Monday October 24, 1988

Part VIII

# Department of Health and Human Services

Semiannual Regulatory Agenda

#### DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

### DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

20 CFR Ch. III

21 CFR Ch. I

42 CFR Chs. I-V

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

**Unified Agenda of Regulations** 

**AGENCY:** Department of Health and Human Services.

**ACTION:** Publication of unified agenda of regulations.

SUMMARY: The President's February 17, 1981, Executive Order (12291) and the Regulatory Flexibility Act of 1980 require the Department to publish an agenda of significant regulations being developed and an indication of those regulatory actions that are being analyzed for their effect on small businesses. The Department published its last agenda on April 25, 1988.

#### FOR FURTHER INFORMATION CONTACT:

For further inquiries or comments related to specific regulations listed in the agenda, the public is encouraged to contact the appropriate responsible individual. Questions or comments on the overall agenda should be sent to: W. Keith Lively, Deputy Executive Secretary, Office of the Secretary, Department of Health and Human Services, 200 Independence Avenue, SW., Washington, DC 20201, Telephone: (202) 245-7699.

Aletha R. Owens,

Executive Secretary to the Department.

#### Office of the Secretary-Prerule Stage

Se- quence Number	Title	Regulation Identifier Number
593	Privacy Act Regulation	0991-AA11

#### Office of the Secretary-Proposed Rule Stage

Se- quence Number	Title	Regulation Identifier Number
594	Principles for Determining Costs and Cost Allocation Procedures Applicable to Grants, Contracts, and Other Agreements for Work Performed by Hospitals	0991-AA12
595	Civil Money Penalties and Sanctions for HMOs and Competitive Medical Plans	0991-AA44
596	Prohibition on Use of Physician Incentive Plans	0991-AA45
597	New Civil Money Penalties and Exclusions Authorities Resulting from OBRA 1986 and OBRA 1987	0991-AA46
598	Amendments to OIG Exclusion and CMP Authorities Resulting from PL 100-93	0991-AA47
599	OIG Anti-Kickback Provisions	0991-AA49
600	PRO Rural Practitioners Amendments	0991-AA51
601	Civil Money Penalties and Sanction Authorities Relating to the Medicare Catastrophic Coverage Provisions	0991-AA52
602	Civil Money Penalties for Violations Relating to Medical Supplemental Policies	0991-AA53
603	Civil Money Penalties for Misuse of Departmental Symbols or Emblems	0991-AA54

#### Office of the Secretary-Final Rule Stage

Se- quence Number	Title	Regulation Identifier Number
604	Nondiscrimination Requirements (Including on the Basis of Sex or Religion) Applicable to Block Grants and Standard Nondiscrimination Procedures Applicable to Certain Other Programs	0991-AA02
605	Freedom of Information Act Regulation	0991-AA07
606	Equal Opportunity in Employment: Public Broadcasting, Public Radio and Public Telecommunications Entities Receiving Federal Funds from the Corporation for Public Broadcasting	0991-AA22
607	Audits of Non-governmental Grantees	0991-AA29
608	Civil Money Penalties and Exclusions for Assistants at Cataract Surgery	0991-AA37
609	Civil Money Penalties for Failure to Report Medical Malpractice Payments and for Breaching the Confidentiality of Information	0991-AA40

#### Office of the Secretary—Completed Actions

Se- quence Number	Title	Regulation Identifier Number
610	Enforcement of Nondiscrimination on the Basis of Handicap in the Department of Health and Human Services	0991-AA17
611	Automatic Data Processing Equipment and Services; Conditions for Federal Financial Participation II	0991-AA34
612	Block Grant Programs	0991-AA38
613	Program Fraud Čivil Remedies	0991-AA41
614	Targeting of, and Tolerances for, Income and Eligibility Verification System Data	0991-AA42
615	Governmentwide Debarment and Suspension (Nonprocurement)	0991-AA43
616	Program Fraud Civil Remedies	0991-AA50

#### Departmental Management—Final Rule Stage

Se- quence Number	Title	Regulation Identifier Number
617 618	Implementation of the Equal Access to Justice Act in Agency Proceedings  Testimony by Employees and the Production of Documents in Proceedings Where the United States is not a Party	

#### Office of Human Development Services—Proposed Rule Stage

Se- quence Number	Title	Regulation Identifier Number
619	Foster Care, Adoption Assistance, and Child Welfare Services	0980-AA08
620	Runaway and Homeless Youth Program	0980-AA11
621	Foster Care, Adoption Assistance, and Child Welfare Services	0980-AA17
622	Head Start Staff and Program Options Requirements	0980-AA18
623	Head Start Appeals Process	0980-AA20
624	Head Start Performance Standards for Services to Handicapped Children	0980-AA21
625	Head Start Recruitment Selection and Enrollment of Children	0980-AA27
626	Head Start: Limits on Costs of Development and Administration	0980-AA32
627	Head Start Performance Standards for Infants and Toddlers	0980-AA33
628	Adoption and Foster Care Information	0980-AA35
629	Developmental Disabilities Program	0980-AA36
630	Child Abuse and Neglect: technical amendments	0980-AA40

#### Office of Human Development Services—Final Rule Stage

Se- quence Number	Title	Regulation Identifier Number
631 632	Nonrecurring Costs of Adoption	0980-AA24 0980-AA37

#### Office of Human Development Services—Completed Actions

Se- quence Number	Title	Regulation Identifier Number
633 634	Head Start Personnel Policies	0980-AA10 0980-AA34

#### Social Security Administration—Proposed Rule Stage

Se- quence Number	Title	Regulation Identifier Number
635	Old-Age, Survivors, and Disability Insurance Program; Treatment of OASDI Lump Sum and Monthly Payments in the	
636	Aid to Families with Dependent Children Program.  Old-Age, Survivors, and Disability Insurance Program; Revised Medical Criteria for Determination of Disability;	0960-AA90
637	Cardiovascular System	0960-AA99
638	Respiratory System	0960-AB00
000	Musculoskeletal System	0960-AB01
639 640	Supplemental Security Income Program and Medicaid Assistance; What Is Not Income Old-Age, Survivors, and Disability Insurance and Supplemental Security Income Programs; Adjustments in SSI Benefits on Account of Retroactive Benefits Under Title II	0960-AB09 0960-AB38
641	Supplemental Security Income Program; Limitation on Recoupment Rate in Case of Overpayment	0960-AB40
642	Old-Age, Survivors, and Disability Insurance and Supplemental Security Income Programs; Evaluation Guides for Determining Substantial Gainful Activity (SGA)	0960-AB73
643	OASDI & SSI Programs; Definition of Overpayment and Liability for Repayment of an Overpayment	0960-AB78
644	Supplemental Security Income Program; Treatment of Property Held in Trust or Other Similar Legal Devices When the Property is Available for a Beneficiary's Support and Maintenance	0960-AB79
645	Old-Age, Survivors and Disability Insurance; Black Lung; and Supplemental Security Income Programs; and Organization and Procedures; Application of Circuit Court Law	0960-AB85
646	Supplemental Security Income Program; Exclusions from Income and Resources of Indian Judgement Funds and Per Capita Distributions	0960-AB86
647	Old-Age, Survivors, and Disability Insurance Program; Revised Medical Criteria for Determination of Disability; Mental Disorders-Childhood	0960-AB96
648	Old-Age, Survivors, and Disability Insurance Program; Medical Evaluation Criteria for Acquired Immune Deficiency Syndrome (AIDS)	0960-AC06
649	Old-Age Survivors and Disability Insurance and Supplemental Security Income Programs; The Hearings and Appeals Process and Reopening Determinations and Decisions	0960-AC15
650	Old-Age, Survivors, and Disability Insurance Program; Nonpayment of Benefits to Prisoners, Vocational Rehabilitation Exception	0960-AC16
651	Supplemental Security Income Program; Employment Opportunities for the Disabled	0960-AC22
652	Supplemental Security Income Program; Permanent Residence in the United States Under Color of Law - Additional Category	0960-AC26
653	Supplemental Security Income Program; Payment of Benefits Due Deceased Recipients	0960-AC28
654	Old-Age, Survivors and Disability Insurance Program and Organization and Functions; Records of Earnings	0960-AC30
655	Organization and Procedures, and Old-Age, Survivors, and Disability Insurance Programs; Social Security Number Cards for Aliens	0960-AC34
656	Old-Age Survivors and Disability Insurance and Supplemental Security Income Programs; Past Work Experience and Adjustment to Other Work	0960-AC39
657	Old-Age Survivors and Disability Insurance and Supplemental Security Income Programs; Cancelled Consultative Examinations	0960-AC40
658	Old-Age Survivors and Disability Insurance and Supplemental Security Income Programs; Determining Disability and Blindness; Fee Limitation Policy for Purchase of Laboratory Tests	0960-AC41
659	Supplemental Security Income Program, Proceeds of a Loan, Payment of Pro Rata Share of Household Operating Expenses	0960-AC42
660	Supplemental Security Income Program; Exclusion from Countable Resources of the Value of Promissory Notes in Home Replacement Situations	0960-AC43
661	Old-Age, Survivors, and Disability Insurance Program; Extension of Social Security Coverage to Certain Workers; Medicare Only Coverage of Certain State and Local Government Employees	0960-AC45
662	Old-Age, Survivors, and Disability Insurance Program; Applicability of Government Pension to Certain Federal Employees	0960-AC46
663	Supplemental Security Income Program; Exclusion From Resources of Funds Set Aside for Bunal and Burial Spaces	0960-AC48
664	Supplemental Security Income Program; Exemption of Certain Assistance Payments from Retrospective Monthly Accounting	
665	Supplemental Security Income Program; Increase in Emergency Advance Payments	
666	Supplemental Security Income Program, Modification of Interim Assistance Reimbursement Program	0960-AC51
667	Supplemental Security Income Program; Exclusion from Income of Payments Received For and Used to Pay Last Illness and Death	0960-AC52
668	Supplemental Security Income Program; Continuation of Full Benefit Standard for Person in Medicaid Institution	0960-AC55
669	Old-Age, Survivors, and Disability Insurance Program; Social Security Numbers for Newborn Children	
670	Old-Age, Survivors, and Disability Insurance Program; Revision of Contributions for Support Rules	
671	Old-Age, Survivors, and Disability Insurance Program; Supplemental Earnings Reports	

#### Social Security Administration—Final Rule Stage

Se- quence Number	Title	Regulation Identifier Number
672	Supplemental Security Income Program; Reductions, Suspensions and Terminations	0960-AA22
673	Supplemental Security Income Program; Reopening and Revising Supplemental Security Income Determinations and Decisions Within Four Years of the Notice of the Initial Determination	0960-AA59
674	Old-Age, Survivors, and Disability Insurance Program; Coverage of Certain Federal Employees; Coverage of Earnings of Federal Judges	0960-AA89
675	Old-Age, Survivors, and Disability Insurance and Supplemental Security Income Program; Continued Payment of Benefits to Persons in Vocational Rehabilitation Programs	0960-AB05
676	Old Age Survivors Disability Insurance and Supplemental Security Income Programs; Standards for Consultative Examinations; Existing Medical Evidence	0960-AB22
677	Supplemental Security Income Program; How We Count Unearned IncomeFunds Used to Pay Indebtedness.	0960-AB29
678	Old Age Survivors Disability Insurance and Supplemental Security Income Programs; Determinations of Disability-	COCO / LDEO
	Compliance, and Other Changes	0960-AB36
679	Old Age Survivors Disability Insurance and Supplemental Security Income Programs; Payment of Costs of Rehabilitation Services	0960-AB37
680	Old Age, Survivors, Disability Insurance and Supplemental Security Income Programs; Determining Disability and Blindness; Multiple Impairments	0960-AB39
681	Old-Age, Survivors, Disability Insurance and Supplemental Security Income Programs: Evaluation of Symptoms, Including Pain	0960-AB41
682	Old-Age, Survivors, and Disability Insurance Program; Reduction Because of Entitlement to Other Benefits	0960-AB87
683	Old-Age, Survivors, and Disability Insurance and Supplemental Security Income Programs; Decisions by Administrative Law Judges in Cases Remanded by Courts	0960-AC07
684	Supplemental Security Income Program: Federal Administration of Optional State Supplementation	0960-AC13
685	Old-Age, Survivors, and Disability Insurance Program; Wages Deferred Compensation	0960-AC27
686	Old-Age, Survivors, and Disability Insurance and Supplemental Security Income Programs; Consideration of	
	Vocational Factors	0960-AC31
687	Organization and Procedures, and OASDI Programs; Evidence Required for Original or Duplicate Social Security  Number Card	0960-AC32
688	Old-Age, Survivors, and Disability Insurance Program; Addition of Down Syndrome to the Listing of Impairments	0960-AC35
689	Supplemental Security Income Program; Exclusion of Real Property When It Cannot Be Sold; and Transfer of Assets	
	for Less Than Fair Market Value	0960-AC47
690	Supplemental Security Income Program; Public Emergency Shelters for the Homeless, Exclusion of Underpayments, Increase in Personal Needs Allowance	0960-AC54

#### Social Security Administration—Completed Actions

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691	Old-Age, Survivors, and Disability Insurance Program; Coverage of Employees of State and Local Governments	0960-AA13
692	Old-Age, Survivors, and Disability Insurance Program; Provision for Inferring a Person Is Dead	0960-AA54
693 694	Supplemental Security Income Programs; Assignment of Rights to Third-Party Medical Payments to State	0960-AB28
094	Benefits During Appeal	0960-AB30
695	Supplemental Security Income Program; Treatment of Overpayments When Recipient's Countable Assets Exceed Limits in Certain Cases	0960-AB32
696	Old-Age, Survivors, and Disability Insurance Program; Determining Disability and Blindness, Medical-Vocational Guidelines, Illiteracy and Inability to Communicate in English	0960-AB94
697	Supplemental Security Income Program; Spousal Deeming Computation Involving State Supplementation	0960-AB95
698	Supplemental Security Income Program; Prohibition on Direct Payment of Fees to Representatives	0960-AC08
699	Supplemental Security Income Program; Define Out of Resources for One Morith Certain Cash Payments for	
	Medical/Social Services	0960-AC11
700	Old-Age, Survivors, and Disability Insurance and Supplemental Security Income Programs; Against Equity and Good Conscience: Defined	0960-AC33
701	Old-Age, Survivors, and Disability Insurance Program; Extension of Expiration Date for Mental Disorders Listings	0960-AC44
702	Supplemental Security Income Program; Exclusion of Certain Support and Maintenance Assistance Based on Need	0960-AC53

#### Public Health Service—Centers for Disease Control (CDC)—Proposed Rule Stage

Se- quence Number	Title	Regulation Identifier Number
703	Subchapter J - National Vaccine Program, Part 110 Information and Education, Subpart A - Vaccine Information	0905-AC83
704	Health Assessments and Health Effects Studies of Hazardous Substances Releases and Facilities	0905-AC84

#### Public Health Service—Centers for Disease Control (CDC)—Final Rule Stage

Se- quence Number	Title	Regulation Identifier Number
705	NIOSH Revision of Tests and Requirements of Certification of Permissibility of Respiratory Protective Devices Used in Mines and Mining	0905-AB58

#### Public Health Service—Centers for Disease Control (CDC)—Completed Actions

Se- quence Number	Title	Regulation Identifier Number
706	Project Grants for Health Programs for Refugees	0905-AB43

#### Public Health Service—Food and Drug Administration (FDA)—Prerule Stage

Se- quence Number	Title	Regulation Identifier Number
707 708	Drug Exports	0905-AC44 0905-AC72

#### Public Health Service—Food and Drug Administration (FDA)—Proposed Rule Stage

Se- quence Number	Title	Regulation Identifier Number
709	Current Good Manufacturing Practice for Finished Pharmaceuticals; Retrospective Review	0905-AA73
710	Current Good Manufacturing Practice (CGMP) for Blood and Blood Components; Retrospective Review	0905-AA75
711	New Animal Drug Approval Process.	0905-AA96
712	Policies Concerning Uses of Sulfiting Agents	0905-AB52
713	Requirements for Adverse Experience Reporting for Licensed Biological Products	0905-AB53
714	Proposed Rule to Implement the Orphan Drug Amendments to the Federal Food, Drug, and Cosmetic Act	0905-AB55
715	Implementation of Title I of the "Drug Price Competition and Patent Term Restoration Act of 1984" (Title I)	0905-AB63
716	Abbreviated New Animal Drug Applications for Post-1962 Animal Drugs	0905-AB72
717	Protection of Human Subjects; Informed Consent; Standards for Institutional Review Boards for Clinical Investiga-	
	tions.	0905-AC52
718	Menstrual Tampons; Proposed User Labeling	0905-AC54
719	Action Levels for Added Poisonous or Deleterious Substances in Food (Including Animal Feed)	0905-AC73
720	Prescription Drug Marketing Act of 1987; Implementation	0905-AC81

#### Public Health Service-Food and Drug Administration (FDA)-Final Rule Stage

Se- quence Number	Title	Regulation Identifier Number
721	Over-the-Counter (OTC) Drug Review	0905-AA06
722	Availability of Rulk New Animal Drug Substances for Use Ry Licensed Votorinarians	0905-AB01
723	Provisionally Listed Color Additives	0905-AB60
724	Food Labeling Information Regarding Good Nutrition and Health	0905-AB67
725	Food Labeling: Definitions of Cholesterol Free, Low Cholesterol, and Reduced Cholesterol	0905-AB68
726	Methylene Chloride	0905-AC00
727	Infant Formula Act	0905-AC46
728	Common or Usual Name for Diluted Fruit or Vegetable Juice Beverages Other than Diluted Orange Juice Beverages	0905-AC48
729	Tamper-Resistant Packaging Requirements for Over-the-Counter (OTC) Drugs	0905-AC70

#### Public Health Service—Food and Drug Administration (FDA)—Completed Actions

Se- quence Number	Title	Regulation Identifier Number
730	Proposed User Charge; New Drug Applications, Abbreviated New Drug Applications, New Device Applications, and Antibiotic Applications Review	0905-AB56
731	Patent Term Restoration for Certain Regulated Products (Title II of "Drug Price Competition and Patent Term Restoration Act of 1984")	0905-AB65
732	Menstrual Tampons; Proposed User Labeling	0905-AC58

#### Public Health Service—Health Resources and Services Administration (HRSA)—Proposed Rule Stage

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733	Health Education Assistance Loan (HEAL) Program: Implementation of Pub. L. 99-129	0905-AC28
734	Post-Baccalaureate Faculty Fellowship Program	0905-AC34
735	Grants for Community Health Services: Criteria and Procedure for Determining Medically Underserved Populations	
	(MUP)	0905-AC35
736	(MUP)	0905-AC67
737	Designation of Mental Health Manpower Shortage Areas	0905-AC68
738	Grants for Faculty Training Projects in Geriatric Medicine and Dentistry	0905-AC71
739	Health Education Assistance Loan (HEAL) Program: Bankruptcy Revisions	0905-AC75
740	Nursing Student Loan (NSL) Program: Cash Management	0905-AC76
741	Centers for Excellence	0905-AC77
742	Health Professions Student Loan (HPSL) Program: Cash Management	0905-AC78

#### Public Health Service—Health Resources and Services Administration (HRSA)—Final Rule Stage

Se- quence Number	Title	Regulation Identifier Number
743	Grants for Residency Training and Faculty Development in General Internal Medicine and/or General Pediatrics	0905-AB50
744	Grants for Nurse Practitioner and Nurse Midwifery Traineeship Programs	0905-AC30
745	Nursing Student Loan (NSL) Program: Implementation of the Law (Pub. L. 99-92)	0905-AC31
746	Health Professions Student Loan (HPSL) Program: Implementation of the Law (Pub. L. 99-129)	0905-AC32
747	Grants for Health Professions Projects in Geriatrics	0905-AC33
748	Health Manpower Shortage Area Designation Criteria For Correctional Facilities	0905-AC50
749	Implementation of Health Care Quality Improvement Act of 1986 (Title IV, Public Law 99-660)	0905-AC51
750	National Health Service Corps, State Loan Repayment And Special Repayment Programs	0905-AC65
751	Health Education Assistance Loan (Heal): Litigation	0905-AC69

#### Public Health Service—Health Resources and Services Administration (HRSA)—Completed Actions

Se- quence Number	Title	Regulation Identifier Number
752 753 754 755 756 757 758	Grants for Nurse Anesthetist Traineeships	0905-AC07

#### Public Health Service—National Institutes of Health (NIH)—Prerule Stage

Se- quence Number	Title	Regulation Identifier Number
759	Misconduct in Science	0905-AB91

#### Public Health Service—National Institutes of Health (NIH)—Proposed Rule Stage

Se- quence Number	Title	Regulation Identifier Number
760 761	Changes in NIH Program Regulations due to P.L. 99-158,P.L. 99-499 and Title X of P.L. 99-660	0905-AC02 0905-AC27

#### Public Health Service-National Institutes of Health (NIH)-Final Rule Stage

Se- quence Number	Title	Regulation Identifier Number
762	National Library of Medicine Programs. Revision of General Rules for the National Library of Medicine and National Library of Medicine Grants	0905-AA66

#### Health Care Financing Administration—Proposed Rule Stage

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763	Administrative Appeals Process for Provider Payment Disputes Including Amending Cost Reports & Reopening	0938-AA33
764	Intermediary Payment Determinations & Administrative Review Decisions	0938-AA58
765	MMIS: Definition of "Mechanized Claims Processing and Information Retrieval System"	
766	MMIS: Definition of "Mechanized Claims Processing and Information Retrieval System"	0938-AB07
767	Payment for Clinical Diagnostic Laboratory Services	0938-AB50
768	Payment for the Services of Physicians Furnished in Teaching Settings and Other Providers	0938-AB61
769	Revision of the Clinical Laboratory Regulations for the Medicare, Medicaid, and Clinical Laboratories Improvement	
		0938-AB96
770	Act of 1967 Programs	0938-AC27
771	Use of the HCFA Hospital Wage Index for Determining Payment to Hospices	0938-AC49
772	Hospice/Case Management	0938-AC52
773	Hospice/Case Management	0938-AC81
774	Denial of Payment for Substandard Quality Care, Review of Beneficiary Complaints	
775	Revised Effective Date of Medicare/Medicaid Provider Agreement and Supplier Participation	
776	Recognition of College of American Pathologists Laboratory Accreditation Program	0938-AC89

