

Priority: Substantive, Nonsignificant

Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351; 21 USC 352; 21 USC 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.

Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>Final Action</td>
<td>12/00/04</td>
<td></td>
</tr>
</tbody>
</table>

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, HFZ–215, 1350 Piccard Drive, Rockville, MD 20850

Phone: 301 827–2974

Fax: 301 594–4765

Email: joseph.sheehan@fda.hhs.gov

RIN: 0910–AC32

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

Priority: Substantive, Nonsignificant

Legal Authority: 21 USC 351; 21 USC 352; 21 USC 360e to 360j; 21 USC 360h to 360ss; 21 USC 371; 21 USC 381

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

Legal Deadline: None

Abstract: This rule amends the performance standard for diagnostic x-ray systems and their components in 21 CFR 1020.30, 1020.31, 1020.32, and 1020.33 to address the changes in technology and practice.
death to humans or animals. Specific serious adverse health consequences or be those that are needed by FDA in packaging. The required records would identify the immediate previous establishment and maintenance of records, for not longer than two years, for not longer than two years, but would allow the Secretary to identify the immediate previous sources and the immediate subsequent recipients of food, including its packaging. The required records would be those that are needed by FDA in order to address credible threats of serious adverse health consequences or death to humans or animals. Specific covered entities are those that manufacture, process, pack, transport, distribute, receive, hold, or import food. Farms and restaurants are excluded. The Secretary is directed to take into account the size of a business in promulgating these regulations. Section 306 of the Act also added section 414(a) and amended section 704(a) of FFDCA to permit FDA to inspect these records and other information if the Secretary has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals.

### Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>12/10/02</td>
<td>67 FR 76056</td>
</tr>
<tr>
<td>Final Action</td>
<td>06/00/04</td>
<td></td>
</tr>
</tbody>
</table>

### Regulatory Flexibility Analysis

**Required:** Yes

**Small Entities Affected:** Businesses

**Government Levels Affected:** None

**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, HFZ–215, 1350 Piccard Drive, Rockville, MD 20850

Phone: 301 827–2974
Fax: 301 594–4765
Email: joseph.sheehan@fda.hhs.gov

RIN: 0910–AC34

---

**871. ESTABLISHMENT AND MAINTENANCE OF RECORDS PURSUANT TO THE PUBLIC HEALTH SECURITY AND BIOTERRORISM PREPAREDNESS AND RESPONSE ACT OF 2002**

**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 306

**CFR Citation:** 21 CFR 1

**Legal Deadline:** None

**Abstract:** This rulemaking is one of a number of actions being taken to improve FDA’s ability to respond to threats of bioterrorism. Section 414(b) of the Federal Food, Drug and Cosmetic Act (FFDCA), which was added by section 306 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), directs the Secretary to require facilities engaged in manufacturing, processing, packing, or holding of food for consumption in the United States to be registered with the Secretary. Section 415 directs the Secretary, 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 must include the name and address of each facility at which, and all trade names under which, the registrant conducts business. If the Secretary determines it is necessary through guidance, the registration must include the general food category (as identified under 21 CFR 170.3) of foods manufactured, processed, packed, or held at the facility. The registrant is required to notify the Secretary of changes to the information contained in the registration in a timely manner. Under the interim final rule (IFR) published on October 10, 2003 (68 FR 58894), upon receipt of the completed registration form, FDA will notify the registrant of receipt of the registration and assign a unique registration number to the facility. Section 415 requires the Secretary to compile and maintain an up-to-date list of registered facilities. This list and any registration documents submitted to the Secretary are not subject to disclosure under the Freedom of Information Act. For purposes of section 415, “facility” includes any factory, warehouse, or establishment engaged in the manufacturing, processing, packing, or holding of food. Exempt from the registration requirement are farms, restaurants, other retail food.

**URL For More Information:** www.fda.gov/ohrms/dockets/02n0277/02n0277.htm

**Agency Contact:** Nega Beru, Supervisory Chemist, Office of Plant, Dairy Foods and Beverages, Department of Health and Human Services, Food and Drug Administration, HFS–305, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, College Park, MD 20740

Phone: 301 436–1400
Fax: 301 436–2651
Email: nberu@fcsan.fda.gov

RIN: 0910–AC39

---

**872. 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

**Legal Deadline:** Final, Statutory, December 12, 2003.

**Abstract:** 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.

By the authority of the Act, director the Secretary to require facilities engaged in the manufacturing, processing, packing, or holding of food for consumption in the United States to be registered with the Secretary. The Act allows for registration of foreign facilities subject to the same requirements as domestic facilities. The Secretary is required to notify the Secretary of any changes to the information contained in the registration in a timely manner. Under the interim final rule (IFR) published on October 10, 2003 (68 FR 58894), upon receipt of the completed registration form, FDA will notify the registrant of receipt of the registration and assign a unique registration number to the facility. Section 415 requires the Secretary to compile and maintain an up-to-date list of registered facilities. This list and any registration documents submitted to the Secretary are not subject to disclosure under the Freedom of Information Act. For purposes of section 415, “facility” includes any factory, warehouse, or establishment engaged in the manufacturing, processing, packing, or holding of food. Exempt from 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. On April 14, 2004, FDA issued a notice reopening for 30 days, on a limited range of issues, the comment period on the IFR. FDA took this action consistent with its statement in the IFR that it would reopen the comment period for 30 days in order to ensure that those commenting on the IFR have had the benefit of FDA’s outreach and educational efforts and have had experience with the systems, timeframes, and data elements of the registration system.

Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>02/03/03</td>
<td>68 FR 5377</td>
</tr>
<tr>
<td>Interim Final Rule</td>
<td>10/10/03</td>
<td>68 FR 58894</td>
</tr>
<tr>
<td>Reopened</td>
<td>04/14/04</td>
<td>69 FR 19766</td>
</tr>
<tr>
<td>Interim Final Rule</td>
<td>05/14/04</td>
<td>69 FR 19766</td>
</tr>
<tr>
<td>Reopened End</td>
<td>03/00/05</td>
<td></td>
</tr>
</tbody>
</table>

Regulatory Flexibility Analysis

Required: Yes

Small Entities Affected: Businesses

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

873. PRIOR NOTICE OF IMPORTED FOOD UNDER THE PUBLIC HEALTH SECURITY AND BIOTERRORISM 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


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:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>02/03/03</td>
<td>68 FR 5377</td>
</tr>
<tr>
<td>Interim Final Rule</td>
<td>10/10/03</td>
<td>68 FR 58974</td>
</tr>
</tbody>
</table>

874. 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 anyone 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.

Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>08/25/00</td>
<td>65 FR 51782</td>
</tr>
<tr>
<td>Final Action</td>
<td>08/00/04</td>
<td></td>
</tr>
</tbody>
</table>

Regulatory Flexibility Analysis

Required: No

Government Levels Affected: None

Federalism: Undetermined

Agency Contact: Gail Schmerfeld, Special Assistant, Department of Health
875. 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

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

CFR Citation: 21 CFR 312.120

Legal Deadline: None

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

Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>06/10/04</td>
<td>69 FR 32467</td>
</tr>
<tr>
<td>Final Action</td>
<td>06/00/05</td>
<td></td>
</tr>
</tbody>
</table>

Agency Contact: Brian L. Pendleton, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Suite 3037 (HFD–7), Center for Drug Evaluation and Research, 5515 Security Lane, Suite 1101 (HFD–7), Rockville, MD 20852

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

RIN: 0910–AF15

876. • BLOOD INITIATIVE—REVISIONS TO LABELING AND STORAGE REQUIREMENTS FOR BLOOD AND BLOOD COMPONENTS, INCLUDING SOURCE PLASMA

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

Legal Authority: 21 USC 321; 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; ...

CFR Citation: 21 CFR 606; 21 CFR 601; 21 CFR 606; 21 CFR 607; 21 CFR 610; ...

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 Subcommittee on House Resources and Intergovernmental Relations, the General Accounting Office, and the Institute of Medicine, as well as on public comments. The other remaining subject intended to be addressed in the rulemakings include: donor eligibility requirements (0910–AF25). These actions are intended to help ensure the continued safety of the Nation’s blood supply.

Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>Final Action</td>
<td>06/00/05</td>
<td></td>
</tr>
</tbody>
</table>

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Sharon Carayiannis, Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, Suite 4000 (HFM–17), Center for Biologics Evaluation and Research, 1401 Rockville Pike, Rockville, MD 20852–1448

Phone: 301 827–6210

Related RIN: Split from 0910–AB26

RIN: 0910–AF26

877. • OVER–THE–COUNTER (OTC) DRUG REVIEW—ANTIPERSPIRANT PRODUCTS

Priority: Routine and Frequent

Legal Authority: 21 USC 321p; 21 USC 351 to 353; 21 USC 355; 21 USC 360a; 21 USC 371a; 21 USC 331; 21 USC 360; 21 USC 360b; 21 USC 361; 21 USC 371

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

Legal Deadline: None

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

Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>Final Action</td>
<td>09/00/04</td>
<td></td>
</tr>
</tbody>
</table>

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Gerald M. Rachanow, Regulatory Counsel, Division of Over–the–Counter Drug Products, Department of Health and Human Services, Food and Drug Administration, 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

Related RIN: Split from 0910–AA01

RIN: 0910–AF30
878. • OVER–THE–COUNTER (OTC) DRUG REVIEW—COUGH/COLD (ANTIHISTAMINE) PRODUCTS

Priority: Routine and Frequent
Legal Authority: 21 USC 321p; 21 USC 351 to 353; 21 USC 355; 21 USC 360a; 21USC 371a; 21 USC 331; 21 USC 360; 21 USC 360b; 21 USC 361; 21 USC 371
CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358

Legal Deadline: None

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

Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>Final Action</td>
<td>11/00/04</td>
<td></td>
</tr>
<tr>
<td>(Amendment) (Common Cold)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Gerald M. Rachanow, Regulatory Counsel, Division of Over–the–Counter Drug Products, Department of Health and Human Services, Food and Drug Administration, 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

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

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

Priority: Routine and Frequent
Legal Authority: 21 USC 321p; 21 USC 351 to 353; 21 USC 355; 21 USC 360a; 21USC 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 358

Legal Deadline: None

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

Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>Final Action</td>
<td>11/00/04</td>
<td></td>
</tr>
<tr>
<td>(Amendments) (Warnings)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Gerald M. Rachanow, Regulatory Counsel, Division of Over–the–Counter Drug Products, Department of Health and Human Services, Food and Drug Administration, 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

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

879. • OVER–THE–COUNTER (OTC) DRUG REVIEW—OPHTHALMIC PRODUCTS

Priority: Routine and Frequent
Legal Authority: 21 USC 321p; 21 USC 351 to 353; 21 USC 355; 21 USC 360a; 21USC 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 358

Legal Deadline: None

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

Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>Final Action</td>
<td>11/00/04</td>
<td></td>
</tr>
<tr>
<td>(Amendments)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Gerald M. Rachanow, Regulatory Counsel, Division of Over–the–Counter Drug Products, Department of Health and Human Services, Food and Drug Administration, 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

Related RIN: Split from 0910–AA01
RIN: 0910–AF44
882. 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 335b; 21 USC 335c; 21 USC 341 to 344; 21 USC 348; 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 426; 42 USC 264
CFR Citation: 21 CFR 59
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 proposal 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 sampling service or 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.

Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>04/29/04</td>
<td>69 FR 23460</td>
</tr>
<tr>
<td>Final Action</td>
<td>To Be Determined</td>
<td></td>
</tr>
</tbody>
</table>

Regulatory Flexibility Analysis
Required: Undetermined
Government Levels Affected: Undetermined
Agency Contact: Philip L. Chao, Senior Policy Analyst, Department of Health and Human Services, Food and Drug Administration, Room 15–61 (HF–23), Office of Policy and Planning, 5600 Fishers Lane, Rockville, MD 20857 Phone: 301 827–0587 Fax: 301 827–4774 Email: pchao@oc.fda.gov
RIN: 0910–AB96

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

Priority: Other Significant
Legal Authority: 42 USC 264; 21 USC 301 et seq
CFR Citation: Not Yet Determined
Legal Deadline: None
Abstract: The Food and Drug Administration (FDA) is proposing to prohibit the use of cervids (deer, elk) for food, including dietary supplements, and cosmetics if the cervids have been exposed to chronic wasting disease (CWD). FDA is proposing this regulation because of potential risks to health.

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

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

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

Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>01/00/06</td>
<td></td>
</tr>
</tbody>
</table>

Regulatory Flexibility Analysis
Required: Yes
Small Entities Affected: Businesses

884. 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 356a to 356c; 21 USC 371; 21 USC 374; 21 USC 379
CFR Citation: 21 CFR 314.94(a)(7); 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.

Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>10/29/03</td>
<td>68 FR 61640</td>
</tr>
<tr>
<td>Next Action</td>
<td>Undetermined</td>
<td></td>
</tr>
</tbody>
</table>

Regulatory Flexibility Analysis
Required: Yes
Small Entities Affected: Businesses
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, 5515 Security Lane, Suite 1101 (HFD–7), Rockville, MD 20857
Phone: 301 594–2041
Fax: 301 827–5562

RIN: 0910–AC23

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

Priority: Other Significant

Legal Authority: 21 USC 355b

CFR Citation: 21 CFR 201; 21 CFR 208; 21 CFR 209


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

Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>04/22/04</td>
<td>69 FR 21778</td>
</tr>
<tr>
<td>Final Action</td>
<td>To Be Determined</td>
<td></td>
</tr>
</tbody>
</table>

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Carol Drew, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Suite 3037 (HFD–7), Center for Drug Evaluation and Research, 5515 Security Lane, Suite 1101 (HFD–7), Rockville, MD 20852
Phone: 301 594–2041
Fax: 301 827–5562

RIN: 0910–AC35

886. FOOD LABELING: TRANS FATTY ACIDS IN NUTRITION LABELING: CONSUMER RESEARCH TO CONSIDER NUTRIENT CONTENT AND HEALTH CLAIMS AND POSSIBLE FOOTNOTE OR DISCLOSURE STATEMENTS

Priority: Other Significant

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

CFR Citation: 21 CFR 101

Legal Deadline: None

Abstract: The Food and Drug Administration issued an advance notice of proposed rulemaking on July 11, 2003 (68 FR 41507), to solicit information and data that potentially could be used to establish new nutrient content claims about trans fatty acids; to establish qualifying criteria for trans fat in current nutrient content claims for saturated fat and cholesterol, lean and extra lean claims, and health claims that contain a message about cholesterol-raising lipids; and, in addition, to establish disclosure and disqualifying criteria to help consumers make heart-healthy food choices.

The agency also requested comments on whether it should consider statements about trans fat, either alone or in combination with saturated fat and cholesterol, as a footnote in the Nutrition Facts panel or as a disclosure statement in conjunction with claims to enhance consumers' understanding about such cholesterol-raising lipids and how to use the information to make healthy food choices. Information and data obtained from comments and from consumer studies that will be conducted by FDA also may be used to help draft a proposed rule that would establish criteria for certain nutrient content or health claims or require the use of a footnote, or other labeling approach, about one or more cholesterol-raising lipids in the Nutrition Facts panel to assist consumers in maintaining healthy dietary practices.

Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>07/11/03</td>
<td>68 FR 41507</td>
</tr>
<tr>
<td>ANPRM Comment</td>
<td>10/09/03</td>
<td></td>
</tr>
<tr>
<td>End Period</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Regulatory Flexibility Analysis Required: No

Government Levels Affected: Federal

Agency Contact: Julie Schrimpf, Department of Health and Human Services, Food and Drug Administration, (HFS–832), HFS–800, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, College Park, MD 20740
Phone: 301 436–2373
Fax: 301 436–2639
Email: julie.schrimpf@cfsan.fda.gov

Related RIN: Related to 0910–AB66

RIN: 0910–AC50

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

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

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

CFR Citation: 21 CFR 314.50; 21 CFR 601.2; 21 CFR 314.94

Legal Deadline: None

Abstract: The Food and Drug Administration (FDA) is proposing to amend the regulations governing the format in which clinical study data (CSD) are required to be submitted for new drug applications (NDAs), biological license applications (BLAs), and abbreviated new drug applications (ANDAs). The proposal would revise our regulations to require that CSD submitted for NDAs, ANDAs, BLAs, and their supplements and amendments be provided in electronic format and require the use of standard data structure, terminology, and code sets. The proposal would improve the efficiency of the exchange of information from clinical studies through the adoption of standards for study data submitted in an electronic form that FDA can process, review, and archive.

Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>Next Action</td>
<td>Undetermined</td>
<td></td>
</tr>
</tbody>
</table>

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Undetermined

Agency Contact: Nicole K. Mueller, Regulatory Counsel, Department of Health and Human Services, Food and
888. MEDICAL GAS CONTAINERS AND CLOSURES: CURRENT GOOD MANUFACTURING PRACTICE REQUIREMENTS

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

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

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

**Legal Deadline:** None

**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 Food and Drug Administration is proposing to amend its current good manufacturing practice regulations and other regulations to clarify and strengthen requirements for the label, color, dedication, and design of medical gas containers and closures. Despite existing regulatory requirements and industry standards for medical gases, there have been repeated incidents in which cryogenic containers of harmful industrial gases have been connected to medical oxygen supply systems in hospitals and nursing homes, and subsequently administered to patients. These incidents have resulted in death and serious injury. There have also been several incidents involving high-pressure medical gas cylinders that have resulted in death and injuries to patients. These proposed amendments, together with existing regulations, are intended to ensure that the types of incidents that have occurred in the past, as well as other types of foreseeable and potentially deadly medical gas mixups, do not occur in the future.