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779	Changes Concerning Suspension of Medicare Payments, Interest Rates Charged on Overpayments and Underpayments, and Determinations of Allowable Interest Expense	
780	Changes Concerning the Definition of Accrual Basis of Accounting	0938-AC9
781	Optional Payment System for Low Medicare Volume Skilled Nursing Facilities	0938-AD0
782	Criteria and Procedures for Medical Services Coverage Decisions	0938-AD0
783	Recognition of Joint Commission on Accreditation of Healthcare Organizations' Home Care Program Standards and the National League for Nursing's Standards for Home Health Agencies	0938-AD1
784	Eligibility of Aliens for Medicaid	0938-AD1
785	Medicaid: Eligibility Groups Extended Coverage of Services, and Conditions of Eligibility: OBRA '87, COBRA, and TEFRA	0938-AD1
786	Medicaid Eligibility of Poverty Level Groups and Extended Coverage of Services	
786	Transfer of Assets	0938-AD1
787 788	Payment for Services of Certified Registered Nurse Anesthetists	0938-AD1
789	Withdrawal of Coverage of Single Photon Absorptiometry	0938-AD2
790	Modification of Certain Requirements for Health Insuring Organizations	0938-AD2
791 792	Occupational Therapy, Physician Assistants Prohibition on Unbundling of Hospital Outpatient Services	
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793	Physician Liability on Non-Assigned Claims	0938-AD3
795	PRO Disclosure to Licensing and Certification Bodies	
796	Revision of the Medicare Economic Index	0938-AD4
797 798	Update of Ambulatory Surgical Center Payment Rates for July 1, 1988	0938-AD4
700	After October 1, 1988	
7 <b>9</b> 9	Application of the Comparable Services Limitation in Determining Reasonable Charges	0938-AD5
800	Home and Community-Based Services for the Elderly	0938-AD5
801	Revisions to the Freedom of Information Regulations	0938-AD6
802	Fee Schedules for Radiologist Services	
803	Establishment of Medicare Economic Index for 1989	
804	Payment for Durable Medical Equipment and Orthotic and Prosthetic Devices	
805	Charges to Residents' Funds in Nursing Homes	
806	Criteria for Standard and Extended Home Health Agency Surveys	
807	Outpatient Surgery and Pre-admission Diagnostic Testing for Inpatient Surgery under Medicaid	
808	Changes to the Reasonable Cost Regulation Concerning Investment Income	
809	Medicare Secondary Payer for Disabled Active Individuals	
810	Inherent Reasonableness for Home Dialysis Supplies and Equipment	
811 812	Clarification of Durable Medical Equipment Coverage under Medicare	
813	Prepaid Health Care Plans: Beneficiary and Other Related Provisions	0938-AD
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814	OBRA '87 Long Term Care Facilities Conditions of Participation	
816	Medigap Policy Standards - Direct Transmittal of Claims from Medicare Carriers to Medigap Insurers and Related User Fees	
817	Coverage of Psychologists' Services Furnished at Rural Health Clinics	
818	Coverage of Screening Mammography	
819	Coverage of Home Intravenous Drug Therapy Services	
820	In-Home Care for Chronically Dependent Individuals	
820	Outpatient Drug Coverage and Reimbursement	
822	Survey and Certification	
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#### Health Care Financing Administration—Final Rule Stage

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825	Miscellaneous Medicare and Medicaid Amendments	0938-AB05
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827	Medicare: Health Maintenance Organizations and Competitive Medical Plans: Coordinated Open Enrollment	0938-AB54
828	Indirect Part B Payment Procedure	0938-AB57
829	Hospital Insurance Entitlement and Supplementary Medical Insurance Enrollment and Entitlement	0938-AB59
830	Medicare/Medicaid Revaluation of Assets	0938-AB60
831	Clarification of Policy on Adjusting the Hospital-Specific Portion of the Prospective Payment Rate	0938-AB64 0938-AB71
832	Revision of Medicaid Eligibility Quality Control (MEQC) Program Requirements	
833	Medicare Secondary Payor and Medicare Recovery Against Third Parties	0938-AB85 0938-AC05
834	Medicare Coverage of Hepatitis B Vaccine for High and Intermediate Risk Individuals, Hemophilia Clotting and Certain X-Ray Services.	0938-AC05
835	Medicaid: Eligibility Determinations Based on Disability	0938-AC31
836	Effect of Appeals on Hospital-Specific Portion of the Prospective Payment Rate	0938-AC40
837	Additions to and Deletions From Current List of Covered Surgical Procedures for Ambulatory Surgical Centers	0938-AC45
838	Employers Contribution to Health Maintenance Organizations Option	0938-AC48
839	Home and Community-Based Services and Respiratory Care for Ventilator-Dependent Individuals	0938-AC55
840	Billing and Verification Add-On Relating to Home Health Agencies Cost Per Visit Limits	0938-AC56
841	Reimbursement for Physician's Outpatient Maintenance Dialysis Services	0938-AC57
842	Participation in CHAMPUS and CHAMPVA, Hospital Admissions for Veterans, Discharge Rights Notice, and Hospital Responsibility for Emergency Care	0938-AC58
843	Payment for Kidneys Sent to Foreign Countries or Transplanted in Patients Other than Medicare Beneficiaries	0938-AC59
844	State Plan Requirements and Other Provisions Relating to State Third-Party Liability Programs	0938-AC64
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846	Refunding of Federal Share of Overpayments Made to Medicaid Providers	0938-AC83
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848	Revisions to Conditions of Participation for Hospitals and Conditions for Coverage of Services of Independent Laboratories and Suppliers of ESRD Services	0938-AD11
849	Conditions of Participation for Long Term Care Facilities	0938-AD12
850	Explanation of Rights and Other HMO/CMP Provisions	0938-AD14
851	Discontinuation of Prevailing Charge Differentials for Specialists	0938-AD26
852	Changes to Peer Review Organization Regulations	0938-AD38
853	Medicare, Medicaid, and Clinical Laboratories Improvement Act (CLIA) Patient Confidentiality Rules	0938-AD40
854	Home Health Agencies: Conditions of Participation and Reduction in Recordkeeping Requirements	0938-AD45
855	Schedules of Limits on Home Health Agency Costs Per Visit for Cost Reporting Periods Beginning On or After July 1, 1988	0938-AD47
856	Changes to the Inpatient Hospital Prospective Payment System and Fiscal Year 1989 Rates	0938-AD49
857	Protocol for the Reuse of Dialysis Bloodlines	0938-AD52
858	Uniform Relative Value Guide for Anesthesia Services Furnished by Physicians	0938-AD63
859	Inpatient Hospital Deductible, SNF Coinsurance Amount and Part A Premium for the Uninsured Aged for 1989	0938-AD68
860	Periodic Payments for Hospitals and Other Providers	0938-AD71
861	Hospice Cap	0938-AD75
862	Payment for Outpatient Surgery at Eye Specialty Hospitals and Eye and Ear Specialty Hospitals	0938-AD76
863	Swing-Bed Program Changes	0938-AD83
864	Coverage of and Payment for Certified Nurse-Midwife Services	0938-AD85
865	Second Surgical Opinion Requirements for Medicaid Recipients	0938-AD86
866	Conforming Amendments Resulting from the Omnibus Budget Reconciliation Act of 1987	0938-AD92
867	Catastrophic Coverage Conforming Amendments	0938-AD93
868	Carrier Bonuses for Increasing Physicians' Participation or Payments	0938-AD96
869	National Average Actuarial Value of Duplicative Part A and Part B Medicare Benefits	0938-AD98

#### Health Care Financing Administration—Completed Actions

Se- quence Number	Title	Regulation 'dentifier Number
870	Payments to Institutions	0938-AB00
871	Changes to the Lesser of Costs or Charges Provisions	
872	Revisions in Reporting and Recordkeeping Requirements	
873	Physician Certification and Plan of Care Requirements and Inspection of Care Reviews	
874	Treatment of Social Security Cost of Living Increases for Individuals Who Lose SSI Eligibility	0938-AB62

#### Health Care Financing Administration—Completed Actions—Continued

Se- quence Number	Title	Regulation Identifier Number
875	OMB Review of Information Collection and Recordkeeping Requirements for Home Health Agencies, and Providers	
	of Outpatient, Physical Therapy and/or (cont)	0938-AB68
876	Conditions for Intermediate Care Facilities for the Mentally Retarded	0938-AB76
877	Reasonable Charge Limitations	0938-AC08
878	Assignment and Reassignment of Provider-Based Home Health Agencies and Hospices to Designated Regional Intermedianes	0938-AC20
879	Fire Safety Standards for Hospitals, Skilled Nursing Facilities, Hospices, Intermediate Care Facilities and Ambulatory Surgical Centers	0938-AC28
880	Surgical Centers	0938-AC68
881	Long Term Care Survey	0938-AD4
882	Miscellaneous Changes Affecting Payment for Inpatient Hospital Services	
883	Miscellaneous Changes Affecting Payment for Inpatient Hospital Services	0938-AD5
884	Revisions to Medicaid Eligibility Quality Control Program Requirements Based on Findings of COBRA Studies	0938-AD5
885	Procedures for Terminating Program Participation of Providers and Suppliers	
	Monthly Advantage Dates and Dark Dramium Dates Posinging Layung 1 1000	0930-AD3
886	Monthly Actuarial Rates and Part B Premium Rates Beginning January 1, 1989	0938-AD5 0938-AD6

#### Family Support Administration—Proposed Rule Stage

Se- quence Number	Title	Regulation Identifier Number
888	Aid to Families with Dependent Children Program; Administrative Improvement in the AFDC Program	0970-AA09
889	Standards for Child Support Enforcement Program Operations	0970-AA16
890	Child Support Enforcement Audit Regulations	0970-AA17
891	Child Support Enforcement Audit Regulations	0970-AA18
892	Alien Venfication Procedures for AFDC; State Administered Adult Assistance and Medicaid Programs; Notice of Proposed Rulemaking	0970-AA41
893	Exclusion of Indian Trust Funds and Alaska Native Claims Settlement Act Distributions (ANCSA)	0970-AA47
894	Cooperation in Third Party Health Coverage	0970-AA49
895	Cooperative agreements	0970-AA50
896	Cooperation in Third Party Health Coverage  Cooperative agreements  Omnibus Budget Reconciliation Act of 1987	0970-AA56
897	Services to Post-AFDC and Medicaid only families	0970-AA61

#### Family Support Administration—Final Rule Stage

Se- quence Number	Title	Regulation Identifier Number
898	Scope of Payments	0970-AA00
899	Retroactive Modification of Child Support Arrearages	0970-AA03
900	Aid to Families With Dependent Children; Definition of Permissible State Practice-Quality Control	0970-AA04
901	Aid to Families With Dependent Children Program; Implementation of the Deficit Reduction Act of 1984	0970-AA06
902	Consistency for the Food Stamp Program, AFDC Program, and the Adult Assistance Programs	0970-AA08
903	Refugee Resettlement Program; Refugee Cash and Assistance; Requirements for Job Search, Employment Services, and Employment; Refugee Medical Assistance; and Refugee Social Services	0970-AA10
904	Control System	0970-AA11
905	Control Persons.	0970-AA44
906	Federal Tax Refund Offset Process - Pre-Offset Notice Fee	0970-AA52
907	Emergency Community Services Homeless Grant Program; Interim Final Rule with Request for Comments	0970-AA57
908	Targeting of, and Tolerances for, Income and Eligibility Verification System Data	0970-AA58
909	Automated Data Processing Equipment and Services; Conditions for Federal Financial Participation II	0970-AA59

#### Family Support Administration—Completed Actions

Se- quence Number	Title	Regulation Identifier Number
910	Refugee Cash and Medical Assistance	0970-AA01
911	Aid to Families with Dependent Children; Treatment of Utility Payments By Applicant or Recipients Living in Certain Federally Assistance Housing.  Aid to Families With Dependent Children Program; Extension of Medicaid Eligibility When Support Collections Result in Termination of AFDC Eligibility.	
912		
913	Medical Support Enforcement #2	0970-AA07
914	Disregard of Child Support Payments; Regulations Implementing the Deficit Reduction Act of 1984	0970-AA15
915	Grants to States for Public Assistance Programs, Treatment of Reptacement Checks	0970-AA19
916	Alien Legalization	0970-AA48
917	FY 1988 Scoring System for Performance Indicators	0970-AA51

## DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) Office of the Secretary (OS)

**Prerule Stage** 

#### 593. PRIVACY ACT REGULATION

Legal Authority: 5 USC 552a CFR Citation: 45 CFR 5b

Legal Deadline: None

Abstract: This will be the first complete update since 1975 of the Department's Privacy Act Regulation implementing the Privacy Act of 1974. It will facilitate individuals' access to information and records that the Department maintains about them in more than 330 designated Privacy Act Systems of Records, clarifying and promulgating at one time all the subparts of the regulation. It will also help Departmental personnel

processing Privacy Act requests by providing them with an integrated regulation that is compatible with current procedures for processing such requests. The only alternative to this complete update is to continue to operate with a regulation that in the past has been revised on a piecemeal basis.

#### Timetable:

Action Date FR Cite
ANPRM 03/01/89

Small Entitles Affected: None
Government Levels Affected: None

Agency Contact: Russell M. Roberts, Director, FOI/Priv Div, Department of Health and Human Services, Office of the Secretary, Off of Pub Affairs, Rm 645-F, HIHH Bldg, 200 Independence Avenue, SW, Washington, DC 20201, 202 472-7453

RIN: 0991-AA11

## DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) Office of the Secretary (OS)

**Proposed Rule Stage** 

594. PRINCIPLES FOR DETERMINING COSTS AND COST ALLOCATION PROCEDURES APPLICABLE TO GRANTS, CONTRACTS, AND OTHER AGREEMENTS FOR WORK PERFORMED BY HOSPITALS

Legal Authority: 5 USC 301

CFR Citation: 45 CFR 74, Appendix E; 45 CFR 78

Legal Deadline: None

Abstract: This action will revise the Department's current cost principles for research and development activities under grants and contracts with hospitals to make them clearer, more specific, and compatible with cost principles issued by OMB for educational institutions and nonprofit

organizations. The revision will also broaden the coverage of the principles to include all grants, contracts and other agreements with hospitals (except the Medicare & Medicaid programs).

#### Timetable:

Action Date FR Cite

**Next Action Undetermined** 

Small Entities Affected: None

Government Levels Affected: Local, State

Additional Information: OMB is considering revisions to Circular A-21 and A-122 as a result of the Defense Procurement Improvement Act of 1985 (P.L. 99-145) and the Civilian Employee and Contractor Travel Expenses Act of 1985 (P.L. 99-234). This action should conform to those revisions also.

Agency Contact: Terrance J. Tychan, Director, Office of Procurement & Logistics Policy, Department of Health and Human Services, Office of the Secretary, Office of Procurement, Assist & Logistics, Rm 513D, HHH Bldg, 200 Independence Ave. SW, Washington, DC 20201, 202 245-8670

RIN: 0991-AA12

595. CIVIL MONEY PENALTIES AND SANCTIONS FOR HMOS AND COMPETITIVE MEDICAL PLANS

**Legai Authority:** PL 99-501, Sec 9312; PL 99-501, Sec 9434; PL 100-203, Sec

4014; PL 100-360, Sec 224; PL 100-360, Sec 411

CFR Citation: 42 CFR 1003; 42 CFR 417

Legal Deadline: None

Abstract: This proposed rule would provide for CMPs for each violation against any risk-sharing organization that: (1) fails substantially to provide medically necessary items and services that are required under the contract; (2) imposes premiums on enrolled individuals in excess of premiums permitted; (3) acts to expel or refuse, or to re-enroll an individual; (4) misrepresents or falsifies information; (5) engages in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment; or, (6) fails to provide for prompt payment of claims for services provided to enrollees. In addition, this rule would authorize the Medicare program to suspend enrollment of individuals in, and payment to a risksharing organization that (1) denies medically necessary care to a beneficiary or (2) commits marketing abuses or other violations specified in section 1876(i)(6) of the Social Security Act.

#### Timetable:

Action	Date	FR Cite
NPRM	11/00/88	
NPRM Comment Period End	01/00/89	
Final Action	06/00/89	

Smail Entities Affected: Undetermined

**Government Levels Affected: None** 

Additional information: This joint OIG/HCFA proposed rule is being revised as a result of broadened CMP and sanction authorities contained in PL 100-203, in addition to a technical amendment contained in PL 100-360.

Agency Contact: James Patton,
Director, Health Care Admin. Sanctions
Div., Office of Investigations,
Department of Health and Human
Services, Office of the Secretary, Office
of Inspector General, 6325 Security
Boulevard, Baltimore, MD 21207 21207,
301 965-9601

RIN: 0991-AA44

596. PROHIBITION ON USE OF PHYSICIAN INCENTIVE PLANS

Legal Authority: PL 99-501, Sec 9313

**CFR Citation:** 42 CFR 1001; 42 CFR 1003

Legal Deadline: None

Abstract: This proposed rule would prohibit a hospital from knowingly making incentive payments to a physician as an inducement to that physician to reduce or limit services provided to program beneficiaries who are under the direct care of that physician.

#### Timetable:

Action	Date	FR Cite
NPRM	12/00/88	
NPRM Comment Period End	02/00/89	
Final Action	06/00/89	

Small Entities Affected: Undetermined

**Government Levels Affected: None** 

Additional Information: The effective date for implementing regulations addressing physician incentive plans by risk-sharing HMOs and competitive medical plans has been delayed to 4/1/90 by P.L. 100-203, Sec 4016. This provision will be addressed through separate rulemaking at a later date.

Agency Contact: Joel Jay Schaer, Regulations Officer, Office of Inspector General, AO, Department of Health and Human Services, Office of the Secretary, Legislation, Regulations & Public Affairs, 330 Independence Avenue, S.W., Washington, D.C. 20201207, 202 472-5270

RIN: 0991-AA45

597. NEW CIVIL MONEY PENALTIES AND EXCLUSIONS AUTHORITIES RESULTING FROM OBRA 1986 AND OBRA 1987

Legai Authority: PL 99-501, Sec 9320; PL 99-501, Sec 9331; PL 99-501, Sec 9332; PL 99-501, Sec 9338; PL 100-203, Sec 4022; PL 100-203, Sec 4023; PL 100-203, Sec 4045; PL 100-203, Sec 4049; PL 100-203, Sec 4051; PL 100-203, Sec 4062; PL 100-203, Sec 4064; PL 100-203, Sec 4064; PL 100-203, Sec 4085; PL 100-203, Sec 4118; ...

**CFR Citation:** 42 CFR 1001; 42 CFR 1002; 42 CFR 1003

Legal Deadline: None

Abstract: This proposed rule provides for civil money penalties and exclusions for various program violations resulting from OBRA 1986 and OBRA 1987, as amended by the Medicare Catastrophic Coverage Act of 1988. Penalties and sanctions may be imposed against among other things: (1) those who bill Medicare beneficiaries on a non-assigned basis for services of a certified nurse anesthetist or a physician assistant: (2) non participating physicians billing for actual charges above permitted charges (3) nursing homes: (4) home health care providers: (5) unassigned lab services: (6) DME rental providers: and (7) providers of laboratory tests.

#### Timetable:

Action	Date	FR Cite
NPRM	04/00/89	
NPRM Comment Period End	06/00/89	
Final Action	12/00/89	

Small Entities Affected: Undetermined

Government Levels Affected: State, Federal

Additional information: PL 100-360, Sec 204 PL 100-360, Sec 411 This proposed rule is being revised as a result of broadened CMP and sanction authorities contained in P.L. 100-203. In addition, various technical amendments to the OBRA '87 provisions contained in P.L. 100-360, the Medicare Catastrophic Coverage Act of 1988, will be incorporated into this proposed rulemaking.

Agency Contact: James Patton, Director, Health Care Admin. Sanctions Div., Office of Investigations, Department of Health and Human Services, Office of the Secretary, Office of Inspector General, 6325 Security Boulevard, Baltimore, Maryland 21207, 301 965-9601

RIN: 0991-AA46

598. AMENDMENTS TO OIG EXCLUSION AND CMP AUTHORITIES RESULTING FROM PL 100-93

Significance: Agency Priority

**Legal Authority:** PL 100-93; PL 100-360, Sec 411

**CFR Citation:** 42 CFR 1001; 42 CFR 1002; 42 CFR 1003; 42 CFR 1004

Legal Deadline: None

Abstract: These regulations are designed to protect program beneficiaries from unfit health care practitioners, and otherwise to improve the anti-fraud provisions relating to Titles 5, 11, 18, 19, and 20.

#### Timetable:

Federal

Action	Date	FR Cite
NPRM NPRM Comment Period End	12/00/88 02/00/89	

### Small Entities Affected: Undetermined Government Levels Affected: State,

Additional Information: This proposed rule incorporates two previous items of proposed rulemaking (0991-AA21 and 0991-AAA39) as a result of the passage of PL 100-93. Technical amendments contained in PL 100-360, the Medicare Catastrophic Coverage Act of 1988 are also being incorporated into these proposed regulations.

Agency Contact: James Patton,
Director, Health Care Admin. Sanctions
Div., Office of Investigations,
Department of Health and Human
Services, Office of the Secretary, Office
of Inspector General, 6325 Security
Boulevard, Baltimore, Maryland 21207,
301 966-9601

RIN: 0991-AA47

### 599. OIG ANTI-KICKBACK PROVISIONS

Legal Authority: PL 100-93, Sec 4; PL 100-93, Sec 14

CFR Citation: 42 CFR 1001

Legal Deadline: Final, Statutory, August 18, 1989.

Abstract: This proposed rule will specify payment practices which, although potentially capable of inducing referrals of business under Medicare, are not to be considered kickbacks for purposes of criminal or civil remedies.

#### Timetable:

Action	Date		FR	Cite
ANPRM	10/19/87	52	FR	38794
ANPRM Comment Period End	12/18/87			
NPRM	09/00/88			
NPRM Comment Period End	11/00/88			
Final Action	08/00/89			

## Small Entities Affected: Undetermined Government Levels Affected: None

Agency Contact: Joel Schaer, Regulations Officer, Office of Inspector General, AO, Department of Health and Human Services, Office of the Secretary, 330 Independence Avenue, SW, Washington, D.C. 20201, 202 472-5270

RIN: 0991-AA49

### 600. PRO RURAL PRACTITIONERS AMENDMENTS

Legal Authority: PL 100-203, Sec 4095 CFR Citation: 42 CFR 1004

Legal Deadline: None

Abstract: This proposed rule would permit a hearing before an Administrative Law Judge of a provider in a rural health manpower shortage area, or in a county with a population of less than 70,000 before a program exclusion of that provider took place.

#### Timetable:

Action	Date	FR	Cite
NPRM	12/00/88		

#### Small Entitles Affected: Undetermined

#### Government Levels Affected: Federal

Agency Contact: James Patton,
Director, Health Care Admin. Sanctions
Div., Office of Inspector General,
Department of Health and Human
Services, Office of the Secretary, Office
of Investigations, 6325 Security
Boulevard, Baltimore, MD 21207, 301
966-9601

RIN: 0991-AA51

## 601. ● CIVIL MONEY PENALTIES AND SANCTION AUTHORITIES RELATING TO THE MEDICARE CATASTROPHIC COVERAGE PROVISIONS

Legal Authority: PL 100-360, Sec 202; PL 100-360, Sec 203; PL 100-360, Sec 221

CFR Citation: 42 CFR 1001; 42 CFR 1003

Legal Deadline: None

Abstract: This proposed rule would establish various new sanction and civil money penalties resulting from the Medicare Catastrophic Coverage Act of 1988. Among other provisions, these regulations would address CMPs for (1) failure to provide required survey data relating to covered outpatient drugs; (2) a physician's failure to provide appropriate diagnostic codes and information; and (3) the submission of improper claims for home IV drug therapy services.

#### Timetable:

Action	Date	FR Cite
NPBM	10/00/89	
NPRM Comment Period End	12/00/89	

#### Small Entities Affected: Undetermined

#### Government Levels Affected: Undetermined

Agency Contact: Joel Jay Schaer, Regulations Officer, Office of Inspector, AO, Department of Health and Human Services, Office of the Secretary, Legislation, Regulations & Public Affairs, 330 Independence Avenue, S.W., Washington, D.C. 20201, 202 472-5270

RIN: 0991-AA52

## 602. ● CIVIL MONEY PENALTIES FOR VIOLATIONS RELATING TO MEDICAL SUPPLEMENTAL POLICIES

Legal Authority: PL 100-360, Sec 428(b)

CFR Citation: 42 CFR 1003

Legal Deadline: None

Abstract: This proposed rule would establish CMPs in all cases where only criminal penalties previously applied for deceptive selling practices relating to Medicare Supplemental health insurance - or Medigap - policies.

#### Timetable:

Action	Date	FR Cite
NPRM	01/00/89	
NPRM Comment Period End	03/00/89	

#### Small Entities Affected: Undetermined

#### Government Levels Affected: Undetermined

Agency Contact: Joel Jay Schaer, Regulations Officer, Office of Inspector General, AO, Department of Health and Human Services, Office of the Secretary, Legislation, Regulations & Public Affairs, 330 Independence Avenue, S.W., Washington, D.C. 20201, 202 472-5270

RIN: 0991-AA53

## 603. ● CIVIL MONEY PENALTIES FOR MISUSE OF DEPARTMENTAL SYMBOLS OR EMBLEMS

Significance: Agency Priority

Legal Authority: PL 100-360, Sec 428(a)

CFR Citation: 42 CFR 1003 Legal Deadline: None HHS-OS

**Proposed Rule Stage** 

Abstract: This proposed rule would establish civil money penalties for the unauthorized use, in advertising or solicitation, of certain words letters, symbols or emblems associated with the Department or its programs in a manner that would convey and impression that an item or service was approved, endorsed or authorized by HHS.

Action	Date	FR Cite
NPRM	02/00/89	
NPRM Comment Period End	04/00/89	

Small Entities Affected: None Government Levels Affected: None Agency Contact: Joel Jay Schaer, Regulations Officer, Office of Inspector General, AO, Department of Health and Human Services, Office of the Secretary, Legislation, Regulations & Public Affairs, 330 Independence Avenue, S.W., Washington, D.C. 20201, 202 472-5270

RIN: 0991-AA54

## DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) Office of the Secretary (OS)

Final Rule Stage

604. NONDISCRIMINATION
REQUIREMENTS (INCLUDING ON THE
BASIS OF SEX OR RELIGION)
APPLICABLE TO BLOCK GRANTS
AND STANDARD
NONDISCRIMINATION PROCEDURES
APPLICABLE TO CERTAIN OTHER
PROGRAMS

**Legal Authority:** 42 USC 9906; 42 USC 300x-7; 42 USC 728; 42 USC 8625; 42 USC 9821; 42 USC 9849

CFR Citation: 45 CFR 92

Legal Deadline: None

Abstract: To implement the nondiscrimination requirements applicable to block grants authorized by the Omnibus Budget Reconciliation Act of 1981, P.L. 97-35.

#### Timetable:

Action	Date		FR	Cite	
NPRM	01/21/86	51	FR	2806	
NPRM Comment Period End	03/24/86	51	FR	2806	
Interim Final Rule	12/00/88				

Small Entities Affected: Businesses, Governmental Jurisdictions, Organizations

Government Levels Affected: Local, State

Additional Information: New CFR Subpart to be assigned.

Agency Contact: Marcella Haynes, Director, Policy and Special Projects Staff, Department of Health and Human Services, Office of the Secretary, Policy and Special Staff, OCR, Room 5032, HHS North Bldg, 330 Independence Ave, SW, Washington, DC 20201, 202 245-6671

RIN: 0991-AA02

### 605. FREEDOM OF INFORMATION ACT REGULATION

**Legal Authority:** 5 USC 552; 18 USC 1905; 31 USC 9701; 42 USC 1306a; EO 12600

CFR Citation: 45 CFR 5

Legal Deadline: Final, Statutory, April 25, 1987.

Abstract: This will be the first complete update since August 1974 of the Department's Public Information Regulation implementing the Freedom of Information Act. It will facilitate public access to information by making necessary revisions, clarifying, and promulgating at one time all the subparts of the regulation. It will also help Departmental personnel processing FOIA requests by providing them with an integrated regulation that is compatible with current procedures for processing FOIA requests and assessing search and copy fees that reflect the increased cost of such services. The only alternative to this complete update is to continue to operate with a regulation that in the past has been revised on a piecemeal basis.

#### Timetable:

Action	Date		FR	Cite
NPRM	04/08/86	51	FR	13250
NPRM Comment Period End	06/17/87			
Interim Final Rule	11/13/87	52	FR	43575
Interim Final Rule Public Comment Period Ends	12/14/87	52	FR	43575
Final Action	10/00/88			

Small Entities Affected: Undetermined Government Levels Affected: None

Agency Contact: Russell M. Roberts, Director, FOI/Priv Div, Department of Health and Human Services, Office of the Secretary, Off of Pub Affairs, Rm 645-F, Humphrey Bldg, 200 Independence Ave, SW, Washington, DC 20201, 202 472-7453

RIN: 0991-AA07

606. EQUAL OPPORTUNITY IN EMPLOYMENT: PUBLIC BROADCASTING, PUBLIC RADIO AND PUBLIC TELECOMMUNICATIONS ENTITIES RECEIVING FEDERAL FUNDS FROM THE CORPORATION FOR PUBLIC BROADCASTING

Legal Authority: 47 USC 2405 CFR Citation: 45 CFR 87.1-40

Legal Deadline: None

Abstract: Implements the Equal Opportunity in Employment Provisions of the Public Telecommunications Financing Act of 1978, PUB. L. 95-267, 47 U.S.C. 398(b)(1). This provision requires that equal opportunity in employment be afforded to all persons and that no person shall be subjected to discrimination in employment on the grounds of race, color, religion, national origin, or sex by the Public Broadcasting Service, National Public Radio, and public telecommunications entitles receiving Federal funds from the Corporation for Public Broadcasting.

#### Timetable:

Action	Date	FR Cite	
ANPRM	03/13/79		
NPRM	12/21/79	44 FR 75676	
Final Action	12/00/88		
Final Action Effective	12/00/88		

Small Entities Affected: Businesses

Government Levels Affected: Local, State

Public Compliance Cost: Yearly Recurring Cost: \$6,000 Agency Contact: Frank E. G. Weil, Chief, Policy Branch, Department of Health and Human Services, Office of the Secretary, Office for Civil Rights, 330 Independence Avenue, SW, Room 5411, Washington, DC 20201, 202 245-6700

RIN: 0991-AA22

#### 607. AUDITS OF NON-GOVERNMENTAL GRANTEES

Significance: Agency Priority Legal Authority: 5 USC 301 CFR Citation: 45 CFR 74.62(b),

(Revised)

Legal Deadline: None

Abstract: This action will implement revised OMB Circular A-88 which is expected to be issued sometime this year. The Circular will provide governmentwide standards for non-Federal audits of college and university recipients of Federal grants and contracts. The Circular and these amendments will replace the audit requirements currently contained in OMB Circular A-110.

#### Timetable:

Action	Date	FR Cite
Final Action	00/00/00	

**Small Entities Affected: None** 

**Government Levels Affected: None** 

Additional information: It is expected that OMB will publish a draft of its Circular in the Federal Register and obtain public comments. The specific form and nature of our action is expected to be mandated by OMB.

Agency Contact: Gary Houseknecht, Acting Director, Office of Assistance, and Cost Policy, Department of Health and Human Services, Office of the Secretary, Room 513D, Hubert H. Humphrey Bldg., 200 Independence Ave., SW, Washington, DC 20201, 202 245-7565

RIN: 0991-AA29

## 608. CIVIL MONEY PENALTIES AND EXCLUSIONS FOR ASSISTANTS AT CATARACT SURGERY

**Legal Authority:** PL 99-272, Sec 9307; PL 99-514, Sec 1895(b)(16)

**CFR Citation:** 42 CFR 1001; 42 CFR 1003

Legal Deadline: None

Abstract: These final regulations provide for the imposition of civil money penalties and exclusions against physicians billing the Medicare program or program beneficiaries for services of an assistant at surgery for cataract operations where prior approval has not been granted. This rule specifically responds to various comments raised as a result of the interim final, and makes a number of technical corrections to those final regulations.

#### Timetable:

Action	Date		FR	Cite
Interim Final Rule	04/10/87	52	FR	11649
Final Action	01/00/89			

Small Entitles Affected: None

**Government Levels Affected: None** 

Agency Contact: James Patton, Director, Health Care Admin. Sanctions Div., Office of Investigations, Department of Health and Human Services, Office of the Secretary, Office of Inspector General, 6325 Security Boulevard, Baltimore, MD 21207, 301 966-9601

RIN: 0991-AA37

# 609. CIVIL MONEY PENALTIES FOR FAILURE TO REPORT MEDICAL MALPRACTICE PAYMENTS AND FOR BREACHING THE CONFIDENTIALITY OF INFORMATION

**Legal Authority:** PL 99-660, Sec 421(c) and 427(b)

CFR Citation: 42 CFR 1003 Legal Deadline: None

Abstract: This final rule establishes civil money penalties against any individual or entity that fails to report information on medical malpractice payments in accordance with the Health Care Quality Improvement Act of 1986, and against any individual who breaches the confidentiality of information reported to the data bank established to collect and disseminate required information in accordance with that Act.

#### Timetable:

Action	Date		FR	Cite	
NPRM	03/21/88	53	FR	9260	
NPRM Comment Period End	05/20/88				
Final Action	10/00/88				

#### Small Entities Affected: None

**Government Levels Affected:** None

Agency Contact: James Patton,
Director, Health Care Admin. Sanctions
Div., Office of Investigations,
Department of Health and Human
Services, Office of the Secretary,
Department of Health and Human
Services, Baltimore, MD 21207, Office of
Inspector General, 301 965-9601

RIN: 0991-AA40

## DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) Office of the Secretary (OS)

610. ENFORCEMENT OF NONDISCRIMINATION ON THE BASIS OF HANDICAP IN THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

Significance: Agency Priority CFR Citation: 45 CFR 85.1-62

#### Completed:

Reason	Date		FR	Cite
Final Action	07/08/88	53	FR	25595
Final Action Effective	09/06/88	53	FR	25595

Small Entitles Affected: None

Government Levels Affected: Federal

Completed Actions

Agency Contact: Frank E.G. Weil 202 245-6700

RIN: 0991-AA17

611. AUTOMATIC DATA PROCESSING EQUIPMENT AND SERVICES; CONDITIONS FOR FEDERAL FINANCIAL PARTICIPATION II

Significance: Agency Priority

#### HHS-OS

**Completed Actions** 

CFR Citation: 45 CFR 95.601; 45 CFR 95.605; 45 CFR 95.611; 45 CFR 95.612; 45 CFR 95.613; 45 CFR 95.615; 45 CFR 95.617; 45 CFR 95.619; 45 CFR 95.621; 45 CFR 95.623; 45 CFR 95.624; 45 CFR 95.625; 45 CFR 95.631; 45 CFR 95.633; 45 CFR 95.641

#### Completed:

Heason	Date	FH Cite
Transferred to Family Support Administration under RIN 0970-aa59	08/26/88	

Small Entitles Affected: None

Government Levels Affected: Local, State, Federal

Agency Contact: Ron Lentz 202 245-7354

RIN: 0991-AA34

#### 612. BLOCK GRANT PROGRAMS

Significance: Agency Priority CFR Citation: 45 CFR 96

#### Completed:

Reason	Date		FR	Cite
Final Action	03/03/88	53	FR	6824
Final Action Effective	04/04/88	53	FR	6824

Small Entitles Affected: None

**Government Levels Affected: State** 

Agency Contact: Robert C. Raymond 202 245-7316

RIN: 0991-AA38

### 613. PROGRAM FRAUD CIVIL REMEDIES

Significance: Agency Priority CFR Citation: 45 CFR 79

#### Completed:

Reason	Date		FR	Cite
Final Action	04/08/88	53	FR	11656
Final Action Effective	04/08/88			

Small Entities Affected: Businesses, Organizations

Government Levels Affected: Federal

Agency Contact: D. McCarty Thornton 202 245-6306

RIN: 0991-AA41

#### 614. TARGETING OF, AND TOLERANCES FOR, INCOME AND ELIGIBILITY VERIFICATION SYSTEM DATA

Significance: Agency Priority CFR Citation: 42 CFR 453.952; 45 CFR 205.56

#### Completed:

Reason	Date	FR Cite
Transferred to Family Support Administration under RIN 0970-aa58	08/26/88	

Small Entities Affected: None

Government Levels Affected: State, Federal

Agency Contact: Sheldon Shalit 202 245-0384

RIN: 0991-AA42

#### 615. GOVERNMENTWIDE DEBARMENT AND SUSPENSION (NONPROCUREMENT)

CFR Citation: 45 CFR 76

#### Completed:

Reason	Date		FR	Cite
Final Action Final Action Effective	05/26/88 10/01/88	53	FR	19200

Small Entities Affected: None

**Government Levels Affected:** Local, State

Agency Contact: Gary Houseknecht 202 245-7565

RIN: 0991-AA43

### 616. PROGRAM FRAUD CIVIL REMEDIES

CFR Citation: 45 CFR 79

#### Completed:

Reason	Date	FR Cite
Duplicate of RIN 0991-aa41	08/26/88	

Small Entities Affected: None

**Government Levels Affected:** State, Federal

Agency Contact: Joel Schaer 202 472-5270

RIN: 0991-AA50

## DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) Departmental Management (HHSDM)

Final Rule Stage

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

Legal Authority: 5 USC 504(c)(1) CFR Citation: 45 CFR 13

Legal Deadline: None

Abstract: The Equal Access to Justice Act requires agencies to pay attorney fees to parties prevailing against the Government in certain types of administrative proceedings. It requires each agency to issue rules implementing the Act as it applies to these proceedings. As originally enacted, the Act had a sunset clause. A recent

statutory amendment eliminated the sunset provision and made other changes in the Act. The instant regulation would amend 45 CFR Part 13 (HHS's regulation implementing the Act) to eliminate the corresponding sunset provision and to make other changes conforming with the statutory changes.

#### Timetable-

Action	Date	FR	Cite	
Final Action Effective	10/01/84			
NPRM	06/19/87	52 FR	23311	

Action Date FR Cite

NPRM Comment 08/17/87
Period End
Final Action 12/00/88

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Darrel J. Grinstead, Associate General Counsel, Business and Administrative Law Division, Department of Health and Human Services, Departmental Management, Room 5362, HHS North Building, 330 HHS-HHSDM

Final Rule Stage

Independence Avenue, SW, Washington, DC 20201, 202 475-0150

RIN: 0990-AA02

618. TESTIMONY BY EMPLOYEES AND THE PRODUCTION OF DOCUMENTS IN PROCEEDINGS WHERE THE UNITED STATES IS NOT A PARTY

Significance: Agency Priority

Legal Authority: 5 USC 301; 5 USC 552

CFR Citation: 45 CFR 2

Legal Deadline: None

Abstract: Part 2 of Title 45, CFR, governs the testifying of HHS employees as part of their official duties in litigation where neither the United States nor other Federal agencies are parties. This rule will amend Part 2 to clarify it and to resolve minor technical problems.

Timetable:

Action Date FR Cite
Final Action 10/00/88

Small Entities Affected: None

**Government Levels Affected:** Federal

Agency Contact: Darrel J. Grinstead, Associate General Counsel, Business and Administrative Law Division, Department of Health and Human Services, Departmental Management, Room 5362, Wilbur J. Cohen Building, 330 Independence Avenue, SW, Washington, D.C. 20201, 202 475-0150

RIN: 0990-AA03

## DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) Office of Human Development Services (HDSO)

**Proposed Rule Stage** 

#### 619. FOSTER CARE, ADOPTION ASSISTANCE, AND CHILD WELFARE SERVICES

Legal Authority: 42 USC 670 et seq; Federal Payment for Foster Care and Adoption Assistance; 42 USC 620 et seq Child Welfare Services; 42 USC 1302 Rules and Regulations

**CFR Citation:** 45 CFR 1356; 45 CFR 1357

Legal Deadline: None

Abstract: This NPRM will propose criteria the Department will use to verify that a State has met statutory requirements and is eligible to receive additional funds under Section 427 of the Social Security Act as amended by the Adoption Assistance and Child Welfare Act of 1980 (Pub. L. 96-272). The proposed rule will contain the specific criteria by which State performance in meeting the requirements of Section 427 is determined, the percentage levels and other standards for case record compliance, and procedures for conducting compliance reviews.

#### Timetable:

Action	Date	FR	Cite	
NPRM	00/00/00			

Small Entities Affected: None

**Government Levels Affected: State** 

Agency Contact: Betty Stewart, Associate Commissioner, Children's Bureau, ACYF, Department of Health and Human Services, Office of Human Development Services, P.O. Box 1182, Washington, DC 20201, 202 755-7600

RIN: 0980-AA08

#### 620. RUNAWAY AND HOMELESS YOUTH PROGRAM

Legal Authority: 42 USC 5701 Note The Runaway and Homeless Youth Act, as amended

CFR Citation: 45 CFR 1351

Legal Deadline: None

Abstract: These rules will make technical changes in 45 CFR 1351 to incorporate changes made by reauthorization of the Runaway and Homeless Youth Act.

#### Timetable

Action	Date	FR Cite
NPRM	03/30/89	

Small Entities Affected: Organizations

**Government Levels Affected: None** 

Agency Contact: Paget W. Hinch, Associate Commissioner, ACYF/HDS, Department of Health and Human Services, Office of Human Development Services, Family and Youth Services Bureau, ACYF/HDS, PO Box 1182, Washington, DC 20013, 202 472-4426

RIN: 0980-AA11

### 621. HEAD START CRITERIA FOR SELECTION OF NEW GRANTEES

Legal Authority: 42 USC 9831 et seq Head Start Act

CFR Citation: 42 CFR 1302 Legal Deadline: None **Abstract:** The NPRM will propose additional new criteria that, if adopted, will be used in the selection of new Head Start grantees.

#### Timetable:

Action	Date	FR	Cite
NPRM	12/30/88	-	

**Small Entities Affected: Organizations** 

Government Levels Affected: None

Agency Contact: Doug Klafehn, Head Start Bureau ACYF/OHDS, Department of Health and Human Services, Office of Human Development Services, P. O. Box 1182, Washington, DC 20013, 202 755-0590

RIN: 0980-AA17

### 622. HEAD START STAFF AND PROGRAM OPTIONS REQUIREMENTS

Significance: Agency Priority

Legal Authority: 42 USC 9831 et seq Head Start Act

**CFR Citation:** 45 CFR 1304; 45 CFR

Legal Deadline: None

Abstract: The NPRM will propose changes in existing regulations related to program design including class size, hours of operation, and program options such as center-based and home-based Head Start services. The NPRM will also propose, in a new Part, the requirements for home-based Head Start services.

#### HHS-HDSO

#### **Proposed Rule Stage**

41901

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Action	Date	FR	Cite
NIDDAE	12/20/99		

## Small Entities Affected: Organizations Government Levels Affected: None

Agency Contact: Doug Klafehn, Chief, Program Management and Operations Branch Head Start Bureau, ACYF/OHDS, Department of Health and Human Services, Office of Human Development Services, P. O. Box 1182,

Washington, DC 20013, 202 755-0590

RIN: 0980-AA18

### 623. HEAD START APPEALS PROCESS

Legal Authority: 42 USC 9831 et seq Head Start Act

CFR Citation: 45 CFR 1303

Legal Deadline: None

Abstract: The NPRM will propose revisions to current procedures for appeals from Head Start grantees and delegate agencies to improve the effectiveness and efficiency of the appeals process.

#### Timetable:

Action	Date	FR	Cite
NPRM	01/01/89		

#### Small Entitles Affected: Organizations

#### Government Levels Affected: None

Agency Contact: Doug Klafehn, Chief, Program Management and Operations Branch, Head Start Bureau, ACYF/OHDS, Department of Health and Human Services, Office of Human Development Services, P. O. Box 1182, Washington, DC 20013, 202 755-0590

RIN: 0980-AA20

#### 624. HEAD START PERFORMANCE STANDARDS FOR SERVICES TO HANDICAPPED CHILDREN

Legal Authority: 42 USC 9839 CFR Citation: 45 CFR 1308

Legal Deadline: None

Abstract: The NPRM will propose to establish a new part 1308 setting forth proposed performance standards that must be used in providing Head Start services to handicapped children.

#### Timetable:

Action	Date	`	FR	Cite
NPRM	12/30/88			

## Small Entitles Affected: Organizations Government Levels Affected: None

Agency Contact: Jane DeWeerd, Child Development Specialist, Department of Health and Human Services, Office of Human Development Services, Administration for Children, Youth and Families, PO Box 1182, Washington, DC 20013, 202 755-7944

RIN: 0980-AA21

#### 625. HEAD START RECRUITMENT SELECTION AND ENROLLMENT OF CHILDREN

Legal Authority: 45 USC 9831 et seq

CFR Citation: 45 CFR 1305

Legal Deadline: None

Abstract: In this NPRM, the Head Start Bureau will propose amendments to existing regulations governing recruitment, selection, and enrollment of children.