**Timetable:**

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>To Be Determined</td>
<td></td>
</tr>
</tbody>
</table>

**Regulatory Flexibility Analysis:** Required: Undetermined

**Government Levels Affected:** None

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

**Phone:** 301 594–2041

**Fax:** 301 594–6197

**Email:** muellern@cdr.fda.gov

**RIN:** 0910–AC52

---

889. 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 eight most common food allergens are: 1) peanuts; 2) soybeans; 3) milk; 4) eggs; 5) fish; 6) crustacea (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 ingredients derived from these eight allergens include information on the label in plain English terms that clearly identifies the allergenic source of these ingredients.

The agency is also proposing to require individual label declaration of spices, flavors, noncertified colors and incidental additives. 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 level and do not have any technical or functional effect in the finished food.

**Timetable:**

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>To Be Determined</td>
<td></td>
</tr>
</tbody>
</table>

**Regulatory Flexibility Analysis:** Required: Yes

**Small Entities Affected:** Businesses

**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@cfans.fda.gov

**RIN:** 0910–AF07

---

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

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

**Unfunded Mandates:** Undetermined

**Legal Authority:** 21 USC 351

**CFR Citation:** 21 CFR 211.122

**Legal Deadline:** None

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

**Timetable:**

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>To Be Determined</td>
<td></td>
</tr>
</tbody>
</table>

**Regulatory Flexibility Analysis:** Required: Undetermined

**Small Entities Affected:** Businesses

**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@cfans.fda.gov

**RIN:** 0910–AF07
Federalism: Undetermined
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, 5515 Security Lane, Suite 1101 (HFD-7), Rockville, MD 20852
Phone: 301 594–2041
Fax: 301 827–5562
Email: mullerh@cder.fda.gov

891. CURRENT GOOD MANUFACTURING PRACTICES; QUALITY CONTROL PROCEDURES; NOTIFICATION REQUIREMENTS; RECORDS AND REPORTS
Priority: Other Significant
Legal Authority: 21 USC 321; 21 USC 350a; 21 USC 371; 21 CFR 106; 21 CFR 107
CFR Citation: 21 CFR 106; 21 CFR 107
Legal Deadline: None
Abstract: The agency published a proposed rule on July 9, 1996, that would establish current good manufacturing practice regulations, quality control procedures, quality factors, notification requirements, and records and reports for the production of infant formula. This proposal was issued in response to the 1986 Amendments to the Infant Formula Act of 1980. On April 28, 2003, FDA reopened the comment period to update comments on the proposal. The comment period was extended on June 27, 2003, to end on August 26, 2003.

Timetable:
Action Date FR Cite
Final Action 09/00/05

Regulatory Flexibility Analysis
Required: No
Small Entities Affected: No
Government Levels Affected: None
Agency Contact: Melissa Scales, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, HFS–800, HFS–024, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, College Park, MD 20740
Phone: 301 436–1720
Email: melissa.scales@cfsan.fda.gov

Related RIN: Split from 0910–AA04
RIN: 0910–AF28

892. INFANT FORMULA QUALITY FACTORS
Priority: Other Significant
Legal Authority: 21 USC 321; 21 USC 350a; 21 USC 371; 21 CFR 106; 21 CFR 107
CFR Citation: 21 CFR 106; 21 CFR 107
Legal Deadline: None
Abstract: The agency published a proposed rule on July 9, 1996, that would establish current good manufacturing practice regulations, quality control procedures, quality factors, notification requirements, and records and reports for the production of infant formula. This proposal was issued in response to the 1986 Amendments to the Infant Formula Act of 1980. On April 28, 2003, FDA reopened the comment period to update comments on the proposal. The comment period was extended on June 27, 2003, to end on August 26, 2003.

Timetable:
Action Date FR Cite
Final Action 09/00/05

Regulatory Flexibility Analysis
Required: No
Small Entities Affected: No
Government Levels Affected: None
Agency Contact: Melissa Scales, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, HFS–800, HFS–024, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, College Park, MD 20740
Phone: 301 436–1720
Email: melissa.scales@cfsan.fda.gov

Related RIN: Split from 0910–AA04
RIN: 0910–AF28

894. • OVER–THE–COUNTER (OTC) DRUG REVIEW—LAXATIVE DRUG PRODUCTS
Priority: Routine and Frequent
Legal Authority: 21 USC 310a; 21 USC 351 to 353; 21 USC 360a; 21 USC 371a; 21 USC 331; 21 USC 360d; 21 USC 360b; 21 USC 361; 21 USC 371
CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358
Legal Deadline: None
Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e. final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed.

Timetable: Next Action Undetermined
Regulatory Flexibility Analysis
Required: Yes
Small Entities Affected: Businesses
Government Levels Affected: None
Agency Contact: Gerald M. Rachanow, Regulatory Counsel, Division of Over-the-Counter Drug Products, Department of Health and Human Services, Food and Drug Administration, HFD–560, Center for Drug Evaluation and Research, 5600 Fishers Lane, Rockville, MD 20857
Phone: 301 827–2241
Fax: 301 827–2315
Email: rachanow@ceder.fda.gov

Related RIN: Split from 0910–AA01
RIN: 0910–AF35

893. • OVER–THE–COUNTER (OTC) DRUG REVIEW—EXTERNAL ANALGESIC PRODUCTS
Priority: Routine and Frequent
Legal Authority: 21 USC 310a; 21 USC 351 to 353; 21 USC 360a; 21 USC 371a; 21 USC 331; 21 USC 360d; 21 USC 360b; 21 USC 361; 21 USC 371
CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358
Legal Deadline: None
Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e. final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed.

Timetable: Next Action Undetermined
Regulatory Flexibility Analysis
Required: Yes
Small Entities Affected: Businesses
Government Levels Affected: None
Agency Contact: Gerald M. Rachanow, Regulatory Counsel, Division of Over-the-Counter Drug Products, Department of Health and Human Services, Food and Drug Administration, HFD–560, Center for Drug Evaluation and Research, 5600 Fishers Lane, Rockville, MD 20857
Phone: 301 827–2241
Fax: 301 827–2315
Email: rachanow@ceder.fda.gov

Related RIN: Split from 0910–AA01
RIN: 0910–AF35
896. OVER–THE–COUNTER (OTC) DRUG REVIEW—ORAL HEALTH CARE PRODUCTS

Priority: Routine and Frequent

Legal Authority: 21 USC 321p; 21 USC 351 to 353; 21 USC 355; 21 USC 360a; 21 USC 371a; 21 USC 331; 21 USC 360; 21 USC 360b; 21 USC 361; 21 USC 371

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

Legal Deadline: None

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

Timetable: Next Action Undetermined

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Gerald M. Rachanow, Regulatory Counsel, Division of Over-the-Counter Drug Products, Department of Health and Human Services, Food and Drug Administration, 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

Completed Actions

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

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

- **Antidiarrheal Products (0910–AC82)**
  - NPRM (Amendment) (Trav. Diarr) 04/17/03 (68 FR 18915)
  - Merged With 0910-AF29 06/08/04

- **Antiemetic 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)
  - Final Action (Partial Stay) Merged With 0910-AF30 06/08/04

- **Cough/Cold (Antihistamine) Products (0910–AD31)**
  - Merged With 0910-AF31 06/08/04

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

- **Cough/Cold (Bronchodilator) Products (0910–AD33)**
  - Merged With 0910-AF32 06/08/04

- **Cough/Cold (Combination) Products (0910–AD25)**
  - Final Action 12/23/02 (67 FR 78158)
  - NPRM (Amendment) Merged With 0910-AF33 06/08/04

- **Cough/Cold (Nasal Decongestant) Products (0910–AD43)**
  - Merged With 0910-AF34 06/08/04

- **External Analgesic Products (0910–AD06)**
  - Final Action (Amendment) (Warning) 12/06/02 (67 FR 72555)
  - NPRM (Amendment) (Paracetamol) 07/17/03 (68 FR 43234)
  - Merged With 0910-AF35 06/08/04

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

- **Internal Analgesic Products (0910–AD07)**
  - NPRM (Amendment) (Ibuprofen) 08/21/02 (67 FR 54139)
  - Merged With 0910-AF36 06/08/04

- **Labeling of Drug Products for OTC Human Use (0910–AD47)**
  - NPRM (Sodium Labeling) 03/24/04 (69 FR 13765)
  - Final Action (Sodium Labeling) 03/24/04 (69 FR 13717)
  - Final Action (Ca/Mg/K/Na) 03/24/04 (69 FR 13725)

- **Laxative Drug Products (0910–AC85)**
  - NPRM (Amendment) (Psyllium Granular Dosage Form) 08/05/03 (68 FR 46133)
  - Merged With 0910-AF38 06/08/04

- **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)
  - Final Action (Emerg. First Aid Eyewashes) Merged With 0910-AF39 06/08/04

- **Oral Health Care Products (0910–AC98)**
  - ANPRM (Plaque/Gingivitis) 05/29/03 (68 FR 32232)
  - Merged With 0910-AF40 06/08/04

- **Pediculicide Products (0910–AC79)**
  - NPRM (Labeling Amendment) 05/10/02 (67 FR 31739)
  - Final Action (Labeling Amendment) 12/31/03 (68 FR 75414)

- **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) 12/09/03 (68 FR 68509)
Final Action (Technical Amendment) Merged With 0910-AF42 06/08/04
Sunscreen Products (0910–AC68)
Final Action (Names) 06/20/02 (67 FR 41821)
ANPRM (Bug and Insect Repellent) and NPRM (UV/UVB) Merged With 0910-AF43 06/08/04
Vaginal Contraceptive Products (0910–AD19)
NPRM (Amendment) 01/16/03 (68 FR 2254)
Merged With 0910-AF44 06/08/04
Weight Control Products (0910–AC92)
Merged With 0910-AF45 06/08/04
Regulatory Flexibility Analysis Required: Yes
Small Entities Affected: Businesses
Government Levels Affected: None
Agency Contact: Gerald M. Rachanow, Regulatory Counsel, Division of Over-the-Counter Drug Products, Department of Health and Human Services, Food and Drug Administration, 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

897. 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.

Timetable:
Action: Actions Will Continue
Date: 06/04/04
FR Cite: Under Separate Rulemakings

898. DETERMINATION THAT INFORMED CONSENT IS INFEASIBLE OR IS CONTRARY TO THE BEST INTEREST OF RECIPIENTS
Priority: Other Significant
CFR Citation: 21 CFR 50; 21 CFR 312
Completed:
Reason: Withdrawn
Date: 06/10/04
FR Cite: Regulatory Flexibility Analysis Required: No
Government Levels Affected: Federal
Agency Contact: Philip L. Chao
Phone: 301 827–0587
Fax: 301 827–4774
Email: pchao@oc.fda.gov
RIN: 0910-AA89

899. BLOOD INITIATIVE
Priority: Other Significant
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 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:
Action: Actions Will Continue
Date: 06/04/04
FR Cite: Under Separate Rulemakings

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)
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
Merged With 0910-AF26 06/04/04
Final Action 08/06/01 (66 FR 40886)

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Paula S. McKeever
Phone: 301 827–6210
Fax: 301 827–9434

RIN: 0910–AB27

901. SUPPLEMENTS AND OTHER CHANGES TO AN APPROVED APPLICATION

Priority: Other Significant

CFR Citation: 21 CFR 314

Completed:

Reason Date FR Cite
Final Action 04/08/04 69 FR 18728

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Howard P. Muller
Phone: 301 594–2041
Fax: 301 827–5562
Email: mullerh@cder.fda.gov

RIN: 0910–AB61

902. CURRENT GOOD MANUFACTURING PRACTICE FOR MEDICATED FEEDS

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

CFR Citation: 21 CFR 225

Completed:

Reason Date FR Cite
Withdrawn 05/24/04 69 FR 29786

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: None

Federalism: Undetermined

Agency Contact: George Graber
Phone: 301 827–6651
Email: ggraber@cvm.fda.gov

RIN: 0910–AB70

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

Priority: Other Significant

CFR Citation: 21 CFR 314; 21 CFR 601

Completed:

Reason Date FR Cite
Final Action 12/11/03 68 FR 69009

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: Federal

Agency Contact: Nicole K. Mueller
Phone: 301 594–2041
Fax: 301 594–6197
Email: muellern@cder.fda.gov

RIN: 0910–AB91

904. USE OF MATERIALS DERIVED FROM BOVINE AND OVINE ANIMALS IN FDA–REGULATED PRODUCTS

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

CFR Citation: Not Yet Determined

Completed:

Reason Date FR Cite
Withdrawn 05/19/04

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: None

Federalism: Undetermined

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

RIN: 0910–AC19

905. BAR CODE LABEL REQUIREMENTS FOR HUMAN DRUG PRODUCTS AND BLOOD

Priority: Economically Significant. Major under 5 USC 801.

CFR Citation: 21 CFR 201.25; 21 CFR 601.67

Completed:

Reason Date FR Cite
Final Rule 02/26/04 69 FR 9119

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None
906. ADMINISTRATIVE DETENTION OF FOOD FOR HUMAN OR ANIMAL CONSUMPTION UNDER THE PUBLIC HEALTH SECURITY AND BIOTERRORISM PREPAREDNESS AND RESPONSE ACT OF 2002

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

CFR Citation: 21 CFR 1; 21 CFR 10.45(d); 21 CFR 16.1(b)(1)

Completed:

Regulatory Flexibility Analysis Required: Yes
Small Entities Affected: Businesses
Government Levels Affected: None
Agency Contact: Kelli Giannattasio
Phone: 301-436-2639
Fax: 301-436-2639
Email: kelli.giannattasio@cfsan.fda.gov

RIN: 0910–AC56

907. REQUIREMENTS FOR LIQUID MEDICATED FEED AND FREE–CHOICE MEDICATED FEED

Priority: Substantive, Nonsignificant

CFR Citation: 21 CFR 558.5; 21 CFR 510.455

Completed:

Regulatory Flexibility Analysis Required: No
Government Levels Affected: None
Agency Contact: Valerie Butler
Phone: 301 827–6210
Fax: 301 827–9434

RIN: 0910–AC57

909. REVISION OF THE REQUIREMENTS FOR SPORE–FORMING MICROORGANISMS

Priority: Other Significant

CFR Citation: 21 CFR 600.10(c); 21 CFR 600.11(e)

Completed:

Regulatory Flexibility Analysis Required: No

910. CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKAGING, OR HOLDING HUMAN FOOD (PART 110) (COMPLETION OF A SECTION 610 REVIEW)

Priority: Other Significant

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, packaging, 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 part110 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:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>Begin Review</td>
<td>05/01/03</td>
<td></td>
</tr>
<tr>
<td>End Review</td>
<td>12/31/03</td>
<td></td>
</tr>
</tbody>
</table>

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Richard A. Williams, Director, Division of Market Studies, Department of Health and Human Services, Food and Drug Administration, HFS–725, Center for Food Safety and Applied Nutrition,
911. • OVER–THE–COUNTER (OTC) DRUG REVIEW—ANTIARRHEAL PRODUCTS

Priority: Routine and Frequent
Legal Authority: 21 USC 321p; 21 USC 351 to 353; 21 USC 355; 21 USC 360a; 21 USC 371a; 21 USC 331; 21 USC 360; 21 USC 360b; 21 USC 361; 21 USC 371
CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358

Legal Deadline: None
Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e. final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed.

Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>Final Action</td>
<td>05/12/04</td>
<td>69 FR 26301</td>
</tr>
</tbody>
</table>

(Amendment) (Trav. Diar)

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

Priority: Substantive, Nonsignificant
Legal Authority: 42 USC 11131
CFR Citation: 45 CFR 60.7
Legal Deadline: None

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

Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>12/24/98</td>
<td>63 FR 71255</td>
</tr>
<tr>
<td>Second NPRM</td>
<td>04/00/04</td>
<td></td>
</tr>
</tbody>
</table>

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
Email: rachanow@cder.fda.gov
Related RIN: Split from 0910–AA01
RIN: 0910–AF29

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

Priority: Substantive, Nonsignificant
Legal Authority: 42 USC 254b; 42 USC 254e
CFR Citation: 42 CFR 5; 42 CFR 51c
Legal Deadline: None

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

Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>09/01/98</td>
<td>63 FR 46538</td>
</tr>
<tr>
<td>Second NPRM</td>
<td>09/00/04</td>
<td></td>
</tr>
</tbody>
</table>

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
Related RIN: 0906–AA41
RIN: 0906–AA44
914. • INTESTINES ADDED TO THE DEFINITION OF ORGANS COVERED BY THE RULES GOVERNING THE OPERATION OF THE ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK (OPTN)

Priority: Other Significant. Major status under 5 USC 801 is undetermined.
Legal Authority: 42 USC 274e, sec 301; 42 USC 273 to 274d, sec 371 to 376; 42 USC 1320b–8, sec 1138
CFR Citation: 42 CFR 121
Legal Deadline: None

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

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

Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>09/00/04</td>
<td></td>
</tr>
</tbody>
</table>

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

Agency Contact: Dr. Laura St. Martin, Chief Medical Officer, Department of Health and Human Services, Health Resources and Services Administration, 5600 Fishers Lane, Mail Stop 16C–17, Parklawn Bldg., Rockville, MD 20857
Phone: 202 690–8476
Email: lstmartin@hrsa.gov
RIN: 0906–AA62

915. • NOTICE OF PROPOSED RULEMAKING TO AMEND THE FINAL RULE GOVERNING THE OPERATION OF THE ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK (OPTN)

Priority: Other Significant. Major status under 5 USC 801 is undetermined.
Legal Authority: 42 USC 274e, sec 301; 1984, 42 USC 273 to 274d, sec 371 to 376; 42 USC 1320b–8, sec 1138
CFR Citation: 42 CFR 121
Legal Deadline: None

Abstract: The Department of Health and Human Services (HHS) proposes to amend the final rule governing the operation of the OPTN. This notice of proposed rulemaking provides the legislative and regulatory history of the current rule, the factors that persuaded HHS of the advisability of amending the final rule governing the operation of the OPTN, and the anticipated consequences of this proposal.

As required rapid changes in response to better understanding of the clinical scientific issues have become evident, HHS has determined that the current process for approving and enforcing policies must be amended.

Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>09/00/04</td>
<td></td>
</tr>
</tbody>
</table>

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

Agency Contact: Dr. Hui—Hsing Wong, Medical Officer, Department of Health and Human Services, Health Resources and Services Administration, 5600 Fishers Lane, Mail Stop 16C–17, Parklawn Bldg., Rockville, MD 20857
Phone: 301 443–8104
Fax: 301 594 6095
Email: hwong@hrsa.gov
RIN: 0906–AA63

917. • LIABILITY PROTECTION FOR CERTAIN FREE CLINIC HEALTH PROFESSIONALS

Priority: Substantive, Nonsignificant. Major status under 5 USC 801 is undetermined.
Legal Authority: 42 USC 233(o); PL 108–199, title II
CFR Citation: Not Yet Determined
Legal Deadline: None

Abstract: This notice of proposed rulemaking (NPRM) provides information on the implementation of 42 U.S.C. 233(o), which makes
available medical malpractice liability protection for certain volunteer health professionals in free clinics. This is accomplished by deeming eligible volunteers to be employees of the Public Health Service and, thereby, protected by the Federal Tort Claims Act (FTCA). The NPRM provides information whereby en entity or person can determine when and the extent to which a volunteer health professional at a free clinic is deemed to be a Public Health Service Employee and, therefore, afforded the protections of the FTCA.

Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>09/00/04</td>
<td></td>
</tr>
</tbody>
</table>

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Dr. Felicia Collins, Branch Chief, Clinical Quality Systems Branch HRSA/BPHC/ Division of Clinical Quality, Department of Health and Human Services, Health Resources and Services Administration, 4350 East West Hwy, Bethesda, MD 20814
Phone: 301 594-0818
Fax: 301 594 5224

RIN: 0906-AA67

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

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

Legal Authority: Not Yet Determined

CFR Citation: 42 CFR 100, sec 100.2

Legal Deadline: None

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

Subtitle 2 of title XXI of the Public Health Service Act, as enacted by the National Childhood Vaccine Injury Act of 1986, as amended, (the Act) governs the National Vaccine Injury Compensation Program (VICP). The VICP, administered by the Secretary of Health and Human Services (the Secretary) provides that a proceeding for compensation for a vaccine-related injury or death shall be initiated by service upon the Secretary, and the filing of a petition with the United States Court of Federal Claims (the Court). In some cases, the injured individual may receive compensation for future lost earnings, less appropriate taxes and the “average cost of a health insurance policy, as determined by the Secretary.” The elements of compensation that may be awarded to a successful petitioner are set out in section 2115 of the Public Service Act, 42 U.S.C. section 300aa-15. Subsection (a)(3)(B) specifically provides for compensation.

Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>09/00/04</td>
<td></td>
</tr>
</tbody>
</table>

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Thom E. Balbier Jr., Director, Division of Vaccine Injury Compen., Department of Health and Human Services, Health Resources and Services Administration, Room 8A–46, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857
Phone: 301 443–6593
Fax: 301 443–8196
Email: tbalbier@hrsa.gov

RIN: 0906-AA68

919. 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.

Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interim Final Rule</td>
<td>08/27/03</td>
<td>68 FR 51492</td>
</tr>
<tr>
<td>Final Action</td>
<td>09/00/04</td>
<td></td>
</tr>
</tbody>
</table>

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
920. SMALLPOX VACCINE INJURY COMPENSATION PROGRAM: ADMINISTRATIVE IMPLEMENTATION

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

Legal Authority: PL 108–20, 117 Stat 638

CFR Citation: 42 CFR 102

Legal Deadline: None

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

Timetable:

Action | Date | FR Cite
--- | --- | ---
Interim Final Rule | 09/00/04 | None

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Paul T. Clark, Director, Smallpox Vaccine Injury Compensation Program, Department of Health and Human Services, Health Resources and Services Administration, 10th Floor HRSA/OSP, 4350 East West Highway, Bethesda, MD 20814

Phone: 888 496–0338

Email: small@hrsa.gov

Related RIN: Related to 0906–AA60

RIN: 0906–AA61

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

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

Legal Authority: 42 USC 300ff–71

CFR Citation: Not Yet Determined

Legal Deadline: None

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

Action Date FR Cite
NPRM 08/12/03 68 FR 47923
NPRM Comment Period End 09/11/03
Final Action 08/00/04

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Wayne E. Sauseda Mr., Director, Division of Community Based Programs, Department of Health and Human Services, Health Resources and Services Administration, 5600 Fishers Lane, Rm. 7A–30, Rockville, MD 20857

Phone: 301 443–0493

Fax: 301 443 1839

Email: wsauseda@hrsa.gov

RIN: 0906–AA65

Department of Health and Human Services (HHS)

Health Resources and Services Administration (HRSA)

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

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1396r–2

CFR Citation: 45 CFR 60

Legal Deadline: None

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

Timetable:

Action Date FR Cite
NPRM To Be Determined

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
<table>
<thead>
<tr>
<th>Proposed Rule Stage</th>
<th>Proposed Rule Stage</th>
</tr>
</thead>
<tbody>
<tr>
<td>923. UNDERGRADUATE SCHOLARSHIP PROGRAM REGARDING PROFESSIONS NEEDED BY THE NATIONAL INSTITUTES OF HEALTH (NIH)</td>
<td>926. NATIONAL INSTITUTES OF HEALTH AIDS RESEARCH LOAN REPAYMENT PROGRAM</td>
</tr>
<tr>
<td><strong>Priority</strong>: Substantive, Nonsignificant</td>
<td><strong>Priority</strong>: Substantive, Nonsignificant</td>
</tr>
<tr>
<td><strong>Legal Authority</strong>: 42 USC 216; 42 USC 288–4</td>
<td><strong>Unfunded Mandates</strong>: Undetermined</td>
</tr>
<tr>
<td><strong>CFR Citation</strong>: 42 CFR 68b</td>
<td><strong>Legal Authority</strong>: 42 USC 216; 42 USC 288–1</td>
</tr>
<tr>
<td><strong>Legal Deadline</strong>: None</td>
<td><strong>CFR Citation</strong>: 42 CFR 68</td>
</tr>
<tr>
<td><strong>Abstract</strong>: 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.</td>
<td><strong>Legal Deadline</strong>: None</td>
</tr>
<tr>
<td><strong>Timetable</strong>:</td>
<td><strong>Abstract</strong>: Section 487A of the Public Health Service Act creates a program through which appropriately qualified health professionals may obtain federally funded repayment of educational loans by conducting AIDS research as NIH employees. NIH is issuing regulations that will govern the program.</td>
</tr>
<tr>
<td><strong>Action</strong></td>
<td><strong>Action</strong></td>
</tr>
<tr>
<td><strong>Date</strong></td>
<td><strong>Date</strong></td>
</tr>
<tr>
<td><strong>FR Cite</strong></td>
<td><strong>FR Cite</strong></td>
</tr>
<tr>
<td>NPRM</td>
<td>NPRM</td>
</tr>
<tr>
<td>11/00/04</td>
<td>07/00/04</td>
</tr>
<tr>
<td><strong>Regulatory Flexibility Analysis Required</strong>: No</td>
<td><strong>Regulatory Flexibility Analysis Required</strong>: No</td>
</tr>
<tr>
<td><strong>Government Levels Affected</strong>: None</td>
<td><strong>Government Levels Affected</strong>: None</td>
</tr>
<tr>
<td><strong>Agency Contact</strong>: 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: <a href="mailto:jm40z@nih.gov">jm40z@nih.gov</a></td>
<td><strong>Agency Contact</strong>: 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: <a href="mailto:jm40z@nih.gov">jm40z@nih.gov</a></td>
</tr>
<tr>
<td><strong>RIN</strong>: 0925–AA10</td>
<td><strong>RIN</strong>: 0925–AA31</td>
</tr>
<tr>
<td><strong>925. STANDARDS FOR A NATIONAL CHIMPANZEE SANCTUARY SYSTEM</strong></td>
<td><strong>927. NATIONAL INSTITUTES OF HEALTH EXTRAMURAL LOAN REPAYMENT PROGRAM FOR CLINICAL RESEARCHERS</strong></td>
</tr>
<tr>
<td><strong>Priority</strong>: Substantive, Nonsignificant</td>
<td><strong>Priority</strong>: Substantive, Nonsignificant</td>
</tr>
<tr>
<td><strong>Legal Authority</strong>: 42 USC 287a–3a</td>
<td><strong>Legal Authority</strong>: 42 USC 216; 42 USC 288–5a</td>
</tr>
<tr>
<td><strong>CFR Citation</strong>: 42 CFR 9</td>
<td><strong>CFR Citation</strong>: 42 CFR 68g</td>
</tr>
<tr>
<td><strong>Legal Deadline</strong>: June 18, 2001.</td>
<td><strong>Legal Deadline</strong>: None</td>
</tr>
<tr>
<td><strong>Abstract</strong>: 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.</td>
<td><strong>Abstract</strong>: NIH proposes to establish implementing regulations for the</td>
</tr>
<tr>
<td><strong>Timetable</strong>:</td>
<td><strong>Regulatory Flexibility Analysis Required</strong>: No</td>
</tr>
<tr>
<td><strong>Action</strong></td>
<td><strong>Government Levels Affected</strong>: None</td>
</tr>
<tr>
<td><strong>Date</strong></td>
<td><strong>Agency Contact</strong>: 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: <a href="mailto:jm40z@nih.gov">jm40z@nih.gov</a></td>
</tr>
<tr>
<td><strong>FR Cite</strong></td>
<td><strong>RIN</strong>: 0925–AA32</td>
</tr>
<tr>
<td>NPRM</td>
<td>09/00/04</td>
</tr>
<tr>
<td><strong>Regulatory Flexibility Analysis Required</strong>: No</td>
<td><strong>RIN</strong>: 0925–AA10</td>
</tr>
<tr>
<td><strong>Small Entities Affected</strong>: No</td>
<td><strong>Government Levels Affected</strong>: None</td>
</tr>
<tr>
<td><strong>Agency Contact</strong>: 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: <a href="mailto:jm40z@nih.gov">jm40z@nih.gov</a></td>
<td><strong>Legal Authority</strong>: 42 USC 216; 42 USC 288–5a</td>
</tr>
<tr>
<td><strong>RIN</strong>: 0925–AA10</td>
<td><strong>CFR Citation</strong>: 42 CFR 68g</td>
</tr>
<tr>
<td><strong>Legal Deadline</strong>: None</td>
<td><strong>Regulatory Flexibility Analysis Required</strong>: No</td>
</tr>
<tr>
<td><strong>Small Entities Affected</strong>: No</td>
<td><strong>Government Levels Affected</strong>: None</td>
</tr>
<tr>
<td><strong>Agency Contact</strong>: 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: <a href="mailto:jm40z@nih.gov">jm40z@nih.gov</a></td>
<td><strong>RIN</strong>: 0925–AA31</td>
</tr>
</tbody>
</table>
### Extramural Loan Repayment Program for Clinical Researchers

Authorized under section 487F of the Public Health Service Act, this program provides for the repayment of the existing educational loan debt of qualified health professionals who agree to conduct clinical research.

**Timetable:**

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>11/00/04</td>
<td></td>
</tr>
</tbody>
</table>

**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

---

### 929. 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:**

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>11/00/04</td>
<td></td>
</tr>
</tbody>
</table>

**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

---

### 930. 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:**

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>08/00/04</td>
<td></td>
</tr>
</tbody>
</table>

**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
### HHS—NIH

**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)

#### Redacted

**Priority:** Substantive, Nonsignificant  
**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.

**Timetable:**  
**Action** | **Date** | **FR Cite**  
--- | --- | ---  
NPRM | 08/05/02 | 67 FR 50622  
Final Action | 07/00/04 |  

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

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

#### Redacted

**Priority:** Substantive, Nonsignificant  
**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.

**Timetable:**  
**Action** | **Date** | **FR Cite**  
--- | --- | ---  
NPRM | 11/12/02 | 67 FR 68548  
Final Action | 07/00/04 |  

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

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

#### Redacted

**Priority:** Substantive, Nonsignificant  
**CFR Citation:** 42 CFR 52h

**Completed Action:**  
**Reason** | **Date** | **FR Cite**  
--- | --- | ---  
Final Rule | 01/05/04 | 69 FR 272

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

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

Legal Authority: 5 USC 301; 42 USC 289

CFR Citation: 45 CFR 46

Legal Deadline: None

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

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

936. 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.

Department of Health and Human Services (HHS)
Office of Public Health and Science (OPHS)
937. 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

Abstract: To implement section 493(e) of the Public Health Service Act (added by section 163 of the National Institutes of Health Revitalization Act of 1993, Pub. L. 103-43), the Department is proposing to add a new part 94 to title 42 of the Code of Federal Regulations. Under this proposed regulation, covered institutions must follow certain requirements for preventing and responding to occurrences of retaliation against whistleblowers. The purpose of this part is to protect: 1) persons who make a good faith allegation that a covered institution or member thereof engaged in, or failed to respond adequately to an allegation of research misconduct; and 2) persons who cooperate in good faith with an investigation of research misconduct.

Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>11/28/00</td>
<td>65 FR 70830</td>
</tr>
<tr>
<td>NPRM Comment</td>
<td>01/29/01</td>
<td></td>
</tr>
<tr>
<td>Period End</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Final Action</td>
<td>01/00/05</td>
<td></td>
</tr>
</tbody>
</table>

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
Fax: 301 443–5351

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

938. 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

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.

Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>04/16/04</td>
<td>69 FR 20777</td>
</tr>
<tr>
<td>NPRM Comment</td>
<td>06/15/04</td>
<td></td>
</tr>
<tr>
<td>Period End</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Final Action</td>
<td>12/00/04</td>
<td></td>
</tr>
</tbody>
</table>

Regulatory Flexibility Analysis Required: No
Small Entities Affected: No

939. • FEDERAL POLICY FOR THE PROTECTION OF HUMAN SUBJECTS TECHNICAL AMENDMENT

Priority: Substantive, Nonsignificant
Legal Authority: 5 USC 301; 42 USC 289; 42 USC 300–1(b)
CFR Citation: 45 CFR 46

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

Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>Final Action</td>
<td>09/00/04</td>
<td></td>
</tr>
</tbody>
</table>

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

Agency Contact: Michael A. Carome MD, Department of Health and Human Services, Office of Public Health and Science, Suite 200, The Tower Building, Suite 200, 1101 Wooten Parkway, Rockville, MD 20852
Phone: 301 496–7005
Fax: 301 402–0527
RIN: 0940–AA10
### Department of Health and Human Services (HHS)

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

<table>
<thead>
<tr>
<th>Timetable:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>940. HUMAN SUBJECTS PROTECTION REGULATIONS: TRAINING AND EDUCATION REQUIREMENTS FOR INSTITUTIONAL OFFICIALS, INSTITUTIONAL REVIEW BOARD MEMBERS AND STAFF, HUMAN PROTECTIONS ADMINISTRATORS, AND INVESTIGATOR</strong></td>
</tr>
<tr>
<td><strong>Priority:</strong> Other Significant. Major status under 5 USC 801 is undetermined.</td>
</tr>
<tr>
<td><strong>Legal Authority:</strong> 5 USC 301; 42 USC 289</td>
</tr>
<tr>
<td><strong>CFR Citation:</strong> 45 CFR 46</td>
</tr>
<tr>
<td><strong>Legal Deadline:</strong> None</td>
</tr>
<tr>
<td><strong>Abstract:</strong> This notice of proposed rulemaking proposes to add subpart E to the Department of Health and Human Services (HHS) regulations for protection of human subjects, 45 CFR part 46, and would require that institutions engaged in human subjects research covered by an assurance of compliance filed with the Office for Human Research Protections ensure that institutional officials, institutional review board (IRB) chairpersons, and human protection administrators receive appropriate training and education about the institution’s assurance and that IRB chairpersons and members, IRB staff, investigators, and other personnel involved in the conduct or oversight of human subjects research receive appropriate training and education about relevant human subjects protection requirements. The proposed training and education requirements will help to ensure that responsible individuals at assured institutions understand and meet their regulatory responsibilities for human subjects protection.</td>
</tr>
<tr>
<td><strong>Regulatory Flexibility Analysis Required:</strong> No</td>
</tr>
<tr>
<td><strong>Small Entities Affected:</strong> None</td>
</tr>
<tr>
<td><strong>Government Levels Affected:</strong> None</td>
</tr>
<tr>
<td><strong>Agency Contact:</strong> Michael A. Carome, MD, Department of Health and Human Services, Office of Public Health and Science, Suite 200, The Tower Building, Suite 200, 1101 Wootten Parkway, Rockville, MD 20852 Phone: 301 496–7005 Fax: 301 402–0527 RIN: 0940–AA08</td>
</tr>
</tbody>
</table>

---

<table>
<thead>
<tr>
<th>Timetable:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>941. HOME HEALTH AGENCY (HHA) CONDITIONS OF PARTICIPATION (COPS) (CMS–3819–P)</strong></td>
</tr>
<tr>
<td><strong>Priority:</strong> Other Significant</td>
</tr>
<tr>
<td><strong>Legal Authority:</strong> 42 USC 1302; 42 USC 1395x; 42 USC 1395cc(a); 42 USC 1395hh; 42 USC 1395bb</td>
</tr>
<tr>
<td><strong>CFR Citation:</strong> 42 CFR 484</td>
</tr>
<tr>
<td><strong>Legal Deadline:</strong> None</td>
</tr>
<tr>
<td><strong>Abstract:</strong> This proposed rule would revise 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>
</tr>
<tr>
<td><strong>Regulatory Flexibility Analysis Required:</strong> No</td>
</tr>
<tr>
<td><strong>Small Entities Affected:</strong> Businesses, Organizations</td>
</tr>
<tr>
<td><strong>Government Levels Affected:</strong> None</td>
</tr>
<tr>
<td><strong>Agency Contact:</strong> Mercedes Benitez-McCray, 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>
</tr>
<tr>
<td><strong>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: 410 786–9465 RIN: 0938–AG81</strong></td>
</tr>
</tbody>
</table>

---

<table>
<thead>
<tr>
<th>Timetable:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>942. END STAGE RENAL DISEASE (ESRD) CONDITIONS FOR COVERAGE (CMS–3818–P) (SECTION 610 REVIEW)</strong></td>
</tr>
<tr>
<td><strong>Priority:</strong> Other Significant</td>
</tr>
<tr>
<td><strong>Legal Authority:</strong> 42 USC 1395rr</td>
</tr>
<tr>
<td><strong>CFR Citation:</strong> 42 CFR 400; 42 CFR 405; 42 CFR 406; 42 CFR 409; 42 CFR 410; 42 CFR 412; 42 CFR 488; 42 CFR 489; 42 CFR 494; 42 CFR 413; 42 CFR 414</td>
</tr>
<tr>
<td><strong>Legal Deadline:</strong> None</td>
</tr>
<tr>
<td><strong>Abstract:</strong> This proposed rule would revise the requirements that end stage renal disease (ESRD) facilities must meet to be certified under the Medicare program.</td>
</tr>
<tr>
<td><strong>Regulatory Flexibility Analysis Required:</strong> Yes</td>
</tr>
<tr>
<td><strong>Small Entities Affected:</strong> Businesses</td>
</tr>
<tr>
<td><strong>Government Levels Affected:</strong> None</td>
</tr>
<tr>
<td><strong>Agency Contact:</strong> Robert Miller, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare &amp; Medicaid Services, S3–02–01, Office of Clinical Standards and Quality, 7500 Security Boulevard, Baltimore, MD 21244 Phone: 410 786–6797</td>
</tr>
<tr>
<td><strong>Teresa Casey, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare &amp; Medicaid Services, S3–05–04, Office of Clinical Standards and Quality, 7500 Security Boulevard, Baltimore, MD 21244 Phone: 410 786–7215 RIN: 0938–AG82</strong></td>
</tr>
</tbody>
</table>

---
943. HOSPITAL CONDITIONS OF PARTICIPATION: REQUIREMENTS FOR APPROVAL AND REAPPROVAL OF TRANSPLANT CENTERS TO PERFORM ORGAN TRANSPLANTS (CMS–3835–P)

Priority: Other Significant
Legal Authority: 42 USC 1302; 42 USC 1395hh
CFR Citation: 42 CFR 482
Legal Deadline: None

Abstract: This proposed rule would establish conditions of participation for Medicare-covered transplants.

Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>11/00/04</td>
<td></td>
</tr>
</tbody>
</table>

Regulatory Flexibility Analysis Required: No
Small Entities Affected: Businesses, Organizations

Government Levels Affected: None
Agency Contact: Mary Rossi Coajou, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S3–06–6, Office of Clinical Standards and Quality, 7500 Security Boulevard, Baltimore, MD 21244 Phone: 410 786–6051

Danielle Shearer, 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: 410 786–6617

RIN: 0938–AH87

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

Priority: Other Significant
Legal Authority: 42 USC 1302; 42 USC 1395u(b)(3)(C); 42 USC 1395f(b)
CFR Citation: 42 CFR 405.874
Legal Deadline: None

Abstract: This rule extends 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 appeal provisions of our regulations. In addition, certain appeal provisions are revised to correspond with the existing appeal provisions in those other sections of our regulations. The rule also extends appeal rights to all suppliers not covered by existing regulations to ensure they have a full and fair opportunity to be heard. Rule will incorporate provisions from section 936 of the MMA.

Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>10/25/99</td>
<td>64 FR 57431</td>
</tr>
<tr>
<td>Second NPRM</td>
<td>01/00/05</td>
<td></td>
</tr>
</tbody>
</table>

Regulatory Flexibility Analysis Required: Substantive, Nonsignificant
Small Entities Affected: None

Government Levels Affected: State
Agency Contact: Helen Dietrick, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 51–07–17, Office of Information Services, 7500 Security Boulevard, Baltimore, MD 21244 Phone: 410 786–7448

RIN: 0938–AH87

946. APPEALS OF CARRIER DETERMINATION THAT A SUPPLIER FAILS TO MEET THE REQUIREMENTS FOR MEDICARE BILLING PRIVILEGES (CMS–6003–P2)

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

Abstract: This rule extends 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 appeal provisions of our regulations. In addition, certain appeal provisions are revised to correspond with the existing appeal provisions in those other sections of our regulations. The rule also extends appeal rights to all suppliers not covered by existing regulations to ensure they have a full and fair opportunity to be heard. Rule will incorporate provisions from section 936 of the MMA.

Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>10/25/99</td>
<td>64 FR 57431</td>
</tr>
<tr>
<td>Second NPRM</td>
<td>01/00/05</td>
<td></td>
</tr>
</tbody>
</table>

Regulatory Flexibility Analysis Required: Substantive, Nonsignificant
Small Entities Affected: Businesses

Government Levels Affected: None
Agency Contact: Ralph Goldberg, Division of Provider and Supplier Enrollment, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244 Phone: 410 786–4870

RIN: 0938–AH87

944. 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 the existing conditions of participation that hospices must meet to participate in the Medicare and Medicaid programs. The proposed requirements focus on the actual care delivered to patients and patients' families by hospices and the results of that care, reflect an interdisciplinary view of patient care, allow hospices greater flexibility in meeting quality standards, and eliminate unnecessary procedural requirements.

Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>11/00/04</td>
<td></td>
</tr>
</tbody>
</table>

Regulatory Flexibility Analysis Required: Y es
Small Entities Affected: Businesses

Government Levels Affected: None
Agency Contact: Aucha Prachanronarong, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S3–02–01, 7500 Security Boulevard, Baltimore, MD 21244 Phone: 410 786–7539

Aucha Prachanronarong, 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: 410 786–9614

RIN: 0938–AH17
947. RURAL HEALTH CLINICS: AMENDMENTS TO PARTICIPATION REQUIREMENTS AND PAYMENT PROVISIONS AND ESTABLISHMENT OF A QUALITY ASSESSMENT AND IMPROVEMENT PROGRAM (CMS–1910–P2)

Priority: Other Significant
Legal Authority: 42 USC 1302; 42 USC 1395hh

CFR Citation: 42 CFR 405; 42 CFR 491
Legal Deadline: None

Abstract: This rule amends the Medicare certification and payment requirements for rural health clinics (RHCs), as required by section 4205 of the Balanced Budget Act of 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.

Timetable:
Action Date FR Cite
NPRM 12/24/03 68 FR 74792
Second NPRM 05/05/05

Regulatory Flexibility Analysis
Required: No
Small Entities Affected: Businesses

Agency Contact: Ralph Goldberg, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C3–02–16, Center for Medicaid and State Operations, 7500 Security Boulevard, C3–02–16, Baltimore, MD 21244 Phone: 410 786-4870
RIN: 0938–AJ98

948. SUPPLIER STANDARDS FOR HOME OXYGEN, THERAPEUTIC SHOES, AND HOME NUTRITION THERAPY (CMS–6010–P)

Priority: Substantive, Nonsignificant
Legal Authority: Not Yet Determined

949. 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: Final, Statutory, January 1, 2002, Requires promulgation of new conditions.

Abstract: This rule would establish conditions for coverage for organ procurement organizations (OPOs) to be certified by the Secretary to receive payment from Medicare and Medicaid for organ procurement costs, and to be designated by the Secretary for a specific geographic service area. The Organ Procurement Organization Certification Act of 2000 requires CMS to increase the certification cycle for OPOs from two years to four years and to promulgate new performance standards for OPOs.

Timetable:
Action Date FR Cite
Interim Final Rule 12/28/01 66 FR 67109
NPRM 11/00/04

Regulatory Flexibility Analysis
Required: No
Small Entities Affected: Businesses

Agency Contact: Marcia Newton, Office of Clinical Standards and
<table>
<thead>
<tr>
<th>Proposed Rule Stage</th>
<th>Timetable:</th>
</tr>
</thead>
<tbody>
<tr>
<td>HHS—CMS</td>
<td>952. PROVIDER REIMBURSEMENT DETERMINATIONS AND APPEALS (CMS–1727–P)</td>
</tr>
<tr>
<td>Priority: Substantive, Nonsignificant</td>
<td>42 CFR 405</td>
</tr>
<tr>
<td>Legal Authority: Sec 1878 of the Social Security Act</td>
<td>Legal Deadline: None</td>
</tr>
<tr>
<td>Abstract: This proposed rule would redefine, clarify, and update the guidelines and procedures for Provider Reimbursement Review Board appeals, based on recent court decisions.</td>
<td>CFR Citation: 42 CFR 405</td>
</tr>
<tr>
<td>Timetable:</td>
<td></td>
</tr>
<tr>
<td>Action</td>
<td>Date</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>NPRM</td>
<td>07/00/04</td>
</tr>
<tr>
<td>Regulatory Flexibility Analysis Required: No</td>
<td></td>
</tr>
<tr>
<td>Small Entities Affected: Businesses</td>
<td></td>
</tr>
<tr>
<td>Government Levels Affected: None</td>
<td></td>
</tr>
<tr>
<td>Agency Contact: Morton Marcus, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare &amp; Medicaid Services, 7500 Security Boulevard, C4–25–02, Baltimore, MD 21244</td>
<td></td>
</tr>
<tr>
<td>Phone: 410 786–4477</td>
<td></td>
</tr>
<tr>
<td>RIN: 0938–AL54</td>
<td></td>
</tr>
<tr>
<td>953. HEALTH COVERAGE PORTABILITY’S REQUEST FOR INFORMATION ON BENEFIT–SPECIFIC WAITING PERIODS (CMS–2150–NC)</td>
<td></td>
</tr>
<tr>
<td>Priority: Info./Admin./Other</td>
<td>CFR Citation: 42 CFR 410; 42 CFR 424; 42 CFR 416; 42 CFR 468; 42 CFR 489</td>
</tr>
<tr>
<td>Legal Authority: Sec 1102 of the Social Security Act; Sec 1832 of the Social Security Act; Sec 1871 of the Social Security Act</td>
<td>Legal Deadline: None</td>
</tr>
<tr>
<td>Abstract: This notice requests information on the use of benefit-specific waiting periods by group health plan and group health insurance issuers.</td>
<td>CFR Citation: 42 CFR 410; 42 CFR 424; 42 CFR 416; 42 CFR 468; 42 CFR 489</td>
</tr>
<tr>
<td>Timetable:</td>
<td></td>
</tr>
<tr>
<td>Action</td>
<td>Date</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>NPRM</td>
<td>05/00/05</td>
</tr>
<tr>
<td>Regulatory Flexibility Analysis Required: No</td>
<td></td>
</tr>
<tr>
<td>Small Entities Affected: Businesses</td>
<td></td>
</tr>
<tr>
<td>Government Levels Affected: State</td>
<td></td>
</tr>
<tr>
<td>Agency Contact: Joan Brooks, 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</td>
<td></td>
</tr>
<tr>
<td>Phone: 410 786–5526</td>
<td></td>
</tr>
<tr>
<td>RIN: 0938–AL80</td>
<td></td>
</tr>
</tbody>
</table>

| 954. REVISIONS TO CONDITIONS FOR COVERAGE FOR AMBULATORY SURGICAL CENTERS (CMS–3887–P) | |
| Priority: Other Significant |  |
| Legal Authority: Sec 1102 of the Social Security Act; Sec 1832 of the Social Security Act; Sec 1871 of the Social Security Act | |
| Unfunded Mandates: Undetermined | |
| Legal Deadline: None | |
| Abstract: This proposed rule would revise the ambulatory surgical center conditions for coverage to reflect current innovations in healthcare delivery, quality assessment, and performance improvement. The focus would be to improve outcomes of health care and satisfaction for Medicare beneficiaries, while streamlining structural and procedural requirements when possible. | CFR Citation: 42 CFR 410; 42 CFR 424; 42 CFR 416; 42 CFR 468; 42 CFR 489 |

**Regulatory Flexibility Analysis Required: No**

<table>
<thead>
<tr>
<th>Small Entities Affected: Businesses</th>
<th>Government Levels Affected: State</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agency Contact:льн о</td>
<td></td>
</tr>
<tr>
<td>RIN: 0938–AL64</td>
<td></td>
</tr>
</tbody>
</table>
955. 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 300gg; PL 104–191
CFR Citation: 45 CFR 146.113; 45 CFR 146.115; 45 CFR 146.117; 45 CFR 146.120; 45 CFR 146.145
Legal Deadline: None

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

Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>02/00/05</td>
<td></td>
</tr>
</tbody>
</table>

Regulatory Flexibility Analysis Required: Undetermined
Small Entities Affected: Businesses, Organizations
Government Levels Affected: Federal, Local, State

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

Agency Contact: Stanley B. Nachimson, Senior Technical Advisor, Department of Health and Human Services, Centers for Medicare & Medicaid Services, N2–16–03, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–6153
RIN: 0938–AM50

957. 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 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

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:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>02/00/05</td>
<td></td>
</tr>
</tbody>
</table>

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

Agency Contact: Carey Appold, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicaid and State Operations, 7500 Security Boulevard, S2–14–26, Baltimore, MD 21224
Phone: 410 786–2117
RIN: 0938–AM79

958. TICKET TO WORK: DEFINING INDIVIDUALS WITH POTENTIALLY SEVERE DISABILITIES AND PROVIDING A WORK THRESHOLD (CMS–2172–P)

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.

Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>02/00/05</td>
<td></td>
</tr>
</tbody>
</table>

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

Agency Contact: Cindy Read, Division Director, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare Management, 7500 Security Boulevard, C4–05–07, Baltimore, MD 21244
Phone: 410 786–1852
RIN: 0938–AM75

959. PAYMENT ERROR RATE MEASUREMENT (PERM) PROGRAM (CMS–2186–P)

Priority: Other Significant. Major status under 5 USC 801 is undetermined.
Legal Authority: Sec 1902 (a)(6) of the Social Security Act; Sec 2107 (b)(1) of the Social Security Act; Improper Payments Information Act of 2002 (IPIA) (PL 107–300)
CFR Citation: None
Legal Deadline: None
Abstract: Sections 1902(a)(6) and 2107(b)(1) of the Act, governing Medicaid and State Children’s Health Insurance Program, 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 Improper Payments Information Act of 2002 and through this regulation to estimate improper payments using the CMS PERM methodology for the reporting year in the Medicare and State Children’s Health Insurance Program. 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 Improper Payments Information Act of 2002.

Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>12/00/04</td>
<td></td>
</tr>
</tbody>
</table>

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

HOSPITALS SERVICES (CMS–3140–P)

961. HOSPITAL CONDITIONS OF PARTICIPATION: REQUIREMENTS FOR HISTORY AND PHYSICAL EXAMINATIONS; AUTHENTICATION OF VERBAL ORDERS, SECURING MEDICATIONS AND POST–ANESTHESIA EVALUATIONS (CMS–3122–P)

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 proposed rule would revise four of the conditions of participation that hospitals must meet to participate in the Medicare and Medicaid programs to decrease the burden on hospitals to conform to current standards of practice. They must establish and maintain policies and procedures that ensure that the hospital meets these requirements by using standard practices related to history and physical examinations, and completion of the post-anesthesia evaluation.

Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>06/00/04</td>
<td></td>
</tr>
</tbody>
</table>

Regulatory Flexibility Analysis
Required: Yes
Small Entities Affected: Businesses
Government Levels Affected: Federal
Agency Contact: Lateasha Walker, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare Management, 7500 Security Boulevard, Baltimore, MD 21244 Phone: 410 786–1101
RIN: 0938–AM90

REvised CIVIL MONEY PENALTIES, ASSESSMENTS, EXCLUSIONS, AND RELATED APPEALS PROCEDURES (CMS–6146–P)

Abstract: This proposed rule would make several changes affecting Medicare part B payment. (The statute requires that the final rule be published by November 1, 2004.)

Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>0938–AM88</td>
<td></td>
</tr>
</tbody>
</table>

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

962. REVISIONS TO PAYMENT POLICIES UNDER THE PHYSICIAN FEE SCHEDULE FOR CALENDAR YEAR 2005 (CMS–1429–P)

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

Legal Authority: 42 USC 1395W–4
CFR Citation: 42 CFR 410; 42 CFR 414
Legal Deadline: NPRM, Statutory, June 1, 2004, Revisions to Payment Policies.
Abstract: This rule would make several changes affecting Medicare part B payment. (The statute requires that the final rule be published by November 1, 2004.)

Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>06/00/04</td>
<td></td>
</tr>
</tbody>
</table>

Regulatory Flexibility Analysis
Required: Yes
Small Entities Affected: Businesses
Government Levels Affected: Federal
Agency Contact: Lateasha Walker, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare Management, 7500 Security Boulevard, Baltimore, MD 21244 Phone: 410 786–1101
RIN: 0938–AM90
Abstract: This rule proposes revisions to the CMS civil money penalty authorities. These proposed revisions are intended to add the specific exclusion sanction authorities as established in the procedures for imposing civil money penalties, assessments, and exclusions for certain violations of the Medicare and Medicaid programs.

Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>07/00/04</td>
<td></td>
</tr>
</tbody>
</table>

Regulatory Flexibility Analysis

Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

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

Email: jandrews@cms.hhs.gov

RIN: 0938–AN98

965. • MEDICARE ADVANTAGE PROGRAM TITLE II (CMS–4069–P)

Priority: Other Significant

Unfunded Mandates: Undetermined

Legal Authority: Not Yet Determined

CFR Citation: 42 CFR 417; 42 CFR 422

Legal Deadline: None

Abstract: This proposed rule would implement title II of the Medicare Prescription Drug and Improvement Modernization Act establishing the Medicare Advantage program that would replace the existing Medicare–Choice program. Medicare Advantage offers improved managed care plans with coordinated care and competitive bidding, to promote greater efficiency and responsiveness to Medicare beneficiaries. (Rule needs to be published at least one year before January 1, 2006 implementation to award contracts.)

Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>06/00/04</td>
<td></td>
</tr>
</tbody>
</table>

Regulatory Flexibility Analysis

Required: No

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Jane Andrews, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, C4–13–01, Baltimore, MD 21244–1850

Phone: 410 786–3133

Email: jandrews@cms.hhs.gov

RIN: 0938–AN06

966. • SPECIAL RULES FOR EMPLOYER–SPONSORED DRUG PROGRAMS: SUBSIDIES TO ENCOURAGE RETENTION (TITLE I) (CMS–2199–P)

Priority: Economically Significant. Major under 5 USC 801

Unfunded Mandates: Undetermined


CFR Citation: 42 CFR 423

Legal Deadline: None

Abstract: This proposed rule would implement title I of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA) that establishes a new voluntary outpatient prescription drug benefit under a new Medicare part D, beginning January 1, 2006. Options for coverage of the drug benefit include private prescription drug plans (PDPs) that offer drug only coverage; Medicare Advantage plans; or preferred provider plans (PPOs) that would offer prescription drug and nondrug coverage. Plans would offer a standard drug benefit but have the...
flexibility to vary the drug benefit within actuarial equivalency parameters. Assistance with premiums and cost sharing would be provided to eligible low-income beneficiaries.

### Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>06/00/04</td>
<td></td>
</tr>
</tbody>
</table>

#### Regulatory Flexibility Analysis

Required: Undetermined

#### Government Levels Affected

Federal, State, Tribal

#### Federalism

Undetermined

#### Agency Contact

Tracey McCutcheon, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-6715

Email: tmccutcheon@cms.hhs.gov

RIN: 0938-AN08

---

### 968. • ENHANCED DSH TREATMENT FOR CERTAIN HOSPITALS (CMS–2198–P)

#### Priority

Other Significant

#### Unfunded Mandates

Undetermined

#### Legal Authority

Section 1923(i) of the Social Security Act

#### CFR Citation

Not Yet Determined

#### Legal Deadline

None

#### Abstract

This regulation will implement section 1923(i) of the Social Security Act (the Act). Section 1923(i) of the Act requires States to report DSH payment information (name of DSH providers and amount of payment they received) to CMS. Under the law, States must also furnish CMS with an independent audit that verifies DSH payment to hospitals.

#### Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>11/00/04</td>
<td></td>
</tr>
</tbody>
</table>

#### Regulatory Flexibility Analysis

Required: No

#### Small Entities Affected

No

#### Government Levels Affected

None

#### Agency Contact

Misty D. Whitaker, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786–3087

Email: mwhitaker@cms.hhs.gov

RIN: 0938–AN10

---

### 969. • PRIOR DETERMINATION PROCESS (CMS–6024–P)

#### Priority

Other Significant, Major under 5 USC 801.

#### Unfunded Mandates

Undetermined

#### Legal Authority

Sec 938 of the Medicare Modernization Act of 2003

#### CFR Citation

Not Yet Determined

#### Legal Deadline

Final, Statutory, June 8, 2005.

#### Abstract

Section 938 of the Medicare Modernization Act requires that physicians and beneficiaries be able to receive a prior determination regarding coverage of certain items and physicians' services beginning June 8, 2005. (The final rule must be published by March 25, 2005.)

#### Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>0938–AN09</td>
<td></td>
</tr>
</tbody>
</table>

---

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

#### Priority

Economically Significant, Major under 5 USC 801.

#### Legal Authority

Public Law 108, MMA

#### CFR Citation

42 CFR 414.200; 42 CFR 405.502; 42 CFR 424.57; 42 CFR 410.38

#### Legal Deadline

NPRM, Statutory, April 1, 2005.

#### Abstract

Section 302 of the Medicare Modernization Act establishes DME competitive bidding. National competitive bidding will provide a program for using market forces to set Medicare payment amounts. This will also create incentives for suppliers to provide quality item and services while at the same time providing Medicare with reasonable prices for payment. (The statute requires competitive bidding be implemented by January 1, 2007. Proposed and final rules must be published six months prior to implementation.)

#### Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>10/00/04</td>
<td></td>
</tr>
</tbody>
</table>

#### Regulatory Flexibility Analysis

Required: Undetermined

#### Small Entities Affected

None

#### Government Levels Affected

None

#### Agency Contact

Bob Cerghino, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786–3263

Email: jfrizzera@cms.hhs.gov

RIN: 0938–AN14

---

### 971. • UPDATE OF THE LIST OF COVERED PROCEDURES FOR AMBULATORY SURGICAL CENTERS FOR 2005 (CMS–1478–PN)

#### Priority

Other Significant, Major under 5 USC 801 is undetermined.

#### Legal Authority

Not Yet Determined

#### CFR Citation

None

#### Legal Deadline

NPRM, Statutory, July 1, 2005.

#### Abstract

This proposed notice updates the list of Medicare-covered ASC procedures. (The subsequent final notice must be published by March 25, 2005, to be effective July 1, 2005.)

#### Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>10/00/04</td>
<td></td>
</tr>
</tbody>
</table>

#### Regulatory Flexibility Analysis

Required: Undetermined

#### Government Levels Affected

None

#### Agency Contact

Michael Patrick, Health Policy Analyst, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786–4495

Email: mkeane@cms.hhs.gov

RIN: 0938–AN11
## 972. • REVISIONS TO HIPAA CODE SETS (CMS–0013–P)

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

**Unfunded Mandates:** Undetermined

**Legal Authority:** PL 104–191

**CFR Citation:** 45 CFR 162

**Legal Deadline:** None

**Abstract:** This rule will propose revisions to the adopted transaction and code set standards detailed in regulations published by HHS on August 17, 2000, and February 20, 2003. The Secretary intends to propose any replacements for specific code sets.

**Timetable:**

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>03/00/05</td>
<td></td>
</tr>
</tbody>
</table>

**Regulatory Flexibility Analysis Required:** Yes

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

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

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

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

**Agency Contact:** Maria A. Friedman, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–6333
Email: mfriedman@cms.hhs.gov
RIN: 0938–AN25

## 973. • PAYMENT FOR CLINICAL LABORATORY TESTS (CMS–1494–P)

**Priority:** Substantive, Nonsignificant

**Legal Authority:** Sec 1833(h)(8) of the MMA; Sec 416 of the MMA; PL 108–173

**CFR Citation:** Not Yet Determined

**Legal Deadline:** None

**Abstract:** The Medicare Modernization Act of 2003 (MMA), Public Law 108-173, requires codification of the payment basis for determining Medicare payments for new clinical laboratory tests under the clinical laboratory fee schedule. Also, MMA’s section 416 eliminates the application of the clinical laboratory fee schedule for hospital outpatient laboratory testing by a hospital with fewer than 50 beds in a qualified rural area for cost reporting periods beginning during the two-year period beginning on July 1, 2004. Section 1833(h) of the Act mandates payment for outpatient clinical laboratory tests under a clinical laboratory fee schedule.

**Timetable:**

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>11/00/04</td>
<td></td>
</tr>
</tbody>
</table>

**Regulatory Flexibility Analysis Required:** Yes

**Small Entities Affected:** Businesses

**Government Levels Affected:** None

**Agency Contact:** Anita Greenberg, Health Insurance Specialist, CMS/CMM/HAPG/DAS, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–6333
Email: agreenberg@cms.hhs.gov
RIN: 0938–AN26

## 974. • PROSPECTIVE PAYMENT SYSTEM FOR LONG TERM CARE HOSPITALS: ANNUAL PAYMENT RATE UPDATES AND POLICY CHANGES FOR 2006 (CMS–1483–P)

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

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

**CFR Citation:** Not Yet Determined

**Legal Deadline:** None

**Abstract:** This rule proposes the payment rate update for the 2006 prospective payment system for Medicare long-term care hospitals. The new rates will be based on cost reports from the first LTC PPS rate year. The proposed and final rules must be published by April 29, 2005, to be effective July 1, 2005.

**Timetable:**

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>12/00/04</td>
<td></td>
</tr>
</tbody>
</table>

**Regulatory Flexibility Analysis Required:** Yes

**Small Entities Affected:** Businesses

**Government Levels Affected:** None

**Agency Contact:** Judy Richter, Health Insurance Specialist, CMS/CMM/HAPG/DAS, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–6333
Email: jrrichter@cms.hhs.gov
RIN: 0938–AN28
975. USE OF RESTRAINT AND SECLUSION IN RESIDENTIAL TREATMENT FACILITIES PROVIDING INPATIENT PSYCHIATRIC SERVICES TO INDIVIDUALS UNDER AGE 21 (CMS–2065–F)

Priority: Other Significant
Legal Authority: 42 USC 1302; 42 USC 1396d
CFR Citation: 42 CFR 441 to 442; 42 CFR 483

Legal Deadline: None

Abstract: This final rule addresses standards of practices that residential treatment facilities providing inpatient psychiatric services for individuals under age 21 must meet with regard to the use of restraints and seclusion.

Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interim Final Rule</td>
<td>01/22/01</td>
<td>66 FR 7148</td>
</tr>
<tr>
<td>60–Day Delay of Effective Date To 05/22/2001</td>
<td>03/21/01</td>
<td>66 FR 15800</td>
</tr>
<tr>
<td>Interim Final Rule Comment Period End</td>
<td>03/23/01</td>
<td></td>
</tr>
<tr>
<td>Interim Final Rule Effective</td>
<td>03/23/01</td>
<td></td>
</tr>
<tr>
<td>Interim Final Rule Amendment with Clarification</td>
<td>05/22/01</td>
<td>66 FR 28110</td>
</tr>
<tr>
<td>Interim Final Rule Comment Period End</td>
<td>07/23/01</td>
<td></td>
</tr>
<tr>
<td>Final Action</td>
<td>04/00/05</td>
<td></td>
</tr>
</tbody>
</table>

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

Agency Contact: Larry Cutler, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S2–14–26, Center for Medicaid and State Operations, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–5903
RIN: 0938–AJ96

976. REVISIONS TO THE MEDICARE APPEALS PROCESS (CMS–4004–FC)

Priority: Other Significant
Legal Authority: Sec 521 of BIPA
CFR Citation: 42 CFR 405


Abstract: This final rule with comment period addresses one discrete aspect of the November 15, 2002, proposed rule, "Changes to the Medicare Claims Appeal Procedures" (67 FR 69312). As required by section 1869(b)(1)(F) of the Social Security Act, this rule establishes expedited determination and reconsideration procedures for beneficiaries who are informed by a provider that Medicare coverage of their services is about to end. This rule implements section 937 of the Medicare Modernization Act which requires a process for correction of minor errors and omissions without pursing the appeals process.

Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>11/15/02</td>
<td>67 FR 69312</td>
</tr>
<tr>
<td>Final Action</td>
<td>05/00/05</td>
<td></td>
</tr>
</tbody>
</table>

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

Agency Contact: Janet Miller, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, N2–14–26, S1–06–04, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–1358
RIN: 0938–AL67

977. 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 annual notice updates the payment rates used under the skilled nursing facilities prospective payment system beginning October 1, 2004.

Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>07/00/04</td>
<td></td>
</tr>
</tbody>
</table>

Regulatory Flexibility Analysis Required: Yes
Small Entities Affected: Businesses
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, Baltimore, MD 21244
Phone: 401 786–5667
RIN: 0938–AM46

979. TITLE I: NON–FEDERAL GOVERNMENTAL PLANS EXEMPT FROM HIPAA (CMS–2033–F)

Priority: Substantive, Nonsignificant.
Legal Authority: Sec 2721(b)(2) of the Public Health Service Act
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.

**Timetable:**

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interim Final Rule With</td>
<td>07/26/02</td>
<td>67 FR 48802</td>
</tr>
<tr>
<td>Comment Period</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Final Action</td>
<td>08/00/04</td>
<td></td>
</tr>
</tbody>
</table>

**Regulatory Flexibility Analysis Required:** No

**Government Levels Affected:** Federal

**Agency Contact:** Janet Miller, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, N2–14–26, S1–06–04, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786–1588

**Related RIN:** Related to 0938–AK69

RIN: 0938–AM73

---

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

**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.

---

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

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

**Unfunded Mandates:** Undetermined

**Legal Authority:** Sec 521 of BIPA

**CFR Citation:** 42 CFR 405

**Legal Deadline:** None

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

---

**982. 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, effective date. Wage Index update is effective October 1, of each year.

**Abstract:** This notice announces 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 the recommendations of a negotiated rulemaking advisory committee and were originally published on August 8, 1997.

---

**983. CHANGES TO THE HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEM AND FY 2005 RATES (CMS–1428–F)**

**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

**Legal Deadline:** NPRM, Statutory, April 1, 2004. Final, Statutory, August 1, 2004.

**Abstract:** This proposed rule 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, the Addendum,
985. HOME HEALTH PROSPECTIVE PAYMENT SYSTEM RATE UPDATE FY 2005 (CMS–1265–P)

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

Legal Authority: Sec 1895 of the Social Security Act; ; Sec 421 of the MMA; Sec 701 of the MMA

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. It also proposes to rebase and revise the home health market basket to reflect total cost and modify certain variables for some of the cost categories. It implements sections 421 (one-year increase in rural areas) and 701 (move to CY updates) of the Medicare Modernization Act (effective April 1, 2004). (The proposed and final rules must be published by September 30, 2004, to allow three months for systems changes.)

Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>06/02/04</td>
<td>69 FR 31248</td>
</tr>
<tr>
<td>Final Action</td>
<td>10/00/04</td>
<td></td>
</tr>
</tbody>
</table>

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Federal

Agency Contact: Tzvi Heftel, 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–AM82

---

986. • CHANGES TO MEDICARE PAYMENT FOR DRUGS AND PHYSICIAN FEE SCHEDULE PAYMENTS FOR CALENDAR YEAR 2004—CORRECTION NOTICE CMS–1372–IFC)

Priority: Economically Significant. Major under 5 USC 801.