#### Timetable:

Action	Date	FR	Cite
NPRM	12/30/88		

Small Entitles Affected: Organizations

#### Government Levels Affected: None

Agency Contact: Doug Klafehn. Department of Health and Human Services, Office of Human Development Services, Head Start Bureau, Box 1182. Washington, D.C. 20013, 202 755-0590

RIN: 0980-AA27

#### 626. HEAD START: LIMITS ON COSTS OF DEVELOPMENT AND ADMINISTRATION

Legal Authority: 42 USC 9839

CFR Citation: 45 CFR 1301

Legal Deadline: None

Abstract: 45 CFR 1301.32 is being amended to provide additional clarification to Head Start programs in meeting the requirement that the costs of developing and administering a Head Start program not exceed 15 percent of total costs.

#### Timetable:

Action	Date	FR	Cite
NPRM	03/31/89		

Small Entitles Affected: Organizations

Government Levels Affected: None

Agency Contact: Douglas Klafehn, Head Start Bureau, Department of Health and Human Services, Office of Human Development Services, Room 5851, 400 6th Street, S.W., Washington, DC 20213, 202 755-0590

RIN: 0980-AA32

#### 627. HEAD START PERFORMANCE STANDARDS FOR INFANTS AND TODDLERS

Legal Authority: 42 USC 9831 et seq

CFR Citation: 45 CFR 1307

Legal Deadline: None

Abstract: The NPRM will propose to establish a new Part 1307 setting forth performance standards that must be used in providing Head Start services to infants and toddlers.

#### Timetable:

Action	Date	Cite
NPRM	12/30/88	

#### Small Entities Affected: Organizations

#### Government Levels Affected: None

Agency Contact: Douglas Klafehn, Head Start Bureau, Department of Health and Human Services, Office of Human Development Services, Room 5851, 400 6th Street, S.W., Washington, D.C. 20213, 202 755-0590

RIN: 0980-AA33

### 628. ADOPTION AND FOSTER CARE INFORMATION

Legal Authority: 42 USC 679

**CFR Citation:** 45 CFR 1355; 45 CFR 1356; 45 CFR 1357

Legal Deadline: NPRM, Statutory, December 31, 1988.

Abstract: Section 479 of the Social Security Act requires the Secretary to publish regulations to collect data relating to foster care and adoption in the United States.

#### Timetable:

Action	Date	FR	Cite
NPRM	12/30/88		

Small Entitles Affected: None

HHS-HDSO

**Proposed Rule Stage** 

#### **Government Levels Affected: State**

Agency Contact: Joseph Mottola, Deputy Commissioner, Administration for Children, Youth and Families, Department of Health and Human Services, Office of Human Development Services, Room 5030, 400 6th Street, S.W., Washington, DC 20213, 202 755-7726

RIN: 0980-AA35

### 629. DEVELOPMENTAL DISABILITIES PROGRAM

**Legal Authority:** 42 USC 6000 et seq **CFR Citation:** 45 CFR 1385; 45 CFR 1386; 45 CFR 1387; 45 CFR 1388

Legal Deadline: NPRM, Statutory, April 30, 1988.

Abstract: This proposed rule will amend current regulations to implement statutory changes made by passage of Public Law 100-146, the Developmental Disabilities Assistance and Bill of Rights Act of 1987. The NPRM will include proposals to establish a peer review process for the University Affiliated Facilities program, set forth standards to assure that States supplement and do not supplant program resources, and revise paperwork and reporting requirements.

#### Timetable:

Action	Date	FR	Cite
AIDDAA	10/00/00		

Small Entities Affected: Organizations

**Government Levels Affected: State** 

Agency Contact: James J. Colarusso, Director, Management Services, Administration on Developmental Disabilities, Department of Health and Human Services, Office of Human Development Services, Room 351-D, 200 Independence Ave., S.W., Washington, DC 20201, 202 245-2890

RIN: 0980-AA36

#### 630. ● CHILD ABUSE AND NEGLECT: TECHNICAL AMENDMENTS

Legal Authority: 42 USC 5101 et seq

CFR Citation: 45 CFR 1340

Legal Deadline: None

Abstract: Technical and conforming changes will be made in 45 CFR 1340 to implement statutory changes made by the recent reenactment of the Child Abuse Prevention and Treatment Act.

#### Timetable:

Action	Date	FR	Cite
NPRM	12/30/88		

Small Entitles Affected: None

Government Levels Affected: State

Agency Contact: Susan Weber, Deputy Associate Commissioner, National Center on Child Abuse and Neglect, Department of Health and Human Services, Office of Human Development Services, Room 2030, 400 6th St., S.W., Washington, DC 20213, 202 755-7600

RIN: 0980-AA40

## DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) Office of Human Development Services (HDSO)

Final Rule Stage

### 631. NONRECURRING COSTS OF ADOPTION

Legal Authority: 42 USC 673 CFR Citation: 45 CFR 1356 Legal Deadline: None

Abstract: This rule will implement new statutory requirements for States to establish a program to reimburse parent(s) who adopt a child with special needs for their nonrecurring costs of adoption.

#### Timetable:

Action	Date		FR	Cite	
NPRM	04/14/88	53	FR	12436	
NPRM Comment Period End	06/13/88				
Final Action	12/30/88				

Small Entitles Affected: None

**Government Levels Affected: State** 

Agency Contact: Beverly Stubbee, Department of Health and Human Services, Office of Human Development Services, Children's Bureau, P.O. Box 1182, Washington, D.C. 20201, 202 755-7447

RIN: 0980-AA24

### 632. NATIVE HAWAIIAN LOAN FUND DEMONSTRATION PROJECT

Legal Authority: 42 USC 2991 et seq CFR Citation: 45 CFR 1336

Legal Deadline: Final, Statutory, March 29, 1988.

Abstract: This rule will amend regulations that implement recent statutory changes in the Native American Programs Act to set forth the procedures and criteria to be used in making a demonstration grant to

operate a revolving loan fund for the purpose of economic and social selfsufficiency of Native Hawaiians.

#### Timetable:

Action	Date		FR	Cite
Interim Final Bule	06/24/88	53	FR	23964
Final Action	12/30/88			

Small Entitles Affected: Organizations

**Government Levels Affected: State** 

Agency Contact: Jan Phalen, Program Analyst, Administration for Native Americans, Department of Health and Human Services, Office of Human Development Services, Room 5300, 330 Independence Ave., S.W., Washington, DC 20201, 202 245-7714

RIN: 0980-AA37

## DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) Office of Human Development Services (HDSO)

**Completed Actions** 

### 633. HEAD START PERSONNEL POLICIES

Significance: Regulatory Program
CFR Citation: 45 CFR 1301

Completed:

Reason	Date		FR	Cite	
Final Action Final Action Effective	02/29/88 03/30/88	53	FR	5975	

Small Entitles Affected: Organizations
Government Levels Affected: None

Agency Contact: Doug Klafehn 202 755-0590

RIN: 0980-AA10

634. GRANTS FOR STATE AND COMMUNITY PROGRAMS ON AGING; GRANTS TO INDIAN TRIBES; AND GRANTS TO ORGANIZATIONS SERVING OLDER HAWAIIANS FOR SUPPORTIVE AND NUTRITION SERVICES

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

#### Completed:

Reason	Date		FR	Cite
Final Action Final Action	08/31/88 08/31/88	53	FR	33758
Effective	08/31/88			

Small Entitles Affected: Governmental Jurisdictions, Organizations

**Government Levels Affected: State** 

Agency Contact: Frederick Luhmann 202 245-2618

RIN: 0980-AA34

## DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) Social Security Administration (SSA)

**Proposed Rule Stage** 

635. OLD-AGE, SURVIVORS, AND DISABILITY INSURANCE PROGRAM; TREATMENT OF OASDI LUMP SUM AND MONTHLY PAYMENTS IN THE AID TO FAMILIES WITH DEPENDENT CHILDREN PROGRAM

Significance: Agency Priority

**Legal Authority:** 42 USC 405; 42 USC 407; 42 USC 602; 42 USC 1302; 42 USC 1383(a)

CFR Citation: 20 CFR 404U; 20 CFR 416F

Legal Deadline: None

Abstract: These proposed rules would revise 20 CFR 404.2040, which stipulates the use of benefit payments by a representative payee, explaining that retroactive and monthly title II benefits received by a representative payee may be used for other members of the AFDC Unit. We are also proposing direct payment to a beneficiary under age 18 if the beneficiary is within 7 months of attaining age 18 and is initially filing an application for benefits. This proposed revision represents a policy change and is an extension of the 4-month period in our current regulations.

Timetable:

Action	Date		FR	Cite
NPRM	08/22/88	53	FR	31886
NPRM Comment Period End	10/21/88			
Cinal Action	0E/00/00			

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Phil Berge, Legal Assistant, Department of Health and Human Services, Social Security Administration, Office of Regulations, 6401 Security Boulevard, Baltimore, Maryland 21235, 301 965-1769

RIN: 0960-AA90

636. OLD-AGE, SURVIVORS, AND DISABILITY INSURANCE PROGRAM; REVISED MEDICAL CRITERIA FOR DETERMINATION OF DISABILITY; CARDIOVASCULAR SYSTEM

**Legal Authority:** 42 USC 1302; 42 USC 1383; 42 USC 405

CFR Citation: 20 CFR 404.1500ff Appendix 1

Legal Deadline: None

Abstract: Section 4.00 of Appendix 1 of the Disability regulations (404.1501 through 404.1599) describes cardiovascular impairments considered severe enough to prevent an individual from doing any gainful activity. Because of the advances in medical technologies and practice in this area we anticipate the need to revise the criteria in the Listing of Impairments to bring this section up to date. The Supplemental Security Income program incorporates by reference and uses the same medical criteria as the Old-Age, Survivors, and Disability Insurance program.

Timetable:

Action	Date	FR	Cite	
NPRM	04/00/89			

**Small Entities Affected: None** 

Government Levels Affected: None

Agency Contact: Harry Short, Legal Assistant, Department of Health and Human Services, Social Security Administration, Office of Regulations, 6401 Security Blvd., Baltimore, MD 21235, 301 965-1757

RIN: 0960-AA99

637. OLD-AGE, SURVIVORS, AND DISABILITY INSURANCE PROGRAM; REVISED MEDICAL CRITERIA FOR DETERMINATION OF DISABILITY; RESPIRATORY SYSTEM

**Legal Authority:** 42 USC 1302; 42 USC 1383; 42 USC 405

CFR Citation: 20 CFR 404.1500ff, Appendix 1

Legal Deadline: None

Abstract: Section 3.00 of Appendix 1 to the Disability Regulations (404.1501 through 404.1599) describes those respiratory impairments which are considered severe enough to prevent a person from engaging in any gainful activity. We are proposing comprehensive revisions to that section to require consideration of the nature and clinical manifestations of respiratory disorders, as well as consideration of the degree of limitations such disorders may impose on an individual's ability to work. The Supplemental Security Income program incorporates by reference and uses the same medical criteria as the Old-Age. Survivors, and Disability Insurance programs.

#### Timetable:

Action	Date	FR	Cite	
NPRM	11/00/89			

Smail Entitles Affected: None

Government Leveis Affected: None

Agency Contact: Harry Short, Legal Assistant, Department of Health and Human Services, Social Security Administration, Office of Regulations, 6401 Security Blvd., Baltimore, MD 21235, 301 965-1757

RIN: 0960-AB00

638. OLD-AGE, SURVIVORS, AND DISABILITY INSURANCE PROGRAM; REVISED MEDICAL CRITERIA FOR DETERMINATION OF DISABILITY; MUSCULOSKELETAL SYSTEM

**Legai Authority:** 42 USC 1302; 42 USC 405; 42 USC 1383

CFR Citation: 20 CFR 404.1500ff, Appendix 1

Legai Deadline: None

Abstract: Section 1.00 of Appendix 1 to the Disability Regulations 404.1501 through 404.1599 describes those musculoskeletal impairments which are considered severe enough to prevent a person from doing any gainful activity. We are proposing comprehensive revisions to that section to ensure that the medical evaluation criteria are up to date and consistent with the latest advances in medicine. The Supplemental Security Income program incorporates by reference and uses the same medical criteria as the Old-Age Survivors, and Disability Insurance program.

#### Timetable:

Action	Date	FR	Cite
NPRM ·	01/00/89		

Smail Entities Affected: None

**Government Leveis Affected: None** 

Agency Contact: Henry Lerner, Legal Assistant, Department of Health and Human Services, Social Security Administration, Office of Regulations, 6401 Security Blvd., Baltimore, MD 21235, 301 965-1756

RIN: 0960-AB01

639. • SUPPLEMENTAL SECURITY INCOME PROGRAM AND MEDICAID ASSISTANCE; WHAT IS NOT INCOME

Legal Authority: 42 USC 1382a

CFR Citation: 20 CFR 416.1103(a); 42 CFR 435.725(c); 42 CFR 435.726(c); 42 CFR 435.735(c); 42 CFR 435.735(c); 42 CFR 436.832(c)

Legal Deadline: None

Abstract: The proposed rule changes SSI policy to consider Veterans Administration payments resulting from unusual medical expenses not to be income for SSI purposes.

#### Timetable:

Action	Date		FR	Cite
NPRM	08/24/88	53	FR	32252
NPRM Comment Period End	10/24/88			
Cinct Action	04/00/00			

Small Entitles Affected: None

**Government Levels Affected: None** 

Agency Contact: Irving Darrow, Legal Assistant, Department of Health and Human Services, Social Security Administration, Office of Regulations, 6401 Security Blvd., Baltimore, MD 21235, 301 965-1755

RIN: 0960-AB09

640. OLD-AGE, SURVIVORS, AND DISABILITY INSURANCE AND SUPPLEMENTAL SECURITY INCOME PROGRAMS; ADJUSTMENTS IN SSI BENEFITS ON ACCOUNT OF RETROACTIVE BENEFITS UNDER TITLE II

Significance: Regulatory Program

Legal Authority: 42 USC 405; 42 USC 1320a-6; 42 USC 1302; 42 USC 1383; PL 98-369, Sec 2615; 42 USC 1383b; 42 USC 1327

CFR Citation: 20 CFR 404.408b; 20 CFR 416.1123; 20 CFR 416.1402(m); 20 CFR 416.1123a; 20 CFR 404.902

Legai Deadline: None

Abstract: Sec. 2615 of Pub. L. 98-369 amended sec. 1127 of the Social Security Act to eliminate loopholes that permitted some people who were paid Old-Age, Survivors and Disability Insurance (OASDI) and Supplemental Security Income (SSI) benefits retroactively to receive more in total benefits for the same period than if they had been paid the benefits when regularly due. The two main changes are: (1) SSI benefits will be reduced where retroactive OASDI benefits have been paid before the SSI benefits. Under prior law, reductions could be made only in retroactive OASDI

benefits and only when the retroactive SSI had been paid first. (2) OASDI or SSI benefits payable upon reinstatement following a period of suspension or termination will be reduced by the amount of SSI benefits that would not have been paid if the OASDI benefits had been paid when regularly due. We will amend our regulations to conform to the statutory changes. The program savings to SSA are estimated as \$5 million a year.

#### Timetable:

Action	Date	FR Cite
NPRM	10/00/88	-
Final Action	00/00/00	

Small Entities Affected: None

**Government Levels Affected: None** 

Agency Contact: Jack Schanberger, Legal Assistant, Department of Health and Human Services, Social Security Administration, Office of Regulations, 6401 Security Boulevard, Baltimore, Maryland 21235, 301 965-8471

RIN: 0960-AB38

641. SUPPLEMENTAL SECURITY INCOME PROGRAM; LIMITATION ON RECOUPMENT RATE IN CASE OF OVERPAYMENT

Legal Authority: 42 USC 1302; 42 USC 1381; 42 USC 1381a; 42 USC 1382; 42 USC 1382c; 42 USC 1383; 42 USC 1383b

CFR Citation: 20 CFR 416E

Legal Deadline: None

Abstract: These proposed rules which implement section 2612 of Pub. L. 98-369 will limit the rate at which an overpayment may be recovered from an individual still receiving benefits (SSI or federally administered supplementary payments, or both) to 10 percent of the recipient's total income (countable income plus SSI and State supplementary payments) or the recipient's payment for the month, whichever is less. The 10 percent requirement will apply only to recipients in current payment status. The 10 percent limit will not apply in situations involving conditional disposition of resources agreements, misuse of burial funds, recovery by refund, cross program adjustment for individuals not in SSI current pay or where it is determined that the overpayment occurred because of recipient fraud, willful misrepresentation, or concealment. The

proposed rules, in negotiated cases, set a rate of withholding that is appropriate for the financial condition of the overpaid person after (continued)

#### Timetable:

Action	Date	FR Cite
NPRM	11/00/88	

Small Entitles Affected: None

Government Levels Affected: None

Additional information: ABSTRACT CONT: factual evaluation. Such cases will also be considered initial determinations for which the recipient has appeal rights. Estimated costs are FY 1986 through FY 1989 - program costs of \$18 million per year and administrative costs of \$.5 million per year.

Agency Contact: Larry Dudar, Legal Assistant, Department of Health and Human Services, Social Security Administration, Office of Regulations, 6401 Security Boulevard, Baltimore, MD 21235, 301 965-1795

RIN: 0960-AB40

642. OLD-AGE, SURVIVORS, AND DISABILITY INSURANCE AND SUPPLEMENTAL SECURITY INCOME PROGRAMS; EVALUATION GUIDES FOR DETERMINING SUBSTANTIAL GAINFUL ACTIVITY (SGA)

**Legal Authority:** PL 98-460, Sec 10 **CFR Citation:** 20 CFR 404; 20 CFR 416

Legal Deadline: None

Abstract: These proposed changes will incorporate into regulations of the Social Security Administration a number of policies relating to the evaluation of a person's work activity that are now in Social Security Rulings published in 1983 and 1984.

#### Timetable:

Action	Date	FR	Cite
NIDDA	02/00/89		

Small Entities Affected: None

**Government Levels Affected: None** 

Agency Contact: Harry Short, Legal Assistant, Department of Health and Human Services, Social Security Administration, Office of Regulations, 6401 Security Boulevard, Baltimore, MD 21235, 301 965-1757

RIN: 0960-AB73

643. OASDI & SSI PROGRAMS; DEFINITION OF OVERPAYMENT AND LIABILITY FOR REPAYMENT OF AN OVERPAYMENT

**Legal Authority: 42 USC 404; 42 USC 405; 42 USC 1302** 

**CFR Citation:** 20 CFR 404.501; 20 CFR 404.502; 20 CFR 416.537; 20 CFR 404.501a

Legal Deadline: None

Abstract: These proposed rules implement section 12113 of Pub. L. 99-272 (Consolidated Omnibus Budget Reconciliation Act of 1985) enacted April 7, 1986. That legislation establishes a Social Security benefit overpayment or a Supplemental Security Income benefit overpayment to a joint account owner in certain cases in which the beneficiary is deceased and payment is made after death. Also, we propose to add clarifying changes to the title II and title XVI regulations to explain the procedures used to collect benefit overpayments.

#### Timetable:

Action	Date	FR Cite

**Next Action Undetermined** 

Small Entities Affected: None

**Government Levels Affected:** None

Agency Contact: Duane Heaton, Legal Assistant, Department of Health and Human Services, Social Security Administration, Office of Regulations, 6401 Security Blvd., Baltimore, MD 21235, 301 965-8470

RIN: 0960-AB78

644. SUPPLEMENTAL SECURITY INCOME PROGRAM; TREATMENT OF PROPERTY HELD IN TRUST OR OTHER SIMILAR LEGAL DEVICES WHEN THE PROPERTY IS AVAILABLE FOR A BENEFICIARY'S SUPPORT AND MAINTENANCE

Legal Authority: 42 USC 1302; 42 USC 1381; 42 USC 1381a; 42 USC 1382a; 42 USC 1382b; 42 USC 1382cff); 42 USC 1383

**CFR Citation:** 20 CFR 416.1201

Legal Deadline: None

Abstract: This proposed regulation provides that assets held in any revocable or irrevocable trust or any other similar legal device including but not limited to gifts made in accordance

with the Uniform Gifts to Minors Act, if available for the beneficiary's support and maintenance, will be a countable resource. It would include as a resource trust assets that could be but are not disbursed to the beneficiary either at the discretion of the trustees or at the direction of the truster because such disbursement would adversely affect the beneficiary's eligibility for Supplemental Security Income benefits.

#### Timetable:

Action	Date	FR	Cite

**Next Action Undetermined** 

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Henry D. Lerner, Legal Assistant, Department of Health and Human Services, Social Security Administration, Office of Regulations, 6401 Security Blvd., Baltimore, MD 21235, 301 965-1756

RIN: 0960-AB79

645. OLD-AGE, SURVIVORS AND DISABILITY INSURANCE; BLACK LUNG; AND SUPPLEMENTAL SECURITY INCOME PROGRAMS; AND ORGANIZATION AND PROCEDURES; APPLICATION OF CIRCUIT COURT LAW

Significance: Agency Priority

**Legal Authority:** 42 USC 405; 42 USC 1302; 42 USC 1395; 42 USC 1395(a)(2); 42 USC 1395hb; 5 USC 552

**CFR Citation:** 20 CFR 422E; 20 CFR 404J; 20 CFR 410F; 20 CFR 416N

Legal Deadline: None

Abstract: The proposed regulations describe a new type of Social Security Ruling which is available to the public and which is issued when the decision of a United States Court of Appeals conflicts with Social Security Administration policy. The Ruling states how the decision is applied to claims of persons living in the particular circuit.

#### Timetable:

Action	Date		FR	Cite
Prior Notice of Proposed Rulemaking	01/23/87	52	FR	02557
NPRM	10/00/88			

Small Entitles Affected: None

#### **Government Levels Affected: None**

Agency Contact: Phil Berge, Legal Assistant. Department of Health and Human Services, Social Security Administration, Office of Regulations. 6401 Security Blvd., Baltimore, MD 21235, 301 965-1769

RIN: 0960-AB85

646. SUPPLEMENTAL SECURITY
INCOME PROGRAM; EXCLUSIONS
FROM INCOME AND RESOURCES OF
INDIAN JUDGEMENT FUNDS AND PER
CAPITA DISTRIBUTIONS

**Legal Authority:** PL 97-458; PL 98-64; PL 100-241

**CFR Citation:** 20 CFR 416K Appendix: 20 CFR 416.1234; 20 CFR 416.1236

Legal Deadline: None

Abstract: The proposed regulation reflects the provisions of the following statutes: (1) Pub. L 97-458 enacted January 12, 1983, which provides that Indian judgement funds held in trust or distributed per capita pursuant to a plan approved by Congress or the Secretary of the Interior are excluded from income and resources under the Supplemental Security Income program (2) Pub. L 95-64 enacted August 7, 1983. which provides for the exclusion of all funds held in trust by the Secretary of the Interior for an Indian tribe and distributed per capita to a member of that tribe and (3) Pub. L 100-241 enacted February 3, 1988, which provides for the exclusion from income and resources of certain items received by an individual Alaska native or descendent of an Alaska native from a native corporation. Some savings in program costs may result from these changes.

#### Timetable:

Action	Date	 Cite
NPRM	12/00/88	

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Irv Darrow, Legal Assistant, Department of Health and Human Services, Social Security Administration, Office of Regulations, 6401 Security Blvd., Baltimore, MD 21235, 301 965-1755

RIN: 0960-AB86

647. OLD-AGE, SURVIVORS, AND DISABILITY INSURANCE PROGRAM; REVISED MEDICAL CRITERIA FOR DETERMINATION OF DISABILITY; MENTAL DISORDERS-CHILDHOOD

Significance: Regulatory Program

Legal Authority: 42 USC 405; 42 USC 1302; 42 USC 1383

CFR Citation: 20 CFR 404P

Legal Deadline: None

Abstract: Section 112.00 of Appendix 1 to the Old-Age, Survivors, and Disability Insurance Disability Regulations 404.1501 through 404.1599 describe the medical criteria that apply only to the evaluation of mental impairments of persons under age 18. We are proposing comprehensive revisions to that section to ensure that the medical criteria are up to date and consistent with the latest advances in medicine. The Supplemental Security Income program incorporates by reference and uses the same medical criteria as the Old-Age, Survivors, and Disability Insurance program.

#### Timetable:

Action	Date	FR Cite
NPRM	10/00/88	
Final Action	00/00/00	

Small Entitles Affected: None

Government Levels Affected: None

Agency Contact: William Ziegler, Legal Assistant, Department of Health and Human Services, Social Security Administration, Office of Regulations, 6401 Security Blvd., Baltimore, MD 21235, 301 965-1758

RIN: 0960-AB96

648. OLD-AGE, SURVIVORS, AND DISABILITY INSURANCE PROGRAM; MEDICAL EVALUATION CRITERIA FOR ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS)

Significance: Regulatory Program

Legal Authority: 42 USC 405; 42 USC 1302

CFR Citation: 20 CFR 404P

Legal Deadline: None

Abstract: Section 10.00 of Appendix 1 to the Disability Regulations (404.1501 through 404.1599) describes multiple body system impairments which are severe enough to prevent a person from doing any gainful activity. We are proposing to add the criteria for

evaluation of AIDS to this section. The Supplemental Security Income program incorporates by reference and uses the same medical criteria as the Old-Age, Survivors, and Disability Insurance program. The budgetary impact is unknown at this time.

#### Timetable:

Action	Date	FR	Cite
NPRM	00/00/00		

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: William Ziegler, Legal Assistant, Department of Health and Human Services, Social Security Administration, Office of Regulations, 6401 Security Blvd., Baltimore, MD 21235, 301 695-1759

RIN: 0960-AC06

649. OLD-AGE SURVIVORS AND DISABILITY INSURANCE AND SUPPLEMENTAL SECURITY INCOME PROGRAMS; THE HEARINGS AND APPEALS PROCESS AND REOPENING DETERMINATIONS AND DECISIONS

Significance: Agency Priority

**Legal Authority:** 42 USC 405; 42 USC 1302; 42 USC 1383; 42 USC 401; 42 USC 404

**CFR Citation:** 20 CFR 404J; 20 CFR 404R; 20 CFR 410F; 20 CFR 416N; 20 CFR 416O; 20 CFR 422

Legal Deadline: None

Abstract: These regulations propose changes in the policies and procedures governing the hearings and appeals process, and in the structure of SSA's Appeals Council, which conducts the last step in the administrative review process; clarify certain issues with respect to the scope of that review; and make changes in other parts of the process related thereto. The regulations will also propose changes in the regulations concerning SSA's authority to reopen and revise determinations and decisions which have become final.

#### Timetable:

Action	Date	FR	Cite
NPRM	11/00/88		

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Philip Berge, Legal Assistant, Department of Health and Human Services, Social Security

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Administration, Office of Regulations, 6401 Security Boulevard, Baltimore, MD 21235, **301 965-1769** 

RIN: 0960-AC15

650. ● OLD-AGE, SURVIVORS, AND DISABILITY INSURANCE PROGRAM; NONPAYMENT OF BENEFITS TO PRISONERS, VOCATIONAL REHABILITATION EXCEPTION

**Legal Authority:** 42 USC 402(x)(1); 42 USC 405

CFR Citation: 20 CFR 404D Legal Deadline: None

Abstract: Existing regulations at 20 CFR 404.468(d) provide a vocational rehabilitation exception to the nonpayment of benefits to prisoners provision described at 20 CFR 404.468(a). Under the exception, the nonpayment provision does not apply if a prisoner who is entitled to benefits on the basis of disability is actively and satisfactorily participating in a rehabilitation program which has been specifically approved for the individual by court of law. In addition, the Secretary must determine that the program is expected to result in the individual being able to do substantial gainful activity upon release and within a reasonable time. No benefits will be paid to the prisoner for any month prior to the approval of the program. The proposed regulations would set out more definitive criteria for applying the exception and would define terms, such as "rehabilitation program", "court of law", and "reasonable time", for purposes of applying the exception.

#### Timetable:

Action	Date	FR	Cite
NPRM	06/00/89		

Smail Entitles Affected: None

**Government Levels Affected: None** 

Agency Contact: David Smith, Legal Assistant, Department of Health and Human Services, Social Security Administration, Office of Regulations, 6401 Security Blvd., Baltimore, MD 21235, 301 965-1758

RIN: 0960-AC16

## 651. SUPPLEMENTAL SECURITY INCOME PROGRAM; EMPLOYMENT OPPORTUNITIES FOR THE DISABLED

**Legal Authority:** PL 99-643, Sec 2; PL 99-643, Sec 3; PL 99-643, Sec 4; PL 99-643. Sec 5

**CFR Citation:** 20 CFR 416.260; 20 CFR 416.261; 20 CFR 416.262; 20 CFR 416.263; 20 CFR 416.264; 20 CFR 416.265; 20 CFR 416.268; 20 CFR 416.268; 20 CFR 416.269; 20 CFR 416.211; 20 CFR 416.416; 20 CFR 416.640; 20 CFR 416.901; 20 CFR 416.990; ...

Legai Deadiine: None

Abstract: These proposed regulations will implement statutory changes contained in sections 2, 3, 4, and 5 of P.L. 99-643. These provisions: (1) make section 1619 of the Social Security Act permanent; (2) allow certain blind and disabled beneficiaries to receive up to 2 months of SSI benefits during temporary periods when they are in certain institutions; and (3) simplify the transitions among regular SSI status, special benefit status, and special Medicaid status.

#### Timetable:

Action	Date	FR	Cite
NPRM	00/00/00		

Smail Entitles Affected: None

**Government Leveis Affected: None** 

Agency Contact: Harry Short, Legal Assistant, Department of Health and Human Services, Social Security Administration, Office of Regulations, 6401 Security Blvd., Baltimore, MD 21235, 301 965-1757

RIN: 0960-AC22

652. SUPPLEMENTAL SECURITY INCOME PROGRAM; PERMANENT RESIDENCE IN THE UNITED STATES UNDER COLOR OF LAW - ADDITIONAL CATEGORY

Significance: Agency Priority

Legal Authority: 42 USC 1382c; PL 99-603

**CFR Citation:** 20 CFR 416.1618; 20 CFR 416.1615

Legal Deadline: None

Abstract: This proposed regulation will add the specific categories of aliens legalized by P. L. 99-603 to be considered permanently residing in the United States under color of law or

lawfully admitted for permanent residence in the United States.

#### Timetable:

Action	Date	FR Cite
NPRM	12/00/88	

Small Entitles Affected: None

Government Levels Affected: None

Agency Contact: David Smith, Legal Assistant, Department of Health and Human Services, Social Security Administration, Office of Regulations, 6401 Security Blvd., Baltimore, MD 21235, 301 965-1758

RIN: 0960-AC26

#### 653. SUPPLEMENTAL SECURITY INCOME PROGRAM; PAYMENT OF BENEFITS DUE DECEASED RECIPIENTS

**Legal Authority:** 42 USC 1383(b)(1)(A) **CFR Citation:** 20 CFR 416.340; 20 CFR 416.345; 20 CFR 416.538; 20 CFR 416.542; 20 CFR 416.543; 20 CFR 416.1457(c)(4)

Legal Deadline: None

Abstract: Section 8 of Pub. L. 99-643 provides that effective for benefits payable for months after May 1986, an underpayment shall be paid to any surviving spouse of a deceased SSI recipient whether or not the spouse was eligible for SSI, if such spouse was living in the same household with the recipient at the time of death, or within the 6 months immediately preceding the month of death, or to the parent(s) of a deceased disabled or blind child who was an SSI recipient if the child was living with the parent(s) at the time of death or within the 6 months immediately preceding the month of death. These proposed regulations would also reflect a policy change that would continue the appeals process (versus automatic dismissal), at the Administrative Law Judge or Appeals Council level, for the survivors' entitlement to an underpayment if they meet certain conditions. The cost estimate for these provisions is estimated to be \$2 million per year in program costs and less than \$1 million and 30 workyears in administrative expenses.

#### Timetable:

Action	Date	FR	Cite
NPRM	01/00/89		

Small Entitles Affected: None

**Proposed Rule Stage** 

#### Government Levels Affected: None

Agency Contact: Larry Dudar, Legal Assistant, Department of Health and Human Services, Social Security Administration, Office of Regulations. 6401 Security Blvd., Baltimore, MD 21235, 301 965-1795

RIN: 0960-AC28

## 654. ● OLD-AGE, SURVIVORS AND DISABILITY INSURANCE PROGRAM AND ORGANIZATION AND FUNCTIONS; RECORDS OF EARNINGS

Significance: Agency Priority

Legal Authority: 42 USC 1302; 42 USC 405

**CFR Citation:** 20 CFR 404.810; 20 CFR 404.820; 20 CFR 404.820a; 20 CFR 404.831; 20 CFR 422.125

#### Legal Deadline: None

Abstract: This proposed regulation will establish rules on the evidence an individual must submit with a request to correct the Secretary's record of earnings and state the conditions under which the Secretary will assist the requester in obtaining evidence that establishes such records as incorrect. This proposed regulation will reduce the number of unproductive efforts the agency makes to investigate unsubstantiated assertions that the Secretary's records are incorrect and facilitate the correction process in many cases by relying more upon evidence readily available to the requester, rather than requiring the agency to attempt to obtain evidence from the employer.

#### Timetable:

Action	Date	FR Cite
NPRM	00/00/00	

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Jack Schanberger, Legal Assistant, Department of Health and Human Services, Social Security Administration, Office of Regulations, 6401 Security Blvd., Baltimore, MD 21235, 301 965-8471

RIN: 0960-AC30

655. ORGANIZATION AND PROCEDURES, AND OLD-AGE, SURVIVORS, AND DISABILITY INSURANCE PROGRAMS; SOCIAL SECURITY NUMBER CARDS FOR ALIENS

**Legal Authority:** 42 USC 405; 42 USC 1302

CFR Citation: 20 CFR 422B Legal Deadline: None

Abstract: The proposed regulation will reflect the role of the Immigration and Naturalization Service in obtaining applications for Social Security numbers from aliens when they apply for temporary legal resident status. Rules on evidence needed to support an application are being updated and revised. The proposed regulations will also reflect the role of the States in obtaining applications for Social Security numbers from welfare claimants and recipients. Savings for the Federal government are estimated to be \$5.9 million for FY 1988 and \$6.3 million for subsequent years. Virtually all of the savings are derived from the provision to reflect the role of the States in enumeration of welfare recipients.

#### Timetable:

Action	Date	FR	Cite
NPRM	11/00/88		

Small Entities Affected: None

**Government Levels Affected:** None

Agency Contact: Jack Schanberger, Legal Assistant, Department of Health and Human Services, Social Security Administration, Office of Regulations, 6401 Security Boulevard, Baltimore, MD 21235, 301 965-8471

RIN: 0960-AC34

656. OLD-AGE SURVIVORS AND DISABILITY INSURANCE AND SUPPLEMENTAL SECURITY INCOME PROGRAMS; PAST WORK EXPERIENCE AND ADJUSTMENT TO OTHER WORK

**Legal Authority:** 42 USC 405; 42 USC 1302; 42 USC 1383

CFR Citation: 20 CFR 404.1562; 20 CFR 404.1565; 20 CFR 416.962; 20 CFR 416.965

Legal Deadline: None

Abstract: We are proposing to include in our regulations vocational evaluation standards used in determining disability

under titles II and XVI of the Social Security Act (the Act). The guidelines apply to assessing past work as a vocational factor and evaluating medical-vocational circumstances demonstrating an inability to make an adjustment to other work. These standards are presently contained in Social Security Rulings (SSR's) and the Program Operating Manual System (POMS).

#### Timetable:

Action	Date	FR	Cite
NPRM	02/00/89		

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: William J. Ziegler, Legal Assistant, Department of Health and Human Services, Social Security Administration, Office of Regulations, 6401 Security Boulevard, Baltimore, MD 21235, 301 965-1759

RIN: 0960-AC39

# 657. OLD-AGE SURVIVORS AND DISABILITY INSURANCE AND SUPPLEMENTAL SECURITY INCOME PROGRAMS; CANCELLED CONSULTATIVE EXAMINATIONS

Significance: Agency Priority

**Legal Authority:** 42 USC 405; 42 USC 1302; 42 USC 1383

CFR Citation: 20 CFR 404.1624; 20 CFR 416.1024

Legal Deadline: None

Abstract: We are proposing to no longer pay for consultative examinations when services are not rendered because the scheduled appointment was broken or otherwise not kept. Presently, the States decide whether to pay for these canceled examinations and such payments have already been abolished in 22 States. The total elimination of these payments will establish a uniform national policy.

#### Timetable:

Action	Date	FR	Cite
NPRM	10/00/88		

Small Entitles Affected: None

**Government Levels Affected: State** 

Agency Contact: William J. Ziegler, Legal Assistant, Department of Health and Human Services, Social Security Administration, Office of Regulations, 6401 Security Boulevard, Baltimore, MD 21235, 301 965-1759

RIN: 0960-AC40

658. OLD-AGE SURVIVORS AND DISABILITY INSURANCE AND SUPPLEMENTAL SECURITY INCOME PROGRAMS; DETERMINING DISABILITY AND BLINDNESS; FEE LIMITATION POLICY FOR PURCHASE OF LABORATORY TESTS

Legal Authority: 42 USC 1302; 42 USC 1383b

**CFR Citation:** 20 CFR 404.1624; 20 CFR 416.1024

Legal Deadline: None

Abstract: These proposed regulations will place a limitation on the rates of payment a State may pay for laboratory tests purchased by the disability determination services (DDS). Under these proposed regulations a DDS will be required to limit the amounts it pays for laboratory tests to the maximum payment level contained in the Health Care Financing Administration's (HCFA) Medicare Limitation Amounts for Laboratory Fee Schedules. Currently the only payment requirement is that the rates of payment not exceed the highest rates paid by Federal or other agencies in the State for the same or similar types of services.

#### Timetable:

Action	Date	FR Cite
NPRM	04/00/89	

Small Entities Affected: None

**Government Levels Affected: State** 

Agency Contact: Harry J. Short, Legal Assistant, Department of Health and Human Services, Social Security Administration, Office of Regulations, 6401 Security Boulevard, Baltimore, MD 21235, 301 965-1757

RIN: 0960-AC41

659. ● SUPPLEMENTAL SECURITY INCOME PROGRAM; PROCEEDS OF A LOAN, PAYMENT OF PRO RATA SHARE OF HOUSEHOLD OPERATING EXPENSES

Significance: Agency Priority Legal Authority: 42 USC 1102

**CFR Citation:** 20 CFR 416.1103; 20 CFR 416.1133

Legal Deadline: None

Abstract: It is our policy that money borrowed (a loan) is not income for SSI purposes and therefore has no effect on a person's SSI benefits. These proposed regulations will state that only cash transactions may be considered loans. These proposed regulations will also provide that the one-third reduction rule which applies when a person who lives in another's household and receives inkind support and maintenance will not apply if the SSI recipient pays his or her pro rata share in cash and no later than the month under consideration. No additional costs or savings are anticipated since these proposed regulations will codify existing policy.

#### Timetable:

Action	Date	FR	Cite
NPRM	01/00/89		

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: David Smith, Legal Assistant, Department of Health and Human Services, Social Security Administration, Office of Regulations, 6401 Security Blvd., Baltimore, MD 21235, 301 965-1758

RIN: 0960-AC42

660. ● SUPPLEMENTAL SECURITY INCOME PROGRAM; EXCLUSION FROM COUNTABLE RESOURCES OF THE VALUE OF PROMISSORY NOTES IN HOME REPLACEMENT SITUATIONS

**Legal Authority:** 42 USC 1302; 42 USC 1383

**CFR Citation:** 20 CFR 416.1212

Legal Deadline: None

Abstract: We propose to amend the regulations under the Supplemental Security Income program to provide that the current market value of an installment sales contract is excluded as part of an excluded home when certain conditions are met. The costs will be insignificant since the policy is currently in use under our operating instructions.

#### Timetable:

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Action	Date	FR	Cite
NPRM	03/00/89		

Small Entities Affected: None

**Government Levels Affected: None** 

Agency Contact: Henry Lerner, Legal Assistant, Department of Health and Human Services, Social Security Administration, Office of Regulations, 6401 Security Blvd., Baltimore, MD 21235, 301 965-1756

RIN: 0960-AC43

661. ● OLD-AGE, SURVIVORS, AND DISABILITY INSURANCE PROGRAM; EXTENSION OF SOCIAL SECURITY COVERAGE TO CERTAIN WORKERS; MEDICARE ONLY COVERAGE OF CERTAIN STATE AND LOCAL GOVERNMENT EMPLOYEES

**Legal Authority:** PL 100-203, Sec 9001; PL 100-203, Sec 9002; PL 100-203, Sec 9003; PL 100-203, Sec 9004; PL 100-203, Sec 9005; PL 100-203, Sec 9022; PL 99-272, Sec 13205; PL 99-514, Sec 1895

**CFR Citation:** 20 CFR 404.429(c)(3); 20 CFR 404.1015; 20 CFR 404.1018b; 20 CFR 404.1019; 20 CFR 404.1020; 20 CFR 404.1021; 20 CFR 404.1055; 20 CFR 404.1059; 20 CFR 404.1059; 20 CFR 404.1059

Legal Deadline: None

Abstract: These regulations reflect statutory changes that extend social security coverage to work situations not previously covered. These newly covered work situations include: (1) Inactive duty training in the uniformed services; (2) Certain agriculture labor situations; and (3) Work for a spouse or parent. Additionally, employer-paid insurance premiums may be wages and the year for reporting corporate directors income has been changed. Last, Medicare coverage is provided to many previously uncovered State and local government employees.

#### Timetable:

Action	Date	FR	Cite
NPRM	01/00/89		

Small Entities Affected: Businesses, Governmental Jurisdictions

Government Levels Affected: Local, State, Federal

Agency Contact: Charles Campbell, Legal Assistant, Department of Health and Human Services, Social Security Administration, Office of Regulations, 6401 Security Blvd., Baltimore, MD 21235, 301 965-1794

RIN: 0960-AC45

# 662. ● OLD-AGE, SURVIVORS, AND DISABILITY INSURANCE PROGRAM; APPLICABILITY OF GOVERNMENT PENSION TO CERTAIN FEDERAL EMPLOYEES

Significance: Agency Priority Legal Authority: 42 USC 402 (b),(c),(e),(f),(g); PL 100-203, Sec 9007

CFR Citation: 20 CFR 404.408a Legal Deadline: None

Abstract: We are proposing to revise our rules on reducing the Social Security spouse's benefits of a person who is also receiving a Government pension based on noncovered employment. The Omnibus Budget Reconciliation Act of 1987 (Pub. L. 100-203, sec 9007) requires that a Federal Government employee who elects to be covered under Social Security after December 31, 1987 must work for at least 60 months after that date in order to avoid the reduction after he or she becomes entitled to Social Security spouse's benefits.

#### Timetable:

Action	Date	Cite
NPRM	12/00/88	

Small Entities Affected: None

**Government Levels Affected: None** 

Agency Contact: Jack Schanberger, Legal Assistant, Department of Health and Human Services, Social Security Administration, Office of Regulations, 6401 Security Blvd., Baltimore, MD 21235, 301 965-8471

RIN: 0960-AC46

# 663. ● SUPPLEMENTAL SECURITY INCOME PROGRAM; EXCLUSION FROM RESOURCES OF FUNDS SET ASIDE FOR BURIAL AND BURIAL SPACES

Significance: Agency Priority

Legal Authority: 42 USC 1302; 42 USC 1383

**CFR Citation: 20 CFR 416.1231** 

Legal Deadline: None

Abstract: We propose to amend our regulations to reflect the changes made by section 9105 of Pub. L. 100-203 (the Omnibus Budget Reconciliation Act of 1987) and to make other policy changes concerning the treatment of burial spaces and certain funds set aside for burial expenses in the Supplemental Security Income program. The

cost/savings and workyear impact for this NPRM have been estimated to be insignificant.

#### Timetable:

Action	Date		FR	Cite
NPRM	09/15/88	53	FR	35830
NPRM Comment Period End	11/14/88			
Final Action	06/00/89			

Small Entitles Affected: None

**Government Levels Affected: None** 

Agency Contact: Henry Lerner, Legal Assistant, Department of Health and Human Services, Social Security Administration, Office of Regulations, 6401 Security Blvd., Baltimore, MD 21235, 301 965-1756

RIN: 0960-AC48

# 664. ● SUPPLEMENTAL SECURITY INCOME PROGRAM; EXEMPTION OF CERTAIN ASSISTANCE PAYMENTS FROM RETROSPECTIVE MONTHLY ACCOUNTING

Legal Authority: PL 100-203, Sec 9106 CFR Citation: 20 CFR 416.420

Legal Deadline: None

Abstract: Section 9106 of P.L. 100-203 exempts certain income from retrospective monthly accounting in determining a person's Supplemental Security Income (SSI) benefit amount. Generally, an SSI benefit for a month is computed using income from two months prior. Section 9106, which is reflected in this regulation change, provides for the following types of income to be used only in the month received to compute the benefit amount: (1) Aid to Families with Dependent Children (AFDC); (2) Foster Care (Title IV-E); (3) Refugee Cash Assistance; (4) Cuban and Haitian Entrant Assistance; and (5) Bureau of Indian Affairs general assistance and child welfare assistance. Program costs are expected to be negligible.