Legal Authority: Medicare Prescription Drug, Improvement and Modernization Act of 2003

Legal Citation: 42 CFR 405; 42 CFR 414


Abstract: This final rule with comment implements section 602 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003. Specifically, it revises the payment methodology under Medicare for Part B covered drugs and biologicals that are not paid on a cost or prospective payment basis; makes adjustments to payment for certain drug administration services under the physician fee schedule; makes revisions to the geographic practice expense cost indices used for determining payment under the physician fee schedule and announces a 1.5 percent increase in the calendar year 2004 physician fee schedule conversion factor.

Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interim Final Rule</td>
<td>01/07/04</td>
<td>69 FR 1084</td>
</tr>
<tr>
<td>Interim Final Rule</td>
<td>03/04/04</td>
<td></td>
</tr>
<tr>
<td>Correction</td>
<td>03/26/04</td>
<td>69 FR 15703</td>
</tr>
<tr>
<td>Correction</td>
<td>06/00/04</td>
<td></td>
</tr>
</tbody>
</table>

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: Federal

Agency Contact: Marc Hartstein, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Blvd, Baltimore, MD 21244

Phone: 410 786–4539

Email: mhartstein@cms.hhs.gov

RIN: 0938–AM97
987. • PHYSICIANS’ REFERRALS TO HEALTH CARE ENTITIES WITH WHICH THEY HAVE FINANCIAL RELATIONSHIPS: EXTENSION OF PARTIAL DELAY OF EFFECTIVE DATE (CMS–1809–F5)

Priority: Routine and Frequent
Legal Authority: Sec 1877 of the Social Security Act
CFR Citation: None
Legal Deadline: None
Abstract: This final rule delays for six months the effective date of the last sentence of 42 CFR 411.354(d)(1) of the physician self-referral rule published on January 4, 2001. This sentence defines compensation that is “set in advance” as it relates to percentage compensation methodologies.

<table>
<thead>
<tr>
<th>Timetable:</th>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Final Action</td>
<td>07/00/04</td>
<td></td>
</tr>
<tr>
<td>Regulatory Flexibility Analysis</td>
<td>Required: No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Small Entities Affected</td>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Government Levels Affected</td>
<td>None</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Agency Contact</td>
<td>Karen Raschke, Department of Health and Human Services, Centers for Medicare &amp; Medicaid Services, 7500 Security Blvd, Baltimore, MD 21244</td>
<td>Phone: 410 786–0016</td>
<td>Email: <a href="mailto:kraschke@cms.hhs.gov">kraschke@cms.hhs.gov</a></td>
</tr>
<tr>
<td>Related RIN</td>
<td>Related to 0938–AL29, Related to 0938–AM58, Related to 0938–AM95</td>
<td></td>
<td></td>
</tr>
<tr>
<td>RIN</td>
<td>0938–AN11</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

988. • TIME LIMITATION ON RECORD KEEPING REQUIREMENTS UNDER THE DRUG REBATE PROGRAM (CMS–2188–P)

Priority: Other Significant. Major status under 5 USC 801 is undetermined.
Unfunded Mandates: Undetermined
Legal Authority: Not Yet Determined
CFR Citation: Not Yet Determined
Legal Deadline: None
Abstract: This proposed rule would establish ten-year record keeping requirements for drug manufacturers under the Medicaid drug rebate program.

<table>
<thead>
<tr>
<th>Timetable:</th>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Final Action</td>
<td>06/00/04</td>
<td></td>
</tr>
<tr>
<td>Regulatory Flexibility Analysis</td>
<td>Required: No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Small Entities Affected</td>
<td>Governmental Jurisdictions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Government Levels Affected</td>
<td>State</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Agency Contact</td>
<td>Richard Strauss, Division Director, Division of Financial Management, Department of Health and Human Services, Centers for Medicare &amp; Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244</td>
<td>Phone: 410 786–2019</td>
<td>Email: <a href="mailto:rstrauss@cms.hhs.gov">rstrauss@cms.hhs.gov</a></td>
</tr>
<tr>
<td>RIN</td>
<td>0938–AN03</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

990. • FY 2005 SCHIP ALLOTMENTS (CMS–2201–N)

Priority: Economically Significant
Legal Authority: Title XXI of the Social Security Act, sec 2104
CFR Citation: 42 CFR 457
Legal Deadline: None
Abstract: This notice sets forth the final allotments of Federal funding available to each State, the District of Columbia, and each U.S. Territory and Commonwealth for fiscal year 2005. (The notice must be published as soon as possible so that the funds can be distributed to the States before September 30, 2004, as required by the statute.)

<table>
<thead>
<tr>
<th>Timetable:</th>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Final Action</td>
<td>08/00/04</td>
<td></td>
</tr>
<tr>
<td>Regulatory Flexibility Analysis</td>
<td>Required: No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Small Entities Affected</td>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Government Levels Affected</td>
<td>State</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Agency Contact</td>
<td>Richard Strauss, Director, Division of Financial Management, Department of Health and Human Services, Centers for Medicare &amp; Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244</td>
<td>Phone: 410 786–2019</td>
<td>Email: <a href="mailto:rstrauss@cms.hhs.gov">rstrauss@cms.hhs.gov</a></td>
</tr>
<tr>
<td>RIN</td>
<td>0938–AN11</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

991. • SCHEDULE FOR PUBLISHING MEDICARE FINAL REGULATIONS AFTER A PROPOSED OR INTERIM FINAL REGULATION (CMS–9026–N)

Priority: Info./Admin./Other
Legal Authority: Sec 902 of the Medicare Modernization Act of 2003
CFR Citation: None
Legal Deadline: None
Abstract: In accordance with Section 902 of the Medicare Modernization Act of 2003, this rule establishes a regular timeline for the publication of final regulations based on the previous publication of a proposed or interim final regulation.

<table>
<thead>
<tr>
<th>Timetable:</th>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Notice</td>
<td>09/00/04</td>
<td></td>
</tr>
<tr>
<td>Regulatory Flexibility Analysis</td>
<td>Required: No</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Renee Swann, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–4492
Email: rswann@cms.hhs.gov
RIN: 0938–AN12

992. • EVALUATION CRITERIA AND STANDARDS FOR QUALITY IMPROVEMENT PROGRAM CONTRACTS (CMS–3142–NC)

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

Legal Authority: Sec 1153(h)(2) of the Social Security Act

CFR Citation: None


There is a 60 day comment period required for the evaluation criteria used in evaluating the Quality Improvement Organizations.

Abstract: Section 1153(h)(2) of the Act requires the Secretary to publish in the Federal Register the general criteria and standards that will be used to evaluate the Quality Improvement Organizations (QIOs), and provide opportunity for public comment. This notice will describe the evaluation criteria CMS will use to evaluate the QIOs. There should be no additional costs associated with this requirement. The evaluation portion of the contract has already been factored into the award. (This notice with comment period must already been factored into the award. This notice will use to evaluate the QIOs. There will be no additional costs associated with this requirement. The evaluation portion of the contract has already been factored into the award.)

Timetable:

Action Date FR Cite
Notice 10/00/04
Regulatory Flexibility Analysis Required: No
Small Entities Affected: No

993. • PART A PREMIUMS FOR CALENDAR YEAR 2005 FOR THE UNINSURED AGED AND FOR CERTAIN DISABLED INDIVIDUALS WHO HAVE EXHAUSTED OTHER ENTITLEMENT (CMS–8022–N)

Priority: Other Significant

Legal Authority: 42 USC 1395–2(d)(2); Social Security Act, sec 1818(d)(2); Social Security Act, sec 1818A(d)(2)

CFR Citation: None


Abstract: This notice announces the hospital insurance premium for Calendar Year 2005 under Medicare's Hospital Insurance Program (Medicare part A) for the uninsured aged and for certain disabled individuals who have exhausted other entitlement. (CMS generally publishes this notice to coincide with the SSA Cola announcement.)

Timetable:

Action Date FR Cite
Notice 10/00/04
Regulatory Flexibility Analysis Required: No
Small Entities Affected: No

994. • INPATIENT HOSPITAL DEDUCTIBLE AND HOSPITAL AND EXTENDED CARE SERVICES COINSURANCE AMOUNTS FOR CALENDAR YEAR 2005 (CMS–8021–N)

Priority: Other Significant

Legal Authority: 42 USC 1395–2 (b) (2); Social Security Act section 1813 (b) (2)

CFR Citation: None


Abstract: This notice announces the inpatient hospital deductible and the hospital and extended care services coinsurance amounts for services furnished in Calendar Year 2005 under Medicare's Hospital Insurance program (Medicare part A). The Medicare statute specifies the formula used to determine these amounts. (CMS generally publishes this notice to coincide with the SSA Cola announcement.)

Timetable:

Action Date FR Cite
Notice 10/00/04
Regulatory Flexibility Analysis Required: No
Small Entities Affected: No

995. • MEDICARE PART B MONTHLY ACTUARIAL RATES AND PREMIUM RATE BEGINNING JANUARY 1, 2005 (CMS–8020–N)

Priority: Other Significant

Legal Authority: 42 USC 1395r; Social Security Act, sec 1839; MMA, sec 629; MMA, sec 811

CFR Citation: None


Abstract: Section 629 of the Medicare Modernization Act requires indexing the part B deductible to inflation beginning January 1, 2005. This notice announces the monthly actuarial rates for aged (65 and over) and disabled

Timetable:

Action Date FR Cite
Notice 10/00/04
Regulatory Flexibility Analysis Required: No
Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Renee Swann, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–4492
Email: rswann@cms.hhs.gov
RIN: 0938–AN12

Government Levels Affected: None

Agency Contact: Maria L, Hammel, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–1775
Email: mhammel@cms.hhs.gov
RIN: 0938–AN13

Government Levels Affected: None

Agency Contact: Clare McFarland, Deputy Director, Medicare & Medicaid Cost Estimates Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–6390
Email: cmcfarland@cms.hhs.gov
RIN: 0938–AN16

Government Levels Affected: None

Agency Contact: Clare McFarland, Deputy Director, Medicare & Medicaid Cost Estimates Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–6390
Email: cmcfarland@cms.hhs.gov
RIN: 0938–AN15
(under age 65) enrollees in part B of Medicare for 2005. It also announces the monthly Part B premium to be paid by all enrollees during 2005. (CMS generally publishes this notice to coincide with the SSA Cola announcement.)

Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>Final Action</td>
<td>10/00/04</td>
<td></td>
</tr>
</tbody>
</table>

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

Agency Contact: Carter Warfield, Deputy Director, Medicare & Medicaid Cost Estimates Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–6396
Email: cwarfield@cms.hhs.gov
RIN: 0938–AN18

996. • FEE SCHEDULE FOR PAYMENT OF AMBULANCE SERVICES—UPDATE FOR CALENDAR YEAR 2005 (CMS–1267–N)

Priority: Economically Significant. Major under 5 USC 801.
Legal Authority: 1861(S)(7); 1834(i)(3)(B); 221 BIPA
CFR Citation: 414.610(c)(5) CFR; 414.615 CFR; 414.620 CFR

Abstract: This notice updates the fee schedule for ambulance services under the Medicare program, implementing regulations published in 2004, to be consistent with the SSA Cola

Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>Final Action</td>
<td>08/00/04</td>
<td></td>
</tr>
</tbody>
</table>

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

Agency Contact: Vadim Lubarsky, Technical Advisor, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–0840
Email: vlubarsky@cms.hhs.gov
RIN: 0938–AN22

999. • MEDICARE AMBULANCE FEE SCHEDULE UPDATE (CMS–1492–IFC)

Priority: Economically Significant. Major under 5 USC 801 is undetermined.
Legal Authority: Sec 1834(i) of the Social Security Act; Sec 414 of the MMA
CFR Citation: 42 CFR 414, subpart H

Abstract: This notice updates the fee schedule for ambulance services under the Medicare program, implementing regulations published in 2004, to be consistent with the SSA Cola

Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interim Final Rule</td>
<td>07/00/04</td>
<td></td>
</tr>
</tbody>
</table>
1001. • RANDOM PREPAYMENT REVIEW (CMS–6022–IFC)

Priority: Other Significant. Major under 5 USC 801.

Legal Authority: Sec 934 of the MMA

CFR Citation: Not Yet Determined


Abstract: Section 934 of the Medicare Modernization Act establishes requirements for prepayment medical review of a provider beginning December 8, 2004. This regulation will establish contractor standards relating to the initiation and termination of nonrandom prepayment review.

Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interim Final Rule With Comment Period</td>
<td>12/00/04</td>
<td></td>
</tr>
</tbody>
</table>

1002. • ADDITIONAL PAYMENTS FOR CERTAIN MEDICARE PART B DRUGS (CMS–1280–FC)

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

Legal Authority: Sec 303(e)(2) of the Medicare Modernization Act of 2003

CFR Citation: 42 CFR 414.1002

Legal Deadline: None

Abstract: This final rule with comment period continues the implementation of section 303(e)(2) of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 by establishing a separate billable fee to be paid to pharmacies for supplying certain Medicare part B drugs and biologicals.
### 1004. FIRE SAFETY REQUIREMENTS FOR CERTAIN HEALTH CARE FACILITIES, AMENDMENT (CMS–3047–F2)

**Priority:** Other Significant  
**Legal Authority:** Not Yet Determined  
**CFR Citation:** None  
**Legal Deadline:** None

**Abstract:** This final rule amends the fire safety standard for religious nonmedical health care institutions, hospices, programs of all-inclusive care for the elderly, hospitals, long term care facilities, intermediate care facilities for the mentally retarded, and critical access hospitals that participate in Medicare and Medicaid. The rule would adopt a change made to the 2000 edition of the Life Safety Code (LSC) published by the National Fire Protection Association (NFPA). We adopted the 2000 edition of the LSC in January 2003. The LSC change will allow facilities to place alcohol-based hand sanitizer dispensers in exit corridors under certain conditions. These sanitizers have proven to be effective in increasing hand hygiene and have the potential to improve infection control practice. Adopting the LSC change would increase a provider’s flexibility in meeting infection control goals while minimizing potential fire safety concerns.

#### Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date (FR Cite)</th>
<th>Final Action 05/00/05</th>
</tr>
</thead>
</table>

#### Final Rule Stage

**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** None

**Government Levels Affected:** None

**Agency Contact:** Danielle Shearer, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of Clinical Standards and Quality, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786–6617  
RIN: 0938–AN36

---

### 1005. REQUIREMENTS FOR ESTABLISHING AND MAINTAINING MEDICARE BILLING PRIVILEGES (CMS–6002–F)

**Priority:** Other Significant  
**Legal Authority:** 42 USC 1302; 42 USC 1395hh  
**CFR Citation:** 42 CFR 424  
**Legal Deadline:** None

**Abstract:** This final rule is needed as part of the Administration’s anti-fraud and abuse efforts. It would give HHS the authority to enroll and re-enroll providers with time frames for re-enrollment.

#### Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date (FR Cite)</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>04/25/03, 68 FR 22064</td>
</tr>
<tr>
<td>Final Action</td>
<td>04/00/06</td>
</tr>
</tbody>
</table>

**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** Businesses

**Government Levels Affected:** None

**Agency Contact:** Michael Collett, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of Financial Management, C3–02–06, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786–6121  
RIN: 0938–AH73

---

### 1006. MEDICARE OUTCOME AND ASSESSMENT INFORMATION SET (OASIS) DATA REPORTING REQUIREMENTS (CMS–3006–F)

**Priority:** Other Significant. Major under 5 USC 801.  
**Unfunded Mandates:** This action may affect State, local or tribal governments and the private sector.  
**Legal Authority:** 42 USC 1302; 42 USC 1395hh  
**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>
<thead>
<tr>
<th>Action</th>
<th>Date (FR Cite)</th>
<th>Final Action 05/00/05</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>04/25/03</td>
<td>68 FR 22064</td>
</tr>
<tr>
<td>Final Action</td>
<td>04/00/06</td>
<td></td>
</tr>
</tbody>
</table>

**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 Boulevard, Baltimore, MD 21244  
Phone: 410 786–9614  
RIN: 0938–AJ10

---

### 1007. 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 HCV infection; notify transfusion recipients, as appropriate, of the need for HCV testing and counseling; and maintain records for at least 10 years.

#### Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date (FR Cite)</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>11/16/00</td>
</tr>
<tr>
<td>Final Action</td>
<td>To Be Determined</td>
</tr>
</tbody>
</table>

**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** Businesses

**Government Levels Affected:** None
1008. MEDICARE HOSPICE CARE AMENDMENTS (CMS–1022–F)

Priority: Substantive, Nonsignificant
Legal Authority: PL 105–33, sec 1961(dd); PL 105–33, sec 1814(i); PL 105–33, sec 4441 to 4444; PL 105–33, sec 4448; PL 106–113, sec 131; PL 106–554, sec 321; PL 106–554, sec 322; PL 105–33, sec 4449
CFR Citation: 42 CFR 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.
Timetable:
<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>11/22/02</td>
<td>67 FR 70363</td>
</tr>
<tr>
<td>Final Action</td>
<td>11/00/05</td>
<td></td>
</tr>
</tbody>
</table>

Regulatory Flexibility Analysis
Required: No
Small Entities Affected: Businesses, Organizations
Government Levels Affected: None
Agency Contact: Mary Collins, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of Clinical Standards and Quality, 7500 Security Boulevard, S3–02–01, Baltimore, MD 21244
Phone: 410 786–3189
RIN: 0938–AJ29

1009. PHYSICIANS’ REFERRALS TO HEALTH CARE ENTITIES WITH WHICH THEY HAVE FINANCIAL RELATIONSHIPS—PHASE II (CMS–1810–IFC)

Priority: Other Significant
Legal Authority: 42 USC 1877
CFR Citation: 42 CFR 411 & 424
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.