#### Timetable:

Action	Date	FR	Cite
NPRM	03/00/89		

Small Entities Affected: None

**Government Levels Affected: None** 

Agency Contact: Irving Darrow, Legal Assistant, Department of Health and Human Services, Social Security Administration, Office of Regulations, 6401 Security Blvd., Baltimore, MD 21235, 301 965-1755

RIN: 0960-AC49

## 665. ● SUPPLEMENTAL SECURITY INCOME PROGRAM; INCREASE IN EMERGENCY ADVANCE PAYMENTS

Legal Authority: 42 USC 1383(a); PL 100-203, Sec 9109

**CFR Citation:** 20 CFR 416.502; 20 CFR 416.520; 20 CFR 416.1403

Legal Deadline: None

Abstract: The proposed rules will reflect section 9109 of Pub. L. 100-203. They raise the amount of the emergency advance payment that can be paid to a person presumptively eligible for SSI payments. Because the emergency advance payment is an advance of benefits and later deducted from the benefits due an individual, no increased costs are anticipated.

#### Timetable:

Action	Date	FR	Cite
NPRM	01/00/89		

Small Entities Affected: None

**Government Levels Affected: State** 

Agency Contact: David Smith, Legal Assistant, Department of Health and Human Services, Social Security Administration, Office of Regulations, 6401 Security Blvd., Baltimore, MD 21235, 301 965-1758

RIN: 0960-AC50

## 666. ● SUPPLEMENTAL SECURITY INCOME PROGRAM; MODIFICATION OF INTERIM ASSISTANCE REIMBURSEMENT PROGRAM

**Legal Authority:** 42 USC 1302; PL 100-203, Sec 9110

**CFR Citation:** 20 CFR 416.1901; 20 CFR 416.1902; 20 CFR 416.1906

Legal Deadline: None

Abstract: These proposed rules reflect sec. 9110 of Pub.L. 100-203. They extend Interim Assistance Reimbursement to cases in which assistance is provided by a State while an individual's Supplemental Security Income (SSI) payments are suspended or terminated and then subsequently reinstated. Current regulations provide for reimbursement to a State only for interim assistance payments made while an individual's initial application for SSI is pending. No additional

**Proposed Rule Stage** 

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program costs are anticipated since the amount reimbursed to the State is later deducted from the individual's SSI payments.

#### Timetable:

Action	Date	FR	Cite
NPRM	02/00/89		

#### Small Entities Affected: None

#### **Government Levels Affected: State**

Agency Contact: David Smith, Legal Assistant, Department of Health and Human Services, Social Security Administration, Office of Regulations, 6401 Security Blvd., Baltimore, MD 21235, 301 965-1758

RIN: 0960-AC51

# 667. ● SUPPLEMENTAL SECURITY INCOME PROGRAM; EXCLUSION FROM INCOME OF PAYMENTS RECEIVED FOR AND USED TO PAY LAST ILLNESS AND DEATH

Legal Authority: PL 100-203, Sec 9120 CFR Citation: 20 CFR 416.1121; 20 CFR 416.1201

#### Legal Deadline: None

Abstract: The regulation reflects the provisions of section 9120 of Pub. L. 100-203 by providing that payments to an individual (including gifts and inheritances) occasioned by the death of another person are not considered income for supplemental security income purposes to the extent that such payments are expended by such individual for purposes of the deceased person's last illness and burial. Also, the regulations propose a policy change to not consider the same payments as resources for one month following receipt. Any increased costs will be negligible.

#### Timetable:

Date	FR	Cite
03/00/89		

#### Small Entities Affected: None

#### Government Levels Affected: None

Agency Contact: Irving Darrow, Legal Assistant, Department of Health and Human Services, Social Security Administration, Office of Regulations, 6401 Security Blvd., Baltimore, MD 21235, 301 965-1755

RIN: 0960-AC52

## 668. ● SUPPLEMENTAL SECURITY INCOME PROGRAM; CONTINUATION OF FULL BENEFIT STANDARD FOR PERSON IN MEDICAID INSTITUTION

Legal Authority: PL 100-203, Sec 9115

**CFR Citation:** 20 CFR 416.211; 20 CFR 416.414; 20 CFR 416.1149; 20 CFR 416.1167; 20 CFR 416.1325; 20 CFR 416.2040

#### Legal Deadline: None

Abstract: This amendment requires continued payment based on the full payment rate to persons eligible for SSI payments under section 1611(e) of the Act who enter certain medical institutions but whose stay is not expected to last more than 3 months and who have continuing expenses associated with maintaining their homes. For the period of hospitalization, such persons' benefits will be based on living arrangements prior to institutionalization.

#### Timetable:

Action	Date	FR	Cite
NPRM	02/00/89		

#### Small Entities Affected: Undetermined

### Government Levels Affected: Undetermined

Agency Contact: Charles Campbell, Legal Assistant, Department of Health and Human Services, Social Security Administration, Office of Regulations, 6401 Security Blvd., Baltimore, MD 21235, 301 965-1794

RIN: 0960-AC55

## 669. ● OLD-AGE, SURVIVORS, AND DISABILITY INSURANCE PROGRAM; SOCIAL SECURITY NUMBERS FOR NEWBORN CHILDREN

Significance: Agency Priority Legal Authority: 42 USC 405 CFR Citation: 20 CFR 422.103

Legal Deadline: None

Abstract: Under the proposed rule, a parent will be able to request a Social Security number in the hospital when he or she provides birth registration information for a newborn child. The State vital statistics office will receive the information and the request from the hospital and electronically transmit this information to the Social Security Administration (SSA). SSA will assign a Social Security number to the child and send a card to the parents. We

expect annual savings of \$11.4 million. A pilot project in three States has shown this procedure to be efficient and well-received.

#### Timetable:

Action	Date	FR	Cite
NPRM	12/00/88		

Small Entities Affected: None

#### **Government Levels Affected:** None

Agency Contact: Jack Schanberger, Legal Assistant, Department of Health and Human Services, Social Security Administration, Office of Regulations, 6401 Security Blvd., Baltimore, MD 21235, 301 965-8471

RIN: 0960-AC56

## 670. ● OLD-AGE, SURVIVORS, AND DISABILITY INSURANCE PROGRAM; REVISION OF CONTRIBUTIONS FOR SUPPORT RULES

Legal Authority: 42 USC 1302 CFR Citation: 20 CFR 404.366(a)

Legal Deadline: None

Abstract: This proposed rule will change one of the requirements for determining whether an insured person is contributing to the support of a child at a specific time. The requirements that contributions be made regularly and be large enough to meet an important part of a child's living expenses will be replaced by a requirement that consideration be given to the economic circumstances of both the insured person and the child and that recognition also be given to the child's needs. Because of the minimal number of persons who will be affected by these proposed changes any additional program costs will be negligible.

#### Timetable:

Action	Date	FR	Cite
NPRM	03/00/89		

Small Entities Affected: None

#### **Government Levels Affected: None**

Agency Contact: David Smith, Legal Assistant, Department of Health and Human Services, Social Security Administration, Office of Regulations, 6401 Security Blvd., Baltimore, MD 21235, 301 965-1758

RIN: 0960-AC57

**Proposed Rule Stage** 

## 671. ● OLD-AGE, SURVIVORS, AND DISABILITY INSURANCE PROGRAM; SUPPLEMENTAL EARNINGS REPORTS

Legal Authority: 42 USC 403 CFR Citation: 20 CFR 404.455

Legal Deadline: None

Abstract: We have learned that old-age and survivors' insurance beneficiaries whose estimate of earnings for the current year is more than the exempt amount for that year, but is equal to or less than the prior year's earnings, tend to underestimate or fail to report their

work for the next year which results in overpayments. We are proposing an addition to the current regulation which will clarify that our interpretation of Section 203(h)(3) and (h)(4) of the Social Security Act permits SSA to request estimates of earnings for the next taxable year as well as the current taxable year. If a beneficiary does not furnish the requested future year's earnings estimate, we will use the estimate for the current year to determine whether to withhold benefits for the next year. We estimate savings of \$3.5 million per year.

#### Timetable:

Action Date FR Cite

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Jack Schanberger, Legal Assistant, Department of Health and Human Services, Social Security Administration, Office of Regulations, 6401 Security Blvd., Baltimore, MD 21235, 301 965-8471

RIN: 0960-AC58

## DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) Social Security Administration (SSA)

Final Rule Stage

## 672. SUPPLEMENTAL SECURITY INCOME PROGRAM; REDUCTIONS, SUSPENSIONS AND TERMINATIONS

Legal Authority: 42 USC 1302; 42 USC 1382; 42 USC 1382a; 42 USC 1382a; 42 USC 1382b; 42 USC 1382c; 42 USC 1383

CFR Citation: 20 CFR 416M

Legal Deadline: None

Abstract: This regulation reorganizes, revises, and clarifies the rules on withholding, reducing, suspending, and terminating an SSI beneficiary's benefits. This regulation includes changes in the present rules that are required by recent statutory enactments and, additionally, make the rules easier to read and understand. This regulation will have no impact on SSA programs and administrative costs.

#### Timetable:

Action	Date		FR	Cite
Notice of Decision to Develop Regs	06/19/79	44	FR	35241
NPRM	05/08/86	51	FR	17057
NPRM Comment Period End	07/07/86			
Final Action	02/00/89			

#### Small Entities Affected: None

#### Government Levels Affected: None

Agency Contact: Charles H. Campbell, Legal Assistant, Department of Health and Human Services, Social Security Administration, Office of Regulations, 6401 Security Boulevard, Baltimore, MD 21235, 301 965-1794

RIN: 0960-AA22

673. SUPPLEMENTAL SECURITY INCOME PROGRAM; REOPENING AND REVISING SUPPLEMENTAL SECURITY INCOME DETERMINATIONS AND DECISIONS WITHIN FOUR YEARS OF THE NOTICE OF THE INITIAL DETERMINATION

Legal Authority: 42 USC 1302; 42 USC 1383; 42 USC 1383b

**CFR Citation: 20 CFR 416.1488** 

Legal Deadline: None

Abstract: The proposed rules would provide for the reopening and revising of Supplemental Security Income determinations within four years of the notice of the initial determination if we discovered an error affecting a claimant's eligibility or benefit amount during this period through the use of information exchange and data gathering involving either our records or our records and those of other Federal or State agencies.

#### Timetable:

Action	Date		FR	Cite
NPRM NPRM Comment Period End	08/27/86 10/27/86	51	FR	30499

**Next Action Undetermined** 

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Philip Berge, Legal Assistant, Department of Health and Human Services, Social Security Administration, Office of Regulations, 6401 Security Boulevard, Baltimore, Maryland 21235, 301 965-1769

RIN: 0960-AA59

674. OLD-AGE, SURVIVORS, AND DISABILITY INSURANCE PROGRAM; COVERAGE OF CERTAIN FEDERAL EMPLOYEES; COVERAGE OF EARNINGS OF FEDERAL JUDGES

Significance: Agency Priority

**Legal Authority:** PL 98-21, Sec 101; PL 98-118, Sec 4; PL 99-272, Sec 12112; PL 99-335, Sec 301; PL 97-248, Sec 278; PL 98-369, Sec 2601; PL 99-221, Sec 3

**CFR Citation: 20 CFR 404.1018** 

Legal Deadline: None

Abstract: The proposed regulations would codify section 101 of Pub. L. 98-21, as amended by sec. 4 of Pub. L. 98-118, which generally provides Social Security coverage for certain Federal employees and covers certain payments to retired Federal judges after 1985. Also, the proposed regulations would codify section 12112 of Pub. L. 99-272 which provides exemption from Social Security coverage for retired Federal judges on active duty. In addition, the proposed regulations would provide: 1) that Federal employees not otherwise subject to the Social Security tax are nevertheless subject to the Health Insurance portion of the tax under Pub. L. 97-248, 2) that individuals covered by the Civil Service Retirement System may elect during a limited time to be covered under the Federal Employees Retirement System, which includes Social Security coverage under Pub. L. 99-335, and 3) that certain periods are

Final Rule Stage

excluded in determining continuous Federal service under Pub. L. 98-369 and Pub. L. 99-221.(continued)

#### Timetable:

Action	Date	FR	Cite	
Final Action	18/00/88			

#### Small Entitles Affected: None

#### **Government Levels Affected: None**

Additional Information: With the exception of Pub. L. 99-335, there are no additional cost/savings associated with this regulation because the provisions are already in effect. Pub. L. 99-335 is expected to produce trust fund tax revenue of approximately \$2 billion for fiscal year (FY) 1988 to FY 1993 and administrative costs of approximately \$300 million for the same period.

Agency Contact: Duane Heaton, Legal Assistant, Department of Health and Human Services, Social Security Administration, Office of Regulations, 6401 Security Boulevard, Baltimore, MD 21235, 301 965-8470

RIN: 0960-AA89

675. ● OLD-AGE, SURVIVORS, AND DISABILITY INSURANCE AND SUPPLEMENTAL SECURITY INCOME PROGRAM; CONTINUED PAYMENT OF BENEFITS TO PERSONS IN VOCATIONAL REHABILITATION PROGRAMS

Significance: Agency Priority

**Legal Authority:** 42 USC 405; 42 USC 425; 42 USC 1302; 42 USC 1383

**CFR Citation:** 20 CFR 404.316; 20 CFR 404.337; 20 CFR 404.352; 20 CFR 404.902; 20 CFR 404.1586; 20 CFR 404.1596; 20 CFR 404.1597; 20 CFR 416.1321; 20 CFR 416.1338; 20 CFR 416.1331; 20 CFR 416.140?

Legal Deadline: None

Abstract: This change permits the continued payment of disability benefits to persons who medically recover while participating in a vocational rehabilitation (VR) program, without regard to whether the person was expected at the onset of the VR program to medically recover before the scheduled completion date of the program and without regard to whether the person has any residual functional limitation. These changes bring the regulations into conformity with certain recent court decisions.

#### Timetable:

Action	Date		FR	Cite
Interim Final Rule	05/14/86	51	FR	17616
Final Action	10/00/88			

#### Small Entities Affected: None

#### Government Levels Affected: None

Agency Contact: Harry Short, Legal Assistant, Department of Health and Human Services, Social Security Administration, Office of Regulations, 6401 Security Blvd., Baltimore, MD 21235, 301 965-1757

RIN: 0960-AB05

676. OLD AGE SURVIVORS
DISABILITY INSURANCE AND
SUPPLEMENTAL SECURITY INCOME
PROGRAMS; STANDARDS FOR
CONSULTATIVE EXAMINATIONS;
EXISTING MEDICAL EVIDENCE

Significance: Regulatory Program

Legal Authority: PL 98-460, Sec 9; 42 USC 405; 42 USC 421; 42 USC 423; 42 USC 1302; 42 USC 1382c; 42 USC 1383

CFR Citation: 20 CFR 404.1512; 20 CFR 416.912; 20 CFR 404.1519; 20 CFR 416.919; 20 CFR 404.1502; 20 CFR 416.920; 20 CFR 404.1593; 20 CFR 416.993; 20 CFR 416.902; 20 CFR 404.1513; 20 CFR 416.913; 20 CFR 404.1520; 20 CFR 404.1546; 20 CFR 416.945; 20 CFR 404.1546; ...

Legal Deadline: None

Abstract: The proposed regulations include standards for obtaining consultative examinations, the types of consultative examination referrals to be made, and monitoring procedures for consultative examinations and the referral process. The proposed regulations also provide for evaluating all medical evidence of record and developing a 12-month medical history. References to "medical assessments" will be replaced by references to medical source statements as to what a person can still do despite his or her impairment(s). The regulations also set forth the standards to be used in evaluating the medical opinions of treating and other medical sources. The changes will not have any significant impact on either administrative or program costs.

#### Timetable:

Action	Date		FR	Cite
NPRM	04/20/87	52	FR	13014
NPRM Comment Period End	06/19/87			
Final Action	12/00/88			

Small Entities Affected: None

**Government Levels Affected: State** 

Agency Contact: William Ziegler, Legal Assistant, Department of Health and Human Services, Social Security Administration, Office of Regulations, 6401 Security Blvd., Baltimore, MD 21235, 301 965-1759

RIN: 0960-AB22

## 677. SUPPLEMENTAL SECURITY INCOME PROGRAM; HOW WE COUNT UNEARNED INCOME-FUNDS USED TO PAY INDEBTEDNESS

Legal Authority: 42 USC 1302; 42 USC 1382a

CFR Citation: 20 CFR 416.1123(b)

Legal Deadline: None

Abstract: The issue is whether amounts otherwise due an individual assigned to repay a legal obligation should continue to be included in income under the Supplemental Security Income (SSI) program. The proposed regulation will clarify that we count such amounts as income. Because this clarification only will reflect current operating policy, no costs/savings are anticipated.

#### Timetable:

Action	Date		FR	Cite	
NPRM	09/15/87	52	FR	34813	
NPRM Comment Period End	11/16/87				
Final Action	01/00/89				

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Irving Darrow, Legal Assistant, Department of Health and Human Services, Social Security Administration, Office of Regulations, 6401 Security Blvd., Baltimore, Maryland 21235, 301 965-1755

RIN: 0960-AB29

# 678. OLD AGE SURVIVORS DISABILITY INSURANCE AND SUPPLEMENTAL SECURITY INCOME PROGRAMS; DETERMINATIONS OF DISABILITY-COMPLIANCE, AND OTHER CHANGES

**Legal Authority:** 42 USC 405; 42 USC 421; 42 USC 1302; PL 98-460, Sec 17; 42 USC 1383

**CFR Citation:** 20 CFR 404.1601; 20 CFR 416.1001; 20 CFR 404.1602; 20 CFR 416.1002; 20 CFR 404.1615; 20 CFR 416.1015; 20 CFR 404.1620; 20 CFR 416.1020; 20 CFR 404.1632; 20 CFR 416.1023; 20 CFR 404.1626; 20 CFR 416.1026; 20 CFR 404.1627; 20 CFR 416.1027; 20 CFR 404.1633; ...

#### Legal Deadline: None

Abstract: These regulations for administering the disability determination function make changes to improve the disability determination process by modifying our State agency monitoring and technical and management assistance procedures, administrative standards, and fiscal, audit, and appeals requirements. They also clarify when we will find that a State agency has substantially failed to make disability determinations consistent with the regulations and other written guidelines.

#### Timetable:

Action	Date		FR	Cite
NPRM	04/25/86	51	FR	15638
NPRM Comme Period End	ent 06/24/86			
Final Action	01/00/89			

#### Small Entities Affected: None

#### **Government Levels Affected: State**

Agency Contact: Irving Darrow, Legal Assistant, Department of Health and Human Services, Social Security Administration, Office of Regulations, 6401 Security Blvd., Baltimore, MD 21235, 301 965-1755

RIN: 0960-AB36

# 679. OLD AGE SURVIVORS DISABILITY INSURANCE AND SUPPLEMENTAL SECURITY INCOME PROGRAMS; PAYMENT OF COSTS OF REHABILITATION SERVICES

**Legal Authority:** PL 98-460, Sec 11; 42 USC 405; 42 USC 422; 42 USC 1302; 42 USC 1382d; 42 USC 1383

CFR Citation: 20 CFR 404V; 20 CFR 416V

#### Legal Deadline: None

Abstract: Public Law 98-460 created 2 new provisions under which SSA will pay vocational rehabilitation (VR) agencies for the costs of services provided to disabled or blind social security beneficiaries or SSI recipients. Under the first new provision, SSA will allow payment to vocational rehabilitation agencies (VRAs) for the costs of VR services provided to individuals continuing to receive payment because they are participating in a VR program after their period of disability has ceased due to their medical recovery. The second new provision allows payment to VRAs for the costs of VR services provided to beneficiaries/recipients who refuse without good cause to continue or to cooperate in a VR program in such a way as to preclude their successful rehabilitation with such refusal resulting in the nonpayment of their disability or blindness payments. It is estimated that the first year costs of this program will be less than 1 million

#### Timetable:

Action	Date		FR	Cite
NPRM	10/10/86	51	FR	36510
NPRM Comment Period End	12/09/86			
Final Action	12/00/88			

#### **Small Entities Affected: None**

#### **Government Levels Affected: None**

Agency Contact: Dave Smith, Legal Assistant, Department of Health and Human Services, Social Security Administration, Office of Regulations. 6401 Security Blvd., Baltimore, MD 21235, 301 965-1758

RIN: 0960-AB37

#### 680. OLD AGE, SURVIVORS, DISABILITY INSURANCE AND SUPPLEMENTAL SECURITY INCOME PROGRAMS; DETERMINING DISABILITY AND BLINDNESS; MULTIPLE IMPAIRMENTS

Legal Authority: PL 98-460, Sec 4; 42 USC 405; 42 USC 423; 42 USC 1302; 42 USC 1382c

**CFR Citation:** 20 CFR 404.1520; 20 CFR 404.1521; 20 CFR 404.1522; 20 CFR 404.1523; 20 CFR 416.920; 20 CFR 416.921; 20 CFR 416.922; 20 CFR 416.923

Legal Deadline: None

Abstract: This provision of the law requires us to consider the combined effect of all of a person's impairments in determining disability regardless of whether any single impairment, if considered separately, would be of sufficient severity. If we do find a medically severe combination of impairments, the combined impact of the impairments must be considered throughout the disability determination process. We are revising regulations to reflect that we will now consider the combined effect of impairments to determine severity. When the combined effect is found to be severe, the person's impairments are evaluated throughout the full sequential evaluation process.

#### Timetable:

Action	Date		FR	Cite
Interim Final Rule	03/05/85	50	FR	08726
Final Action	00/00/00			

#### **Small Entities Affected: None**

#### **Government Levels Affected: None**

Agency Contact: William Ziegler, Legal Assistant, Department of Health and Human Services, Social Security Administration, Office of Regulations, 6401 Security Blvd., Baltimore, MD 21235, 301 965-1759

RIN: 0960-AB39

#### 681. OLD-AGE, SURVIVORS, DISABILITY INSURANCE AND SUPPLEMENTAL SECURITY INCOME PROGRAMS: EVALUATION OF SYMPTOMS, INCLUDING PAIN

Significance: Agency Priority

**Legal Authority:** 42 USC 405; 42 USC 423; 42 USC 1382c; 42 USC 1383; 42 USC 1302

CFR Citation: 20 CFR 404P; 20 CFR 416I

#### Legal Deadline: None

Abstract: These proposed regulations expand the existing regulations pertaining to the evaluation of cases involving pain or other symptoms to provide a more detailed explanation of SSA's current policy for evaluating symptoms, including pain.