1010. CONTINUATION OF MEDICARE ENTITLEMENT WHEN DISABILITY BENEFIT ENDS BECAUSE OF SUBSTANTIAL GAINFUL ACTIVITY (CMS–4018–F)

Priority: Substantive, Nonsignificant
Legal Authority: Sec 202 of the TWWIIA of 1999; PL 106–170
CFR Citation: 42 CFR 406.12
Legal Deadline: None
Abstract: This final rule will change the formula for computing interest on overpayments and underpayments to make it consistent with the new CMS accounting system, Healthcare Integrated General Ledger Accounting System.

Timetable:
<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>07/25/03</td>
<td>68 FR 43995</td>
</tr>
<tr>
<td>Final Action</td>
<td>07/00/06</td>
<td></td>
</tr>
</tbody>
</table>

Regulatory Flexibility Analysis
Required: No
Small Entities Affected: None
Government Levels Affected: None
Agency Contact: Nancy Braymer, Financial Management Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C3–14–21, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–4323
RIN: 0938–AL14

1011. 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; 42 CFR 411.24
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.
Timetable:
<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>07/25/03</td>
<td>68 FR 43998</td>
</tr>
<tr>
<td>Final Action</td>
<td>07/00/06</td>
<td></td>
</tr>
</tbody>
</table>

Regulatory Flexibility Analysis
Required: No
Small Entities Affected: None
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–AK94
1012. HEALTH COVERAGE PORTABILITY FOR GROUP HEALTH PLANS AND GROUP HEALTH INSURANCE ISSUERS (CMS–2151–F)

Priority: Other Significant. Major under 5 USC 801.

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

CFR Citation: 45 CFR 144.103; 45 CFR 146.111; 45 CFR 146.113; 45 CFR 146.115; 45 CFR 146.117; 45 CFR 146.119; 45 CFR 146.120; 45 CFR 146.125; 45 CFR 146.143; ...

Legal Deadline: None

Abstract: This final rule provides portability requirements for group health plans and issuers of health insurance coverage offered in connection with a group health plan under the Health Insurance Portability and Accountability Act of 1996. This regulation addresses limitations or preexisting exclusion periods on requests for special enrollments.

Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interim Final Rule</td>
<td>04/08/97</td>
<td>62 FR 16894</td>
</tr>
<tr>
<td>Interim Final Rule End</td>
<td>07/07/97</td>
<td></td>
</tr>
<tr>
<td>Effective Final Rule</td>
<td>07/07/97</td>
<td></td>
</tr>
<tr>
<td>Regulatory Flexibility Analysis Required</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Small Entities Affected</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Government Levels Affected</td>
<td>Federal, Local, State</td>
<td></td>
</tr>
</tbody>
</table>

Agency Contact: Lana Price, Director, Division of Chronic Care Management, Chronic Policy Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C5–05–27, Center for Medicare Management, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786–4533

RIN: 0938–AL50

1014. DMERC SERVICE AREAS AND RELATED MATTERS (CMS–1219–F)

Priority: Substantive, Nonsignificant

Legal Authority: Sec 1842 of the Social Security Act; Sec 1834(a)(12) of the Social Security Act; Sec 1834(h)(3) of the Social Security Act; Sec 1834(j)(1) of the Social Security Act

CFR Citation: 42 CFR 421.210

Legal Deadline: None

Abstract: This rule allows flexibility in making changes to the DMERC contractor structure.

Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>12/24/03</td>
<td>68 FR 74607</td>
</tr>
<tr>
<td>Final Action</td>
<td>12/00/06</td>
<td></td>
</tr>
</tbody>
</table>

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

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: 410 786–4635

RIN: 0938–AM36

1015. PROCEDURES FOR MAINTAINING CODE LISTS IN THE NEGOTIATED NATIONAL COVERAGE DETERMINATIONS FOR CLINICAL DIAGNOSTIC LABORATORY SERVICES (CMS–3119–F)

Priority: Other Significant

Legal Authority: 42 USC 1395h(a); 42 USC 1395e; 42 USC 1395x; 42 USC 1395y(a)(1)(A); 42 USC 1395y(a)(7)

CFR Citation: None

Legal Deadline: None

Abstract: This final rule establishes the procedures to be used for maintaining the lists of codes that were included in the national coverage determinations (NCDs) that were announced in 66 FR 58788 on November 25, 2001.

Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>12/24/03</td>
<td>68 FR 74607</td>
</tr>
<tr>
<td>Final Action</td>
<td>12/00/06</td>
<td></td>
</tr>
</tbody>
</table>

Regulatory Flexibility Analysis Required: No

Small Entities Affected: None

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: 410 786–4635

RIN: 0938–AL76

1016. HOSPITAL PATIENTS’ RIGHTS COP—STANDARD SAFETY COMPLIANCE COMMITTEES (CMS–3120–P)

Priority: Economically Significant. Major under 5 USC 801.

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

CFR Citation: 42 CFR 482

Legal Deadline: None

Abstract: This proposed rule would allow hospitals to waive the current requirement that a physician or licensed independent practitioner perform a one-hour face-to-face
evaluation of a patient in restraint or seclusion for the purpose of behavior management. Under this proposed rule, a hospital could choose to have the one-hour assessment performed by another practitioner, such as a registered nurse, if that hospital established a Protections Compliance Committee to oversee the use of restraint or seclusion.

**Timetable:**

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>To Be Determined</td>
<td></td>
</tr>
</tbody>
</table>

**Regulatory Flexibility Analysis**

**Required:** Yes

**Small Entities Affected:** Businesses, Organizations

**Government Levels Affected:** Undetermined

**Federalism:** Undetermined

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

Phone: 410 786–6775

RIN: 0938–AM39

---

**1017. REQUIREMENTS FOR NURSING HOMES TO IDENTIFY THE NUMBER OF LICENSED AND UNLICENSED NURSES (CMS–3121–F)**

**Priority:** Other Significant

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

**CFR Citation:** 42 CFR 483

**Legal Deadline:** None

**Abstract:** This final rule implements section 941 of the Medicare, Medicaid, and SCHIP benefits Improvement and Protection Act and requires nursing homes to post daily, for each shift, the number of full-time equivalents (FTEs) of registered nurses, licensed practical nurses, licensed vocational nurses, and certified nurse aides who are directly responsible for resident care.

**Timetable:**

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Regulatory Flexibility Analysis**

**Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** None

**Agency Contact:** Anita Panicker, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S3–04–26, Office of Clinical Standards and Quality, 7500 Security Boulevard, S3–02–01, Baltimore, MD 21244

Phone: 410 786–5646

RIN: 0938–AM55

---

**1018. COVERED OUTPATIENT DRUGS UNDER THE MEDICAID DRUG REBATE PROGRAM (CMS–2174–P)**

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

**Unfunded Mandates:** Undetermined

**Legal Authority:** Sec 1905 (a) (12) of the Social Security Act; Sec 1903 (a) (10) of the Social Security Act; Sec 1902(a)(4) of the Social Security Act; Sec 1902(a)(54) of the Social Security Act; Sec 1903 of the Social Security Act; Sec 1903 (i) (10) of the Social Security Act; Sec 1927 of the Social Security Act

**CFR Citation:** 42 CFR 441 ; 42 CFR 447

**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:**

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>To Be Determined</td>
<td></td>
</tr>
</tbody>
</table>

**Regulatory Flexibility Analysis**

**Required:** Undetermined

**Government Levels Affected:** Federal, State

**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

---

**1019. REVISIONS TO COST SHARING REGULATIONS (CMS–2144–P)**

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

**Unfunded Mandates:** Undetermined

**Legal Authority:** Sec 1916 of the Social Security Act; Sec 1902(a)(4) of the Social Security Act

**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:**

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>To Be Determined</td>
<td></td>
</tr>
</tbody>
</table>

**Regulatory Flexibility Analysis**

**Required:** Undetermined

**Government Levels Affected:** Federal, State

**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

---

**1020. MEDICARE PROGRAM; HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM PAYMENT REFORM FOR CALENDAR YEAR 2004 CMS–1371–IFC**

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

**Legal Authority:** Not Yet Determined

**CFR Citation:** Not Yet Determined

**Legal Deadline:** Final, Statutory, January 1, 2004.

**Abstract:** This rule revises payment rates for drugs in 2004 and 2005. (Section 621 of MMA requires the rule to be implemented by January 1, 2004.)
### Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interim Final Rule</td>
<td>01/06/04</td>
<td>69 FR 820</td>
</tr>
<tr>
<td>Final Action</td>
<td>01/00/07</td>
<td></td>
</tr>
</tbody>
</table>

### Regulatory Flexibility Analysis Required: Undetermined

### Government Levels Affected: Undetermined

### Federalism: Undetermined

### Agency Contact: Dana Buley, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Blvd, Baltimore, MD 21244

### Phone: 410 786–4547

### Email: dbuley@cms.hhs.gov

### RIN: 0938–AM96

### 1021. • PAYMENT FOR RESPIRATORY ASSIST DEVICES WITH BI–LEVEL CAPABILITY AND A BACK–UP RATE (CMS–1167–F)

#### Priority: Other Significant

#### Unfunded Mandates: Undetermined

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

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

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

#### Abstract: This final rule clarifies that respirator assist devices with bi-level capability and a back-up rate must be classified as capped rental Durable Medical equipment (DME) in accordance with section 1834(a)(3) of the Social Security Act (42 USC 1395(m)(3)).

#### Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interim Final Rule</td>
<td>04/06/04</td>
<td>69 FR 17935</td>
</tr>
<tr>
<td>Final Action</td>
<td>04/00/07</td>
<td></td>
</tr>
</tbody>
</table>

### Regulatory Flexibility Analysis Required: No

### Small Entities Affected: None

### Government Levels Affected: Federal

### Agency Contact: Angela Mason, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, C4–05–17, Baltimore, MD 21244

### Phone: 410 786–7452

### Email: amason@cms.hhs.gov

### RIN: 0938–AN05

### 1022. • MANUFACTURERS’ SUBMISSION OF AVERAGE SALES PRICE DATA FOR MEDICARE PART B DRUGS AND BIOLOGICALS (CMS–1380–IFC)

#### Priority: Other Significant

#### Unfunded Mandates: Undetermined

#### Legal Authority: Sec 303(c) of the MMA 2003

#### CFR Citation: Not Yet Determined

#### Legal Deadline: None

#### Abstract: Section 303(c) of the Medicare Prescription Drug Improvement and Modernization Act requires manufacturers to submit average sales price data on Medicare part B drugs. This regulation provides instruction to manufacturers on the data submission requirements.

#### Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interim Final Rule</td>
<td>04/06/04</td>
<td>69 FR 17935</td>
</tr>
<tr>
<td>Final Action</td>
<td>04/00/07</td>
<td></td>
</tr>
</tbody>
</table>

### Regulatory Flexibility Analysis Required: No

### Small Entities Affected: None

### Government Levels Affected: None

### Agency Contact: Elizabeth Carmody, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244

### Phone: 410 786–7533

### Email: ecarmody@cms.hhs.gov

### RIN: 0938–AN19

### 1023. • NONDISCRIMINATION IN HEALTH COVERAGE AND BONAFIDE WELLNESS PLANS IN THE GROUP MARKET (CMS–2017–F)

#### Priority: Substantive, Nonsignificant.

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

#### Legal Authority: 42 USC 300g

#### CFR Citation: 45 CFR 146.121

#### Legal Deadline: None

#### Abstract: This document contains final rules governing the provisions prohibiting discrimination based on a health factor for group health plans and issuers of health insurance coverage offered in connection with a group health plan. The rules contained in this document implement changes made to the Internal Revenue Code of 1986 (Code), the Employee Retirement Income Security Act of 1974, and the Public Health Service Act enacted as part of the Health Insurance Portability and Accountability Act of 1996. It also addresses comments we received on the Bonafide Wellness Plan proposed rule (CMS-2078-P).

#### Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interim Final Rule</td>
<td>04/08/97</td>
<td>62 FR 16894</td>
</tr>
<tr>
<td>Interim Final Rule</td>
<td>09/17/97</td>
<td></td>
</tr>
<tr>
<td>Effective</td>
<td>07/17/97</td>
<td></td>
</tr>
</tbody>
</table>

### Regulatory Flexibility Analysis Required: None

### Small Entities Affected: None

### Government Levels Affected: None

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

### Phone: 410 786–4499

### Email: jkaiser@cms.hhs.gov

### Related RIN: Related to 0938–AL27

### RIN: 0938–AN02

### 1024. • NONDISCRIMINATION IN POST–HOSPITAL REFERRAL TO HOME HEALTH AGENCIES AND OTHER ENTITIES (CMS–1224–F)

#### Priority: Substantive, Nonsignificant

#### Legal Authority: PL 105–33, sec 4321 of the BBA

#### CFR Citation: 42 CFR 482

#### Legal Deadline: None

#### Abstract: This final rule establishes a process for collecting and maintaining information about hospitals referring Medicare patients to home health agencies (HHAs) with which the hospitals have a financial interest. Collected information will be available to the public to enhance its understanding and awareness of the availability of Medicare-certified HHAs to serve the Medicare population. (This final rule must be published by November 22, 2005, to meet the three-year publication deadline.)

#### Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interim Final Rule</td>
<td>11/22/02</td>
<td>67 FR 70373</td>
</tr>
<tr>
<td>Final Action</td>
<td>11/00/05</td>
<td></td>
</tr>
</tbody>
</table>

### Regulatory Flexibility Analysis Required: No

### Small Entities Affected: None

### Government Levels Affected: None

### Agency Contact: Angela Mason, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, C4–05–17, Baltimore, MD 21244

### Phone: 410 786–7452

### Email: amason@cms.hhs.gov

### RIN: 0938–AN05
1025. • HOSPITAL CONDITIONS OF PARTICIPATION: PATIENTS' RIGHTS (CMS–3018–F)
Priority: Other Significant. Major status under 5 USC 801 is undetermined.
Legal Authority: 42 USC 1395x; 42 USC 1396d; 42 USC 1395bb
CFR Citation: 42 CFR 482

Legal Deadline: None
Abstract: This final rule sets forth standards for the use of restraints and seclusion in Medicare- and Medicaid-participating hospitals as part of the Patients' Rights Condition of Participation (CoP) and finalizes other patients' rights afforded by that CoP. It finalizes six standards that ensure minimum protections of each patient's physical and emotional health and safety. These standards address each patient's right to: 1) notification of his or her rights; 2) the exercise of his or her rights in regard to his or her care; 3) privacy and safety; 4) confidentiality of patient records; 5) freedom from restraints used in the provision of acute medical and surgical care unless clinically necessary; and 6) freedom from seclusion and restraint for behavior management unless clinically necessary.