#### Timetable:

Action	Date		FR	Cite
NPRM	09/14/88	53	FR	35577
Final Action	06/00/89			

#### Small Entitles Affected: None

#### Government Levels Affected: None

Agency Contact: William Ziegler, Legal Assistant, Department of Health and Human Services, Social Security Administration, Office of Regulations, 6401 Security Blvd., Baltimore, Maryland 21235, 301 965-1759

RIN: 0960-AB41

## 682. OLD-AGE, SURVIVORS, AND DISABILITY INSURANCE PROGRAM; REDUCTION BECAUSE OF ENTITLEMENT TO OTHER BENEFITS

**Legal Authority:** 42 USC 405; 42 USC 407; 42 USC 1302; 42 USC 402

**CFR Citation:** 20 CFR 404.407; 20 CFR 404.612

Legal Deadline: None

Abstract: Section 202(k)(4) of the Social Security Act discusses simultaneous entitlement to retirement and disability insurance benefits (RIB/DIB) and provides that SSA will pay the higher benefit unless the claimant elects to be paid the lower. Section 223(a)(1) explains that an application for DIB may be filed by someone other than the insured individual within 3 months after the month of the insured individual's death. We are proposing to change CFR 404.407(c) to clarify that the person described in section 404.612(d) may make the election discussed in section 202(k)(4).

#### Timetable:

Action	Date		FR	Cite
NPRM	06/09/88	53	FR	21687
NPRM Comment Period End	08/08/88			
Final Action	03/00/89			

#### Small Entities Affected: None

#### **Government Levels Affected: None**

Additional Information: We foresee minimal costs from this change since the number of potentially affected beneficiaries is small and the period of time during which they will receive the higher family maximum amount (based on the RIB) will only be for the months during which the deceased NH is simultaneously entitled to DIB. Also, this cost will be offset by administrative savings since overpayments will not be created and have to be recovered in situations where individuals are able to elect the

lower family maximum (based on DIB) on behalf of the deceased NH.

Agency Contact: Lawrence V. Dudar, Legal Assistant, Department of Health and Human Services, Social Security Administration, Office of Regulations, 6401 Security Blvd., Baltimore, MD 21235. 301 965-1795

RIN: 0960-AB87

683. OLD-AGE, SURVIVORS, AND DISABILITY INSURANCE AND SUPPLEMENTAL SECURITY INCOME PROGRAMS; DECISIONS BY ADMINISTRATIVE LAW JUDGES IN CASES REMANDED BY COURTS

Significance: Agency Priority

**Legal Authority:** 42 USC 405; 42 USC 1302; 42 USC 1383; 42 USC 401; 42 USC 421

**CFR Citation:** 20 CFR 404.953; 20 CFR 404.983; 20 CFR 404.984; 20 CFR 416.1453; 20 CFR 416.1484; 20 CFR 404.955; 20 CFR 404.986; 20 CFR 416.1455; 20 CFR 416.1486

#### Legal Deadline: None

Abstract: If the court remands a case and the SSA Appeals Council remands it to an administrative law judge (ALJ), under current regulations the ALJ returns the case to the Appeals Council with a recommended decision, and the Appeals Council must review that decision and take further action in every case before the decision becomes final. This can involve delay. The proposed regulation would permit the ALJ to make a decision which would become final unless, within 30 days after the decision is received, the claimant files exceptions or within that period requests an extension of time to file exceptions, or within 60 days after the date of the decision the Appeals Council decides to review the decision on its own. The change will permit prompter final decisions and some administrative savings. It will not affect program cost.

#### Timetable:

Action	Date		FR	Cite
NPRM	10/16/87	52	FR	38466
NPRM Comment Period End	12/15/87			
Final Action	12/00/88			

Small Entitles Affected: None
Government Levels Affected: None

Agency Contact: Phil Berge, Legal Assistant, Department of Health and Human Services, Social Security Administration, 6401 Security Blvd., Baltimore, MD 21235, 301 965-1769

RIN: 0960-AC07

## 684. SUPPLEMENTAL SECURITY INCOME PROGRAM: FEDERAL ADMINISTRATION OF OPTIONAL STATE SUPPLEMENTATION

**Legal Authority:** 42 USC 1382e; 42 USC 1302

**CFR Citation:** 20 CFR 416.2030(a)(2); 20 CFR 416.2040(b)

Legal Deadline: None

Abstract: 42 USC 1382e provides that at the option of a State with a federally administered optional supplementation program, the supplementation agreement between such State and the Secretary of HHS may be modified to allow Federal administration of optional supplementary payments to any individual in a medical facility where more than 50 percent of the individual's care is covered by the Medicaid program (Living Arrangements (LA) "D" recipients). The proposed regulation will reflect the amendment to the statute discussed above.

#### Timetable:

Date	FR	Cite
12/00/88		

Small Entities Affected: None

Government Levels Affected: State, Federal

**Public Compliance Cost:** Initial Cost: \$0; Yearly Recurring Cost: \$0

Sectors Affected: None

Agency Contact: Irving Darrow, Legal Assistant, Department of Health and Human Services, Social Security Administration, Office of Regulations, 6401 Security Boulevard, Baltimore, MD 21235, 301 965-1755

RIN: 0960-AC13

685. OLD-AGE, SURVIVORS, AND DISABILITY INSURANCE PROGRAM; WAGES—DEFERRED COMPENSATION

**Legal Authority:** PL 98-21; PL 99-514; PL 98-369

CFR Citation: 20 CFR 404.1041; 20 CFR 404.1042; 20 CFR 404.1068; 20 CFR

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404.1049; 20 CFR 404.1050; 20 CFR 404.1001; 20 CFR 404.1026; 20 CFR 404.1046; 20 CFR 404.1052; 20 CFR 404.1051; 20 CFR 404.1052; 20 CFR 404.1053; 20 CFR 404.1054; 20 CFR 404.1058; 20 CFR 404.1070; ...

#### Legal Deadline: None

Abstract: P. L. 98-21, the Social Security Amendments of 1983, changed the timing of crediting deferred compensation for Social Security purposes. It also changed the treatment of retirement pay depending upon whether it is paid under a qualified deferred compensation plan. Further, it excluded from coverage various fringe benefits and payments under a Simplified Employee Pension Plan (SEP). Finally, the amendments codify certain provisions pertaining to meals and lodging and tax-sheltered annuities. P.L. 98-369 amended the wage exclusion for qualified bond purchase plans. P.L. 99-514 excluded from coverage payments under a cafeteria plan as described in section 125 of the Internal Revenue Code. Section 1882 of P.L. 99-514 amends the law for determining self-employment income when an individual works for a church or church-controlled organization which has elected not to pay social security taxes. Section 1704 of P.L. 99-514 amends the law for receiving an exemption from social security coverage for members of religious orders, ministers, and Christian Science practitioners. The regulations will be updated to reflect and implement these statutory provisions.

#### Timetable:

Action	Date		FR	Cite
NPRM	06/30/88	53	FR	24727
NPRM Comment Period End	08/29/88			
Final Action	03/00/89			

#### Small Entities Affected: None

#### Government Levels Affected: None

Additional Information: Since the new rules are mandated by legislation, any costs or effects upon small entities are a result of the legislation and not a result of the proposed regulations.

Agency Contact: Charles Campbell, Legal Assistant, Department of Health and Human Services, Social Security Administration, Office of Regulations, 6401 Security Blvd., Baltimore, MD 21235, **301 965-1794** 

RIN: 0960-AC27

# 686. OLD-AGE, SURVIVORS, AND DISABILITY INSURANCE AND SUPPLEMENTAL SECURITY INCOME PROGRAMS; CONSIDERATION OF VOCATIONAL FACTORS

Significance: Agency Priority

**Legal Authority:** 42 USC 421; 42 USC 423; 42 USC 1302; 42 USC 1382c; 42 USC 405; 42 USC 1383

**CFR Citation:** 20 CFR 404.1560; 20 CFR 416.960

#### Legal Deadline: None

Abstract: These proposed regulations reflect longstanding policies followed by the Social Security Administration in making disability determinations and remove an ambiguity which exists in the present regulations regarding the factors that are considered when it is determined that a claimant is not disabled because he or she is able to do his or her past work. These proposed regulations do not reflect a substantive change in policy and are intended only to clarify what has always been agency policy.

#### Timetable:

Action	Date	FR	Cite
NPRM	06/09/88	53 FR	21685
NPRM Comment Period End	08/08/88		
Final Action	04/00/89		

#### Small Entitles Affected: None

#### **Government Levels Affected:** None

Agency Contact: William J. Ziegler, Legal Assistant, Department of Health and Human Services, Social Security Administration, Office of Regulations, 6401 Security Boulevard, Baltimore, MD 21235, 301 965-1759

RIN: 0960-AC31

#### 687. ORGANIZATION AND PROCEDURES, AND OASDI PROGRAMS; EVIDENCE REQUIRED FOR ORIGINAL OR DUPLICATE SOCIAL SECURITY NUMBER CARD

Legal Authority: 42 USC 405; 42 USC 1302

CFR Citation: 20 CFR 422B Legal Deadline: None

Abstract: The proposed regulations will allow the Social Security
Administration (SSA) to test procedures that will provide an exception to the current requirement that an applicant for a duplicate card must submit corroborative evidence of identity. This will enable us to test procedures that would allow us to conduct much of our business in processing applications for duplicate Social Security number cards by telephone.

#### Timetable:

Action	Date	FR Cite
Interim Final Rule	11/00/88	

Small Entities Affected: None

#### **Government Levels Affected: None**

Agency Contact: Jack Schanberger, Legal Assistant, Department of Health and Human Services, Social Security Administration, Office of Regulations, 6401 Security Boulevard. Baltimore, MD 21235, 301 965-8471

RIN: 0960-AC32

## 688. OLD-AGE, SURVIVORS, AND DISABILITY INSURANCE PROGRAM; ADDITION OF DOWN SYNDROME TO THE LISTING OF IMPAIRMENTS

Legal Authority: 42 USC 1302; 42 USC

CFR Citation: 20 CFR 404P

Legal Deadline: None

Abstract: We propose to add Down Syndrome to the multiple body systems, category of impairments, in Part B of the Listing of Impairments to provide for evaluation of Down syndrome claims according to the impairment criteria for the major system affected. The Listing of Impairments describes, for each of the major body systems, a level of severity which is considered sufficient to find a person disabled or blind under the disability program. Part B contains additional medical criteria that apply only to the evaluation of impairments of persons under age 18.

#### Timetable:

Action	Date		FR	Cite
NPRM	10/05/87	52	FR	37161
NPRM Comment Period End	12/04/87			
Final Action	03/00/89			

Small Entitles Affected: None

**Government Levels Affected: None** 

Final Rule Stage

Agency Contact: Harry J. Short, Legal Assistant, Department of Health and Human Services, Social Security Administration, Office of Regulations, 6401 Security Boulevard, Baltimore, MD 21235, 301 965-1757

RIN: 0960-AC35

689. ● SUPPLEMENTAL SECURITY INCOME PROGRAM; EXCLUSION OF REAL PROPERTY WHEN IT CANNOT BE SOLD; AND TRANSFER OF ASSETS FOR LESS THAN FAIR MARKET VALUE

Significance: Agency Priority

**Legal Authority:** 42 USC 1302; 42 USC 1383

**CFR Citation:** 20 CFR 416.1242; 20 CFR 416.1245; 20 CFR 416.1246

Legal Deadline: Final, Statutory, April 1, 1988.

Abstract: We have amended regulations under the Supplemental Security Income program to implement sections 9103 and 9104 of Pub. L. 100-203 (the Omnibus Budget Reconciliation Act of 1987) dealing with the disposition and transfer of resources in determining eligibility for SSI benefits. The cost/savings and workyear impact for these regulations have been estimated to be insignificant.

Timetable:				
Action	Date		FR	Cite
Interim Final Rule	04/22/88	53	FR	13254
Final Action	00/00/00			

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Henry Lerner, Legal Assistant, Department of Health and Human Services, Social Security Administration, Office of Regulations. 6401 Security Blvd., Baltimore, MD 21235, 301 965-1756

RIN: 0960-AC47

690. ● SUPPLEMENTAL SECURITY INCOME PROGRAM; PUBLIC EMERGENCY SHELTERS FOR THE HOMELESS, EXCLUSION OF UNDERPAYMENTS, INCREASE IN PERSONAL NEEDS ALLOWANCE

**Legal Authority:** PL 100-203, Sec 9113; PL 100-203, Sec 9114; PL 100-203, Sec 9110

**CFR Citation:** 20 CFR 416.201; 20 CFR 416.211; 20 CFR 416.414; 20 CFR 416.432; 20 CFR 416.1160; 20 CFR 416.1163; 20 CFR 416.1165; 20 CFR 416.1233; 20 CFR 416.2095; 20 CFR 416.2096; 20 CFR 416.2097; 20 CFR 416.2098; 20 CFR 416.1099

Legal Deadline: None

Abstract: These interim regulation will reflect sections 9113, 9114, and 9119 of Pub.L. 100-203 by increasing the number of months an individual who resides in a public emergency shelter for the homeless may be eligible for SSI payments, by temporarily extending the time period during which any retroactive payments made under the title II and title XVI programs will be excluded from resources, and increasing the benefit rate for persons in medical institutions where Medicaid pays more than one-half the cost of their care. We anticipate only a negligible increase in program costs.

Timetable:

Action		Date	FR	Cite
Interim Rule	Final	12/00/88		

Small Entities Affected: None

**Government Levels Affected: None** 

Agency Contact: Harry J. Short, Legal Assistant, Department of Health and Human Services, Social Security Administration, Office of Regulations, 6401 Security Blvd., Baltimore, MD 21235, 301 965-1753

RIN: 0960-AC54

## DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) Social Security Administration (SSA)

**Completed Actions** 

691. OLD-AGE, SURVIVORS, AND DISABILITY INSURANCE PROGRAM; COVERAGE OF EMPLOYEES OF STATE AND LOCAL GOVERNMENTS

CFR Citation: 20 CFR 404M

Completed:

 Reason
 Date
 FR Cite

 Final Action
 08/29/88
 53 FR 32972

Small Entitles Affected: None

**Government Levels Affected:** Local, State

Agency Contact: Duane Heaton 301 965-8470

RIN: 0960-AA13

692. OLD-AGE, SURVIVORS, AND DISABILITY INSURANCE PROGRAM; PROVISION FOR INFERRING A PERSON IS DEAD

CFR Citation: 20 CFR 404H

Completed:

Reason Date FR Cite
Regulatory Action 05/00/88

Discontinued

Small Entities Affected: None Government Levels Affected:

Agency Contact: Phil Berge 301 965-1769

RIN: 0960-AA54

Undetermined

693. SUPPLEMENTAL SECURITY INCOME PROGRAMS; ASSIGNMENT OF RIGHTS TO THIRD-PARTY MEDICAL PAYMENTS TO STATE

**CFR Citation:** 20 CFR 416.2101 to 416.2176

Completed:

 Reason
 Date
 FR Cite

 Final Action
 04/20/88
 53 FR 12938

Small Entities Affected: None

Government Levels Affected: State

Agency Contact: C. H. Campbell 301 965-1794

RIN: 0960-AB28

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**Completed Actions** 

694. OLD-AGE, SURVIVORS, AND **DISABILITY INSURANCE AND** SUPPLEMENTAL SECURITY INCOME PROGRAMS: CONTINUED PAYMENT OF BENEFITS DURING APPEAL

Significance: Agency Priority

CFR Citation: 20 CFR 404.1597; 20 CFR 404.1597a; 20 CFR 416.995; 20 CFR 416.996

Completed:

Reason FR Cite Date Final Action 08/02/88 53 FR 29011

Small Entities Affected: None

**Government Levels Affected: None** 

Agency Contact: Larry Dudar 301 965-1795

RIN: 0960-AB30

695, SUPPLEMENTAL SECURITY **INCOME PROGRAM; TREATMENT OF OVERPAYMENTS WHEN RECIPIENT'S COUNTABLE ASSETS EXCEED LIMITS** IN CERTAIN CASES

CFR Citation: 20 CFR 416

Completed:

FR Cite Reason Date Final Action 05/10/88 53 FR 16615

Small Entities Affected: None

**Government Levels Affected: None** 

Agency Contact: Larry Dudar 301 965-1795

RIN: 0960-AB32

696. OLD-AGE, SURVIVORS, AND **DISABILITY INSURANCE PROGRAM; DETERMINING DISABILITY AND BLINDNESS, MEDICAL-VOCATIONAL GUIDELINES, ILLITERACY AND INABILITY TO COMMUNICATE IN ENGLISH** 

CFR Citation: 20 CFR 404P; 20 CFR 416I

Completed:

Reason Date FR Cite

Regulatory action 07/00/88 discontinued

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Harry Short 301 965-1757

RIN: 0960-AB94

697. SUPPLEMENTAL SECURITY INCOME PROGRAM; SPOUSAL DEEMING COMPUTATION INVOLVING STATE SUPPLEMENTATION

CFR Citation: 20 CFR 416.1163(d); 20 CFR 416.2025(b)

Completed:

Reason Date FR Cite Final Action 07/05/88 53 FR 25150

Small Entitles Affected: None

Government Levels Affected: State

Agency Contact: Dave Smith 301 965-1758

RIN: 0960-AB95

698. SUPPLEMENTAL SECURITY INCOME PROGRAM: PROHIBITION ON DIRECT PAYMENT OF FEES TO REPRESENTATIVES

CFR Citation: 20 CFR 416.1520; 20 CFR 416.1525; 20 CFR 416.1528; 20 CFR 416.1335

Completed:

Reason Date FR Cite Withdrawn 05/23/88 53 FR 18292

Small Entities Affected: None

Government Levels Affected: None Agency Contact: Jack Schanberger 301 965-8471

RIN: 0960-AC08

699. SUPPLEMENTAL SECURITY INCOME PROGRAM; DEFINE OUT OF RESOURCES FOR ONE MONTH **CERTAIN CASH PAYMENTS FOR** MEDICAL/SOCIAL SERVICES

CFR Citation: 20 CFR 416.1201(a)

Completed:

Reason Date FR Cite Final Action 06/21/88 53 FR 23230

Small Entities Affected: None

Government Levels Affected: Federal Agency Contact: Henry Lerner 301 965-

R!N: 0960-AC11

1756

700. OLD-AGE, SURVIVORS, AND **DISABILITY INSURANCE AND** SUPPLEMENTAL SECURITY INCOME PROGRAMS; AGAINST EQUITY AND **GOOD CONSCIENCE: DEFINED** 

CFR Citation: 20 CFR 404.509: 20 CFR 416.554

Completed:

Reason Date FR Cite Final Action 07/07/88 53 FR 25481

Small Entities Affected None

Government Levels Affected: None

Agency Contact: Duane Heaton 301 965-8470

RIN: 0960-AC33

701. ● OLD-AGE, SURVIVORS, AND DISABILITY INSURANCE PROGRAM: **EXTENSION OF EXPIRATION DATE** FOR MENTAL DISORDERS LISTINGS

Significance: Agency Priority Legal Authority: 42 USC 1102

CFR Citation: 20 CFR 404P (Appendix)

Legal Deadline: None

Abstract: These final regulations will extend the expiration date of the mental disorders listing (12.00 of Part A of the Appendix to subpart P of Part 404) through August 27, 1990. No changes are being made and no additional costs are anticipated.

Timetable:

Action Date FR Cite Final Action 08/09/88 53 FR 29878

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: William J. Ziegler, Legal Assistant, Department of Health and Human Services, Social Security Administration, Office of Regulations, 6401 Security Blvd., Baltimore, MD 21235, 301 965-1759

RIN: 0960-AC44

702. O SUPPLEMENTAL SECURITY INCOME PROGRAM; EXCLUSION OF **CERTAIN SUPPORT AND** MAINTENANCE ASSISTANCE BASED ON NEED

Legal Authority: PL 100-203, Sec 9101 **CFR Citation: 20 CFR 416.1157** 

Legal Deadline: None

#### HHS-SSA

**Completed Actions** 

Abstract: These final regulations implement section 9101 of Pub.L. 100-203, which makes permanent the provisions of section 1612(b)(13) of the Social Security Act. Section 1612(b)(13) provides that certain support and maintenance assistance not be counted as income when determining an individual's eligibility for and the amount of his or her supplemental security income payments. We

anticipate minimal, if any, additional costs.

#### Timetable:

Action	Date		FR	Cite
Final Action Final Action	09/15/88 09/15/88	53	FR	35807
Effective				

Small Entities Affected: None
Government Levels Affected: None

Agency Contact: Harry Short, Legal Assistant, Department of Health and Human Services, Social Security Administration, Office of Regulations, 6401 Security Blvd., Baltimore, MD 21235, 301 965-1757

RIN: 0960-AC53

# DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) Public Health Service (PHS)—Centers for Disease Control (CDC)

**Proposed Rule Stage** 

703. SUBCHAPTER J - NATIONAL VACCINE PROGRAM, PART 110 INFORMATION AND EDUCATION, SUBPART A - VACCINE INFORMATION MATERIALS

Significance: Agency Priority

Legal Authority: 42 USC 300aa-26; PL 99-660, Sec 311(a)

CFR Citation: 42 CFR 110

Legal Deadline: Final, Statutory, December 22, 1988.

Abstract: This new regulation is required to implement the statutory requirements of Section 2126, Title XXI, Public Health Service Act as amended. The statute requires the Secretary to develop and disseminate vaccine information materials for distribution by health care providers. These materials will be published as an appendix of this regulation. The regulation describes the vaccine information materials and the health care providers' duties to disseminate a copy of the materials to any adult to whom the provider intends to administer vaccine and to the legal representative of any child to whom the provider intends to administer vaccine. The NPRM has a 90-day comment period, with the final rule to be published by December 22, 1988.

#### Timetable:

Action	Date	FR Cite
NPRM	10/01/88	
Public Hearingapprox 30 days after publication	11/00/88	
NPRM Comment Period End	12/30/88	
Final Action	03/00/89	
Final Action  Effective	09/00/89	

Small Entities Affected: None

**Government Levels Affected:** Local, State

Agency Contact: Walter A. Orenstein, M.D., Director, Division of Immunization, Center for Prevention Services, Department of Health and Human Services, Public Health Service, Centers for Disease Control, 1600 Clifton Road, Atlanta, GA 30333, 404 639-1860

RIN: 0905-AC83

704. ● HEALTH ASSESSMENTS AND HEALTH EFFECTS STUDIES OF HAZARDOUS SUBSTANCES RELEASES AND FACILITIES

Legal Authority: 42 USC 9601 et seq. Sec 104(i) amended by Sec 110 of SARA; 42 USC 6939a(c)

CFR Citation: 42 CFR 90

Legal Deadline: None

Abstract: This regulation sets forth procedures the Agency for Toxic

Substances and Disease Registry (ATSDR) will follow in determining when and how to conduct health assessments and health effects studies at hazardous substances releases and facilities. In addition to CERCLAauthorized health assessments and health effects studies, this regulation also applies to ATSDR health assessment activity under the Resource Conservation and Recovery Act (RCRA) (42 USC 6939a(c)). This proposal also contains provisions pertaining to the establishment of administrative records for ATSDR health assessments and health effects studies, for tracking costs of these studies for cost recovery purposes, and for safeguarding trade secret and other confidential information.