Timetable:
Action Date FR Cite
Final Action 12/00/06
Regulatory Flexibility Analysis Required: No
Small Entities Affected: Businesses, Governmental Jurisdictions
Government Levels Affected: Local, State
Agency Contact: David Mlawsky, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–6851
Email: dmlawsky@cms.hhs.gov
RIN: 0938–AN29

1026. HEALTH INSURANCE REFORM: STANDARD UNIQUE HEALTH CARE PROVIDER IDENTIFIER (CMS–0045–F)
Priority: Other Significant. Major under 5 USC 801.
CFR Citation: 42 CFR 160; 42 CFR 162

Completed:
Reason Date FR Cite
Withdrawn 06/02/04
Regulatory Flexibility Analysis Required: Yes
Small Entities Affected: Businesses
Government Levels Affected: Federal, Local, State, Tribal
Agency Contact: Patricia Peyton
Phone: 410 786–1812
Email: ppeyton@cms.hhs.gov
RIN: 0938–AH99

1027. COVERAGE OF RELIGIOUS NONMEDICAL HEALTH CARE INSTITUTIONS (CMS–1909–F)
Priority: Substantive, Nonsignificant
CFR Citation: 42 CFR 403.736; 42 CFR 403.738; 42 CFR 403.102

Completed:
Reason Date FR Cite
Withdrawn 06/02/04
Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: None
Agency Contact: Katie Walker
Phone: 410 786–7278
Email: kwalker@cms.hhs.gov
RIN: 0938–AK02

1028. ALL PROVIDER BAD DEBT PAYMENT (CMS–1126–F)
Priority: Other Significant
Legal Authority: 42 USC 1395x; 42 USC 1396d
CFR Citation: 42 CFR 413.180; 42 CFR 413.178

Completed:
Reason Date FR Cite
Withdrawn 06/02/04
Regulatory Flexibility Analysis Required: No
Small Entities Affected: No
Government Levels Affected: None
Agency Contact: Vadim Lubarsky
Phone: 410 786–0840
Email: vlubarsky@cms.hhs.gov
RIN: 0938–AK60

1029. REVIEW OF NATIONAL COVERAGE DETERMINATIONS AND LOCAL COVERAGE DETERMINATIONS (CMS–3063–F)
Priority: Other Significant
CFR Citation: 42 CFR 405

Completed:
Reason Date FR Cite
Final Action 11/07/03 68 FR 63691
Regulatory Flexibility Analysis Required: No
Small Entities Affected: No
Government Levels Affected: None
Agency Contact: Vadim Lubarsky
Phone: 410 786–0840
Email: vlubarsky@cms.hhs.gov
RIN: 0938–AK60

1030. RATE OF REIMBURSEMENT OF PHOTOCOPY EXPENSES FOR QUALITY IMPROVEMENT ORGANIZATIONS (CMS–3055–F)
Priority: Substantive, Nonsignificant
CFR Citation: 42 CFR 476.78

Completed:
Reason Date FR Cite
Final Action 12/05/03 68 FR 67955
Regulatory Flexibility Analysis Required: No
Small Entities Affected: No
Government Levels Affected: None
Agency Contact: Katie Walker
Phone: 410 786–7278
Email: kwalker@cms.hhs.gov
RIN: 0938–AK02
### HHS—CMS

<table>
<thead>
<tr>
<th>Regulatory Flexibility Analysis</th>
<th>Completed:</th>
<th>Reason</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>Required: No</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Small Entities Affected: No</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Government Levels Affected: None</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Agency Contact: Les Caplan</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phone: 410 786–7223</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RIN: 0938–AK68</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1031. **ELIMINATION OF STATEMENT OF INTENT PROCEDURES FOR FILING MEDICARE CLAIMS (CMS–1185–F)**

**Priority:** Other Significant  
**CFR Citation:** 42 CFR 424

**Completed:**

<table>
<thead>
<tr>
<th>Reason</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>Final Action</td>
<td>11/07/03</td>
<td>68 FR 63398</td>
</tr>
</tbody>
</table>

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

**Agency Contact:** Les Caplan  
**Phone:** 410 786–7223  
**RIN:** 0938–AK68

1032. **PERMITTING PREMIUM REDUCTIONS AS ADDITIONAL BENEFITS UNDER MEDICARE+CHOICE PLANS (CMS–6016–F)**

**Priority:** Substantive, Nonsignificant  
**CFR Citation:** 42 CFR 408

**Completed:**

<table>
<thead>
<tr>
<th>Reason</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>Final Action</td>
<td>11/28/03</td>
<td>68 FR 66721</td>
</tr>
</tbody>
</table>

**Regulatory Flexibility Analysis Required:** No  
**Small Entities Affected:** No  
**Government Levels Affected:** Federal, Local, State

**Agency Contact:** Michele Sanders  
**Phone:** 410 786–0808  
**RIN:** 0938–AL49

1033. **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.  
**CFR Citation:** Not Yet Determined

**Completed:**

<table>
<thead>
<tr>
<th>Reason</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>Final Action</td>
<td>11/07/03</td>
<td>68 FR 63398</td>
</tr>
</tbody>
</table>

**Regulatory Flexibility Analysis Required:** Yes  
**Small Entities Affected:** Businesses  
**Government Levels Affected:** Federal

**Agency Contact:** Cindy Read  
**Phone:** 410 786–1852  
**RIN:** 0938–AK79

1034. **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.  
**CFR Citation:** Not Yet Determined

**Completed:**

<table>
<thead>
<tr>
<th>Reason</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>Withdrawn</td>
<td>04/26/04</td>
<td></td>
</tr>
</tbody>
</table>

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

**Federalism:** Undetermined  
**Agency Contact:** Angela Mason  
**Phone:** 410 786–7452  
**Email:** amason@cms.hhs.gov  
**RIN:** 0938–AM13

1035. **INPATIENT HOSPITAL DEDUCTIBLE AND HOSPITAL AND EXTENDED CARE SERVICES COINSURANCE AMOUNTS FOR CALENDAR YEAR 2004 (CMS–8016–N)**

**Priority:** Other Significant  
**CFR Citation:** None

**Completed:**

<table>
<thead>
<tr>
<th>Reason</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>Notice</td>
<td>10/24/03</td>
<td>68 FR 61002</td>
</tr>
</tbody>
</table>

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

**Agency Contact:** Clare McFarland  
**Phone:** 410 786–6390  
**RIN:** 0938–AM31

1036. **MONTHLY ACTUARIAL RATES AND MONTHLY SUPPLEMENTARY MEDICAL INSURANCE PREMIUM RATE BEGINNING JANUARY 1, 2004 (CMS–8017–N)**

**Priority:** Other Significant  
**CFR Citation:** None

**Completed:**

<table>
<thead>
<tr>
<th>Reason</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>Notice</td>
<td>10/24/03</td>
<td>68 FR 60997</td>
</tr>
</tbody>
</table>

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

**Agency Contact:** Clare McFarland  
**Phone:** 410 786–6390  
**RIN:** 0938–AM32

1037. **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  
**CFR Citation:** None

**Completed:**

<table>
<thead>
<tr>
<th>Reason</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>Notice</td>
<td>10/24/03</td>
<td>68 FR 61002</td>
</tr>
</tbody>
</table>

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

**Agency Contact:** James Mayhew  
**Phone:** 410 786–9244  
**RIN:** 0938–AM33

1038. **GRANTS TO STATES FOR OPERATION OF QUALIFIED HIGH RISK POOLS (CMS–2179–FC)**

**Priority:** Other Significant  
**CFR Citation:** 45 CFR 148

**Completed:**

<table>
<thead>
<tr>
<th>Reason</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>Notice</td>
<td>10/24/03</td>
<td>68 FR 61002</td>
</tr>
</tbody>
</table>

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

**Agency Contact:** Clare McFarland  
**Phone:** 410 786–6390  
**RIN:** 0938–AM33
### HHS—CMS

#### 1039. FEE SCHEDULE FOR PAYMENT OF AMBULANCE SERVICES UPDATE FOR CALENDAR YEAR 2004 (CMS–1232–FCC)

- **Priority:** Other Significant
- **CFR Citation:** None
- **Completed:**
  - Reason: Final Rule
  - Date: 12/05/03
  - FR Cite: 68 FR 67960

#### Regulatory Flexibility Analysis
- **Required:** Yes
- **Small Entities Affected:** Businesses
- **Government Levels Affected:** None
- **Agency Contact:** Anne Tayloe
  - Phone: 410 786–4546
- **RIN:** 0938–AM44

#### 1040. EXCLUSION OF MEDICARE BENEFITS FOR ALIENS NOT LAWFULLY PRESENT IN THE UNITED STATES (CMS–1222–FC)

- **Priority:** Other Significant
- **CFR Citation:** 42 CFR 411.11
- **Completed:**
  - Reason: Withdrawn
  - Date: 11/28/03

#### Regulatory Flexibility Analysis
- **Required:** No
- **Small Entities Affected:** No
- **Government Levels Affected:** None
- **Agency Contact:** Frederick William Grabau
  - Phone: 410 786–0206
- **RIN:** 0938–AM47

#### 1041. REVISED CIVIL MONEY PENALTIES, ASSESSMENTS, EXCLUSIONS, AND RELATED APPEALS PROCEDURES (CMS–6146–P)

- **Priority:** Other Significant
- **CFR Citation:** 42 CFR 402, subpart C & 402.3
- **Completed:**
  - Reason: Withdrawn
  - Date: 05/11/04

#### Regulatory Flexibility Analysis
- **Required:** No
- **Small Entities Affected:** No
- **Government Levels Affected:** None
- **Agency Contact:** Joel Cohen
  - Phone: 410 786–3349
- **Related RIN:** Duplicate of 0938–AM98

#### 1042. CHANGES TO THE CRITERIA FOR BEING CLASSIFIED AS AN INPATIENT REHABILITATION FACILITY (CMS–1262–F)

- **Priority:** Economically Significant
- **CFR Citation:** 42 CFR 412
- **Completed:**
  - Reason: Final Rule
  - Date: 05/07/04
  - FR Cite: 69 FR 25751

#### Regulatory Flexibility Analysis
- **Required:** No
- **Small Entities Affected:** No
- **Government Levels Affected:** None
- **Agency Contact:** Robert Kuhl
  - Phone: 410 786–4597
- **Related RIN:** Split from 0938–AL95

#### 1043. PROSPECTIVE PAYMENT SYSTEM FOR LONG-TERM CARE HOSPITALS: ANNUAL PAYMENT RATE UPDATES AND POLICY CHANGES (EFFECTIVE 7/1/04) (CMS–1263–F)

- **Priority:** Other Significant
- **CFR Citation:** 42 CFR 412 ; 42 CFR 413
- **Completed:**
  - Reason: NPRM
  - Date: 01/30/04
  - FR Cite: 69 FR 4754
  - Final Action
  - Date: 05/07/04
  - FR Cite: 69 FR 25673

#### Regulatory Flexibility Analysis
- **Required:** No
- **Small Entities Affected:** Businesses
- **Government Levels Affected:** None
- **Agency Contact:** Tzvi Hefter
  - Phone: 410 786–4487
- **RIN:** 0938–AM84

#### 1044. DISPROPORTIONATE SHARE HOSPITAL (DSH) PAYMENTS INSTITUTIONS FOR MENTAL DISEASE (IMDS) (CMS–2062–N)

- **Priority:** Other Significant
- **CFR Citation:** None
- **Completed:**
  - Reason: Notice
  - Date: 03/26/04
  - FR Cite: 69 FR 15850

#### Regulatory Flexibility Analysis
- **Required:** No
- **Small Entities Affected:** No
- **Government Levels Affected:** None
- **Agency Contact:** Jim Frizzera
  - Phone: 410 786–9535
- **Related RIN:** Related to 0938–AL29, Related to 0938–AM58

#### 1045. PHYSICIANS’ REFERRALS TO HEALTH CARE ENTITIES WITH WHICH THEY HAVE FINANCIAL RELATIONSHIPS: EXTENSION OF PARTIAL DELAY OF EFFECTIVE DATE (CMS–1809–F4)

- **Priority:** Other Significant
- **Legal Authority:** None
- **Legal Deadline:** None
- **Abstract:** This final rule delays for six months the effective date of the last sentence of 42 CFR 411.354(d)(1) of the physician self-referral rule published on January 4, 2001. This sentence defines compensation that is “set in advance” as it relates to percentage compensation methodologies. (The rule will be published only if Stark II, Phase II (CMS–1810–FC) is not published by December 31, 2003.)
- **Timetable:**
  - Action: Final Action
  - Date: 12/24/03
  - FR Cite: 68 FR 74491

#### Regulatory Flexibility Analysis
- **Required:** No
- **Small Entities Affected:** Businesses
- **Government Levels Affected:** None
- **Agency Contact:** Karen Raschke, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Blvd, Baltimore, MD 21244
  - Phone: 410 786–0016
  - Email: kraschke@cms.hhs.gov
- **Related RIN:** Related to 0938–AL29, Related to 0938–AM58

#### 1046. NOTICE OF ONE-TIME APPEAL PROCESS FOR HOSPITAL WAGE INDEX CLASSIFICATION (CMS–1373–N)

- **Priority:** Info./Admin./Other
- **Legal Authority:** Sec 508(a) of the Medicare Prescription Drug Improvement and Modernization Act of 2003
### 1047. 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 303.70
- **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>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>01/00/05</td>
<td></td>
</tr>
</tbody>
</table>

#### Regulatory Flexibility Analysis

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

### 1048. 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.
- **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>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>01/00/05</td>
<td></td>
</tr>
</tbody>
</table>

#### Regulatory Flexibility Analysis

- **Required:** No
- **Small Entities Affected:** Governmental Jurisdictions, Organizations
- **Government Levels Affected:** State, Local, Tribal

### 1049. ADMINISTRATIVE COSTS FOR CHILDREN IN TITLE IV–E FOSTER CARE

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

#### Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>12/00/04</td>
<td></td>
</tr>
</tbody>
</table>

#### Regulatory Flexibility Analysis

- **Required:** No
- **Small Entities Affected:** No
- **Government Levels Affected:** State, Local, Tribal

---

**Agency Contact:** Stephen Phillips, Deputy Division Director, Division of Acute Care, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-4548

Email: sphillips@cms.hhs.gov

**RIN:** Related to 0938–AN17

**RIN:** 0938–AN00

---

**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

---

**Agency Contact:** Elsbeth Wyatt, Program Specialist, Department of Health and Human Services, Administration for Children and Families, ADD HHH–300F, 370 L’Enfant Promenade SW., Washington, DC 20447

Phone: 202 690–5841

**RIN:** 0970–AC07
1050. ADMINISTRATIVE COST SHARING UNDER TANF

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

Legal Authority: 42 USC 1302

CFR Citation: 45 CFR 263; 45 CFR 263.14

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 Stamp Programs, in accordance with the primary program cost allocation methodology previously allowed under the former AFDC program.

Department of Health and Human Services (HHS)
Administration for Children and Families (ACF)

1051. 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:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interim Final Rule</td>
<td>06/26/03</td>
<td>68 FR 37978</td>
</tr>
<tr>
<td>Final Action</td>
<td>01/01/05</td>
<td></td>
</tr>
</tbody>
</table>

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: State

Agency Contact: Eileen C. Brooks, Deputy Director, Policy Division, Department of Health and Human Services, Administration for Children and Families, Room 2411, 330 C Street SW., Washington, DC 20447

Email: ebrooks@acf.hhs.gov

RIN: 0970–AC09

1052. • HEAD START TRANSPORTATION

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

Legal Authority: Not Yet Determined

CFR Citation: 45 CFR 1310

Legal Deadline: None

Abstract: This interim final rule will extend for 150 days those parts of the Head Start transportation regulation that deal with the requirement that each vehicle used to transport children is equipped for use of child safety restraint systems and the requirement that each bus have a bus monitor. Additionally, these rules will provide Head Start grantees the opportunity to request further extension of the effective date when such an extension is in the best interest of the children they serve.

Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interim Final Rule</td>
<td>01/16/04</td>
<td>69 FR 2513</td>
</tr>
<tr>
<td>Final Action</td>
<td>12/00/04</td>
<td></td>
</tr>
</tbody>
</table>

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Windy Hill, Associate Commissioner, Head Start Bureau, Department of Health and Human Services, 330 C Street SW., Washington, DC 20447

Email: whill@acf.hhs.gov

RIN: 0970–AC15
### Department of Health and Human Services (HHS) Completed Actions

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

<table>
<thead>
<tr>
<th>Action</th>
<th>CFR Citation</th>
<th>Completed</th>
<th>Reason</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>Final Rule</td>
<td>45 CFR 309</td>
<td>03/30/04</td>
<td>69 FR 16638</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**1053. CHILD SUPPORT ENFORCEMENT FOR INDIAN TRIBES**

**Priority:** Other Significant

**CFR Citation:** 45 CFR 309

**Completed:**

<table>
<thead>
<tr>
<th>Reason</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>Final Rule</td>
<td>03/30/04</td>
<td>69 FR 16638</td>
</tr>
</tbody>
</table>

**Regulatory Flexibility Analysis Required:** No

**Government Levels Affected:** State, Tribal

**Agency Contact:** Paige Biava

Phone: 202 401–9386

**RIN:** 0970–AB73

<table>
<thead>
<tr>
<th>Action</th>
<th>CFR Citation</th>
<th>Completed</th>
<th>Reason</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>Final Rule</td>
<td>45 CFR 260.30; 45 CFR 260.34</td>
<td>09/30/03</td>
<td>68 FR 56449</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**1054. CHARITABLE CHOICE PROVISIONS APPLICABLE TO THE TEMPORARY ASSISTANCE FOR NEEDY FAMILIES PROGRAM**

**Priority:** Other Significant

**CFR Citation:** 45 CFR 260.30; 45 CFR 260.34

**Completed:**

<table>
<thead>
<tr>
<th>Reason</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>Final Rule</td>
<td>09/30/03</td>
<td>68 FR 56449</td>
</tr>
</tbody>
</table>

**Regulatory Flexibility Analysis Required:** No

**Government Levels Affected:** State

**Agency Contact:** April Kaplan

Phone: 202 401–5138

Email: akaplan@acf.hhs.gov

**RIN:** 0970–AC12

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

#### Administration on Aging (AOA)

<table>
<thead>
<tr>
<th>Action</th>
<th>CFR Citation</th>
<th>Legal Authority</th>
<th>Priority</th>
<th>Legal Deadline</th>
<th>Government Levels Affected</th>
<th>Federalism</th>
<th>Agency Contact</th>
<th>Proposed Rule Stage</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>45 CFR 1321; 45 CFR 1326; 45 CFR 1328</td>
<td>42 USC 3001 et seq</td>
<td>Substantive, Nonsignificant</td>
<td>None</td>
<td>None</td>
<td>Undetermined</td>
<td>Edwin Walker, Deputy Assistant Secretary for Policy and Programs, Department of Health and Human Services, Administration on Aging, Washington, DC 20201</td>
<td>0985–AA00</td>
</tr>
</tbody>
</table>

**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 fall of 2004.

**Timetable:**

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPRM</td>
<td>10/00/04</td>
<td>68 FR 56466</td>
</tr>
</tbody>
</table>

**Regulatory Flexibility Analysis Required:** Yes

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