#### Timetable:

Action	Date		FR	Cite
NPRM	08/24/88	53	FR	32259
NPRM Comment Period End	10/24/88			
Final Action	07/00/89			

Small Entities Affected: Undetermined

Government Levels Affected: Local, State, Federal

Agency Contact: Ralph J. Touch, Jr., Director, Planning and Special Programs, ATSDR, Department of Health and Human Services, Public Health Service, Chamblee 27, F38, 1600 Clifton Road, Atlanta, GA 30333, 404 488-4853

RIN: 0905-AC84

#### 41920

# DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) Public Health Service (PHS)—Centers for Disease Control (CDC)

Final Rule Stage

# 705. NIOSH REVISION OF TESTS AND REQUIREMENTS OF CERTIFICATION OF PERMISSIBILITY OF RESPIRATORY PROTECTIVE DEVICES USED IN MINES AND MINING

Significance: Regulatory Program
Legal Authority: 30 USC 801; 30 USC 844; 30 USC 957

CFR Citation: 30 CFR 11; 42 CFR 84 Legal Deadline: None

Abstract: There are three major problems that the proposed regulatory action is intended to solve. First, the current regulatory provisions in 30 CFR 11 in some instances date back almost fifty years. As a result the provisions are not current with many of the extensive changes in respirator technology. Second, the current regulations do not provide for testing of respirators under either actual or simulated use conditions prior to certification. Third, the resources required to conduct routine respirator

certification testing made it important for NIOSH alone to keep respirator performance standards current with advances in respirator technology and with new knowledge on respirator performance characteristics. Alternatives considered: (1) the Federal government could relinquish the field entirely to the private sector. (2) The Federal government could promulgate performance standards but not be involved in assuring compliance with those standards. (3) The Federal government could continue to be the certifier of respirators but have manufacturers conduct testing. (4) The Federal Government could continue its present role of total operation of the

#### Timetable:

Action	Date		FR	Cite	
NPRM	08/27/87	52	FR	32402	
Final Action	10/00/88				

Small Entities Affected: Undetermined

#### Government Levels Affected: None

Additional Information: ABSTRACT CONT: respirator system. NIOSH selected alternative number (3). Cost is yet to be determined. Public hearings on the proposal were held on January 20, 1988, in San Francisco, and on January 27-28 in Washington, DC. The record for these hearings closed February 27, 1988.

Agency Contact: Dr. Nelson A. Leidel, Senior Science Advisor, Office of the Director, NIOSH, Department of Health and Human Services, Public Health Service, Centers for Disease Control, 1600 Clifton Road, Atlanta, GA 30333, 404 639-3901

RIN: 0905-AB58

# DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) Public Health Service (PHS)—Centers for Disease Control (CDC)

**Completed Actions** 

## 706. PROJECT GRANTS FOR HEALTH PROGRAMS FOR REFUGEES

CFR Citation: 42 CFR 51e

Reason	Date	FR	Cite
Withdrawn	05/25/88		

Government Levels Affected: Local,

Agency Contact: Anthony M. Scardaci 404 639-1802

RIN: 0905-AB43

# DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) Public Health Service (PHS)—Food and Drug Administration (FDA)

**Prerule Stage** 

#### 707. DRUG EXPORTS

Significance: Agency Priority

Legal Authority: PL 99-660 Drug Export Amendments Act of 1986

CFR Citation: Not yet determined

Legal Deadline: None

Abstract: The Drug Export
Amendments Act of 1986 authorizes the
export for commercial marketing
abroad of veterinary and human drugs
not approved for marketing in the
United States. Under previous law, the
export of new human and animal drugs
for marketing was confined to drugs
that were approved by FDA for
domestic use. The law establishes three
separate pathways for the export of
unapproved products. Under each
pathway, FDA approval is required

before export is permitted. As a prerulemaking activity, FDA is developing guidance material for manufacturers instructing them as to what information must be submitted to the agency to obtain approval for the export of unapproved products. The guidance material will also identify FDA sources of information on agency practices and policies concerning the implementation of the Drug Export Amendments Act of 1986. The agency will then decide what, if any, regulations are necessary for the efficient implementation of the amendments, and establish timeframes for the development of those regulations.

Timetable:			
Action	Date	FR	Cit

**Next Action Undetermined** 

Small Entities Affected: Undetermined

**Government Levels Affected: None** 

Agency Contact: Wayne Mitchell, Regulatory Counsel, Division of Regulatory Affairs, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (HFD-362), 5600 Fishers Lane, Rockville, MD 20857, 301 295-8046

RIN: 0905-AC44

#### HHS-PHS-FDA

Prerule Stage

### 708. ● COMPUTER PRODUCTS; POLICY GUIDANCE

Significance: Regulatory Program Legal Authority: 21 USC 321(h) CFR Citation: 21 CFR 800

Legal Deadline: None

Abstract: As a prerulemaking activity, FDA is developing guidance for manufacturers respecting how FDA would apply existing statutory requirements to the regulation of computer products (i.e., both hardware and software) when such products meet the definition of a medical device under the act.

On September 25, 1987, FDA made available a draft policy guidance intended to clarify how FDA would apply existing statutory requirements to the regulation of such products to provide opportunity for public participation in this activity.

Upon analysis of the public comments on the complex issues pertaining to the regulation of computer products, the agency will decide whether any additional steps are necessary to clarify which computer products meet the definition of a medical device and what level of regulation, if any, is appropriate under the act.

#### Timetable:

Action	Date		FR	Cite
Proposed Draft Guideline	09/25/87	52	FR	36104
Final Policy Guidance	11/00/88			

Small Entities Affected: Undetermined Government Levels Affected: None

Agency Contact: Charles S. Furfine, Office of Standards and Regulations, Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health (HFZ-84), 5600 Fishers Lane, Rockville, MD 20857, 301 443-4874

RIN: 0905-AC72

# DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) Public Health Service (PHS)—Food and Drug Administration (FDA)

**Proposed Rule Stage** 

# 709. CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS; RETROSPECTIVE REVIEW

Significance: Agency Priority

Legal Authority: 21 USC 351 Federal Food, Drug, and Cosmetic Act; 21 USC 352 Federal Food, Drug, and Cosmetic Act; 21 USC 360b Federal Food, Drug, and Cosmetic Act; 21 USC 371(a) Federal Food, Drug, and Cosmetic Act

CFR Citation: 21 CFR 211 Legal Deadline: None

Abstract: As part of its retrospective review, FDA plans to determine the need for any changes in the current GMPs to eliminate unnecessary requirements and to allow flexibility without undermining protection of the public health.

#### Timetable:

Action	Date	 Cite
NPRM	12/00/88	

Small Entitles Affected: None

**Government Levels Affected: None** 

Agency Contact: Robert J. Meyer, Consumer Safety Officer, Division of Regulatory Affairs, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (HFD-362), 5600 Fishers Lane, Rockville, MD 20857, 301 295-8049

RIN: 0905-AA73

710. CURRENT GOOD
MANUFACTURING PRACTICE (CGMP)
FOR BLOOD AND BLOOD
COMPONENTS; RETROSPECTIVE
REVIEW

Significance: Agency Priority

Legal Authority: 21 USC 321 Federal Food, Drug, and Cosmetic Act; 21 USC 352 Federal Food, Drug, and Cosmetic Act; 21 USC 355 Federal Food, Drug, and Cosmetic Act; 21 USC 371 Federal Food, Drug, and Cosmetic Act; 42 USC 262 Public Health Service Act; 5 USC 553 Administrative Procedures Act; 5 USC 702 Administrative Procedures Act; 5 USC 703 Administrative Procedures Act; 5 USC 704 Administrative Procedures Act

CFR Citation: 21 CFR 606

Legal Deadline: None

Abstract: FDA is responsible for issuing regulatory standards for blood and blood components to ensure the continued safety, purity, and potency of such products. Since 1975, CGMP regulations have been in effect that provide standards for facilities, personnel, and manufacturing procedures for blood and blood components. In accordance with the Regulatory Flexibility Act, FDA has conducted a retrospective review of its

CGMP regulations for blood and blood components, to determine how the regulations may be revised to relieve regulatory burdens and increase flexibility without adversely affecting the public health. Part of the retrospective review of the CGMP will be completed through FDA's implementation of an efficacy review of blood and blood derivatives which responds to recommendations of a Committee of scientific experts--the Panel on Review of Blood and Blood Derivatives. To complete the remainder of the retrospective review program regarding the CGMP, FDA will issue a proposed rule to revise the CGMP regulations.

#### Timetable:

Blood & Blood Components; Retrospective Review

NPRM 01/00/89 Final Action 00/00/00

Blood & Blood Derivatives; Implementation of Efficacy Review

NPRM 12/24/85 (50 FR 52602) Comment Period Ends 03/24/86 (50 FR 52602)

Final Action 03/00/89

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Steven F. Falter, Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, Center for Biologics Evaluation and Research (HFB-130), 5600 Fishers Lane, Rockville, MD 20857, 301 295-8046

RIN: 0905-AA75

## 711. NEW ANIMAL DRUG APPROVAL PROCESS

Significance: Agency Priority

Legal Authority: 21 USC 360b Federal, Food, Drug, and Cosmetic Act; 21 USC 371 Federal Food, Drug, and Cosmetic Act

**CFR Citation:** 21 CFR 514.1; 21 CFR 514.8

Legal Deadline: None

Abstract: Based upon an evaluation of an action issues report, the agency has concluded that it will recommend that the Secretary propose revision of the existing regulations in a manner consistent with the current procedural regulations for human drugs where appropriate. The New Animal Drug Application (NADA) revisions would articulate general requirements in regulations containing performance standards and would complement them through detailed guidelines on, among other matters, appropriate ways of meeting requirements for submission of chemistry, pharmacology, and statistical data that would better address the intricate scientific issues involved. Although the guidelines would not establish regulatory requirements, persons would be able to rely on them with confidence that action taken under a guideline would be acceptable to the agency. A separate proposed rule would provide for reporting requirements for marketed animal drugs.

#### Timetable:

New Animal Drug Approval Process NPRM 03/00/89

Rptg. Requirements for Marketed Animal Drugs

NPRM 12/00/88

Small Entities Affected: Undetermined

Government Levels Affected: None

Additional Information: AGENCY CONTACT CONT: For Information Concerning Reporting Requirements for Marketed Animal Drugs Contact: Andrew J. Beaulieu, Director, Division of Surveillance, Center for Veterinary Medicine, Food and Drug Administration, 5600 Fishers Lane, Rockville, Maryland 20857, (301) 443-3044

Agency Contact: Frank G. Pugliese, Supervisory Consumer Safety Officer, Office of New Animal Drug Evaluation, Department of Health and Human Services, Food and Drug Administration, Center for Veterinary Medicine (HFV-102), 5600 Fishers Lane, Rockville, MD 20857, 301 443-4500

RIN: 0905-AA96

## 712. POLICIES CONCERNING USES OF SULFITING AGENTS

Significance: Regulatory Program

Legal Authority: 21 USC 342 Federal Food, Drug, and Cosmetic Act; 21 USC 371(a) Federal Food, Drug, and Cosmetic Act; 21 USC 321(n) and 321(s) Federal Food, Drug, and Cosmetic Act; 21 USC 348 Federal Food, Drug, and Cosmetic Act; 21 USC 336 Federal Food, Drug, and Cosmetic Act; 21 USC 341 Federal Food, Drug, and Cosmetic Act; 21 USC 343 Federal Food, Drug, and Cosmetic Act; 21 USC 343 Federal Food, Drug, and Cosmetic Act

**CFR Citation:** 21 CFR 182.3616; 21 CFR 182.3637; 21 CFR 182.3739; 21 CFR 182.3766; 21 CFR 182.3798; 21 CFR 182.3862; 21 CFR 100; 21 CFR 130.9

#### Legal Deadline: None

Abstract: Acceptable evidence and information exists to show that a subgroup of asthmatics is at moderate to severe risk for a severe reaction upon exposure to sulfites. The agency's primary tool for handling a situation where population subgroups may be at increased risk from a food ingredient that is safe for most people is to use labeling to inform those persons who need or want to avoid the ingredient. The agency issued a final rule, effective January 7, 1987, that requires that when a sulfiting agent is present in a finished food at 10 parts per million or greater, . the sulfiting agent must be declared on the label. In addition, FDA issued a final rule, effective August 8, 1986, prohibiting the use of sulfiting agents on raw fruits and vegetables intended to be served or sold raw to consumers (e.g., in salad bars). The agency is now considering what it options are with regard to the GRAS status of 1) sulfiting agents used on "fresh" potatoes and 2) other food uses of sulfiting agents. Options being considered are: 1) affirming all uses of sulfiting agents as GRAS with specific limitation; 2) affirming most uses of (cont)

#### Timetable:

Food Labeling; Deciaration of Sulfiting Agents

NPRM 04/03/85 (50 FR 13306) Final Action 07/09/86 (51 FR 25012) EFFECTIVE DATE 01/09/87 (51 FR 25012)

GRAS Status of the Use of Sulfiting Agents on Potatoes

NPRM 12/10/87 (52 FR 46968) Final Action 03/00/89

GRAS Status of Certain Other Food Uses of Sulfiting Agents, Etc. NPRM 10/00/88

Final Action 00/00/00
Revoking Use of Sulfiting Agents on Fruits & Vegetables, Etc.

NPRM 08/14/85 (50 FR 32836) Final Action 07/09/86 (51 FR 25021) Final Action Effective 08/09/86 (51 FR 25021)

Suifiting Agents in Standardized Foods; Labeling Requirements NPRM 10/00/88 Final Action 00/00/00

Small Entitles Affected: None

Government Levels Affected: None

Additional Information: ABSTRACT CONT: sulfiting agents as GRAS (excluding certain potato products) with specific limitations; and 3) revoking the GRAS status of all uses of sulfiting agents in food.

Agency Contact: Robert L. Martin, Division of Food and Color Additives, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition (HFF-334), 200 C Street, S.W., Washington, DC 20204, 202 426-9463

RIN: 0905-AB52

# 713. REQUIREMENTS FOR ADVERSE EXPERIENCE REPORTING FOR LICENSED BIOLOGICAL PRODUCTS

Significance: Agency Priority

Legal Authority: 21 USC 351 Federal Food, Drug, and Cosmetic Act; 21 USC 352 Federal Food, Drug, and Cosmetic Act; 21 USC 355 Federal Food, Drug, and Cosmetic Act; 21 USC 371 Federal Food, Drug, and Cosmetic Act; 21 USC 374 Federal Food, Drug, and Cosmetic Act; 42 USC 262 Public Health Service

**CFR Citation:** 21 CFR 211; 21 CFR 310; 21 CFR 600

Legal Deadline: None

**Abstract:** This regulatory action is being taken to improve the safety of marketed drug products by a reporting

scheme that will require serious adverse reactions associated with licensed biological products to be reported to the Food and Drug Administration (FDA).

The purpose of the regulatory action is to require prompt reporting to the agency of serious adverse experiences for all licensed biological products.

The regulatory action being considered by FDA would be consistent with the agency's requirements regarding adverse reactions reporting for approved new drugs under 21 CFR 314.80 (see February 22, 1985; 50 FR 7452). These biologic regulations would require that all "serious and unexpected" adverse experiences and any "significant increase in frequency" of a serious expected event be reported to the agency within 15 working days. Known and nonserious adverse biological product experiences would be required to be reported to the agency at quarterly or annual intervals, depending on the length of marketing experience with the product. This information (cont)

#### Timetable:

Action	Date	FR	Cite
NPRM	00/00/00		

Small Entities Affected: None

Government Levels Affected: None

Additional Information: ABSTRACT CONT: permits the agency to monitor effectively the safety of all licensed biological products.

Agency Contact: Steven F. Falter, Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, Center for Biologics Evaluation and Research (HFB-130), 5600 Fishers Lane, Rockville, MD 20857, 301 295-8046

RIN: 0905-AB53

714. PROPOSED RULE TO IMPLEMENT THE ORPHAN DRUG AMENDMENTS TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

Significance: Regulatory Program

Legal Authority: PL 97-414 Orphan Drug Act; PL 100-290

CFR Citation: Not yet determined

Legal Deadline: None

Abstract: The Orphan Drug Act is intended to provide incentives for drug

companies to invest in the development of drugs for rare diseases or conditions. Certain incentives are necessary because "orphan drugs" are unlikely to be profitable. The agency is required to carry out provisions of the Orphan Drug Act, e.g., by designating a drug as an orphan drug, by providing protocol assistance, and by granting seven years of exclusive approval status. The proposed rule would establish procedures whereby drug sponsors can take advantage of the incentives to encourage development of orphan drugs. While several provisions of the Orphan Drug Act call for promulgation of regulations, the agency is considering the extent to which regulations will be needed to provide the framework and guidance for implementing a program of incentives to drug sponsors and manufacturers.

#### Timetable:

Action	Date		FR	Cite	
Interim Guidelines	09/09/83	48	FR	40784	
Revised Interim Guidelines	05/09/85	50	FR	19583	
NPRM	12/00/88				

Small Entities Affected: Undetermined Government Levels Affected: None

Agency Contact: Emery J. Sturniolo, Assistant to the Director, Department of Health and Human Services, Food and Drug Administration, Office of Orphan Products Development (HF-35), 5600 Fishers Lane, Rockville, MD 20857, 301

RIN: 0905-AB55

715. IMPLEMENTATION OF TITLE I OF THE "DRUG PRICE COMPETITION AND PATENT TERM RESTORATION ACT OF 1984" (TITLE I)

Significance: Agency Priority

Legal Authority: PL 98-417, (Title I)

CFR Citation: Not yet determined

Legal Deadline: None

Abstract: Until the passage of Title I of the "Drug Price Competition and Patent Term Restoration Act of 1984," abbreviated new drug application (ANDA) procedures were only available for generic products equivalent to pioneer drugs approved before 1962. Title I opened up the ANDA policy to generic copies of products approved after 1962. This rulemaking is intended to establish

clear and uniform procedures for the review and timely approval of ANDAs. This should assist the generic drug industry by ending considerable confusion about the procedures governing review of ANDAs. In turn, with the availability of lower-cost generic products, it is estimated that consumers may save millions of dollars. The statute calls for promulgation of implementing regulations, however, the agency also expects to develop guidelines and other policy statements to assist in developing approvable applications. Revised target dates for this regulatory action are appropriate because many new issues have been identified in petitions and letters to the agency from trade associations and attorneys representing individual manufacturers concerning exclusivity, patent coverage, (cont)

#### Timetable:

Action	Date	FR	Cite
NPRM	04/00/89		
Final Action	00/00/00		

Small Entities Affected: Undetermined

Government Levels Affected: None

Additional information: ABSTRACT CONT: and some of the complex provisions of the act. The resolution of these many minor issues will be reflected in the NPRM and will permit the agency to develop a comprehensive proposed rule.

Agency Contact: Marilyn Watson, Special Asst. to the Division Director, Division of Regulatory Affairs, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (HFD-360), 5600 Fishers Lane, Rockville, MD 20857, 301 295-8038

RIN: 0905-AB63

716. ABBREVIATED NEW ANIMAL DRUG APPLICATIONS FOR POST-1962 ANIMAL DRUGS

Significance: Agency Priority

Legal Authority: 21 USC 360b Federal Food, Drug, and Cosmetic Act

**CFR Citation:** 21 CFR 514.1; 21 CFR 514.2; 21 CFR 514.3; 21 CFR 514.11

Legal Deadline: None

Abstract: This proposed rule would permit applicants to file abbreviated new animal drug applications 41924

(ANADAs) for products identical to approved post-1962 drugs and to omit certain reports that are required in full NADAs to show safety and effectiveness of the product. It would apply only to certain drug products specified by FDA. If adopted, the proposed rule would reduce duplicative testing of drugs and also reduce the cost to the manufacturer of getting the affected drugs on the market. This issue is currently under Congressional review. Further agency action contingent upon Congressional review.

#### Timetable:

Action	Date	FR Cite

**Next Action Undetermined** 

Small Entitles Affected: Undetermined

Government Levels Affected: None

Agency Contact: Richard A. Carnevale, Deputy Director, Office of New Animal Drug Evaluation, Department of Health and Human Services, Food and Drug Administration, Center for Veterinary Medicine (HFV-120), 5600 Fishers Lane, Rockville, MD 20857, 301 443-4314

RIN: 0905-AB72

# 717. PROTECTION OF HUMAN SUBJECTS; INFORMED CONSENT; STANDARDS FOR INSTITUTIONAL REVIEW BOARDS FOR CLINICAL INVESTIGATIONS

Significance: Regulatory Program

Legal Authority: 21 USC 346(a) Federal Food, Drug and Cosmetic Act; 21 USC 351 to 357 Federal Food, Drug and Cosmetic Act; 21 USC 360 Federal Food, Drug and Cosmetic Act; 21 USC 360 to 360f Federal Food, Drug and Cosmetic Act; 21 USC 360h to 360j Federal Food, Drug and Cosmetic Act; 21 USC 371(a) Federal Food, Drug and Cosmetic Act; 21 USC 376 Federal Food, Drug and Cosmetic Act; 21 USC 376 Federal Food, Drug and Cosmetic Act; 21 USC 381 Federal Food, Drug and Cosmetic Act; 42 USC 216 Public Health Service Act; 42 USC 262 Public Health Service Act; 42 USC 263b to 263n Public Health Service Act; 42 USC 263b to 263n Public Health Service Act

CFR Citation: 21 CFR 50; 21 CFR 56

**Legal Deadline:** None

Abstract: In the FEDERAL REGISTER of June 3, 1986 (51 FR 20204), the Office of Science and Technology Policy (OSTP) issued for public comment a

proposed Model Federal Policy for the Protection of Human Research Subjects. This Model Policy is to enhance uniformity in the implementation of a common core of regulations governing research with human subjects. FDA has concurred in the proposed Model Policy to the extent permitted by law. FDA will propose to amend its regulations to eliminate certain inconsistencies with the proposed Model Policy. OSTP has advised the Agency that concurrent publication of the final Model Policy and FDA's proposed rule is needed.

#### Timetable:

Action	Date	FR	Cite
NPRM	00/00/00		

**Small Entities Affected: None** 

**Government Levels Affected:** None

Agency Contact: Bonnie M. Lee, Public Health Advisor, Health Assessment Policy Staff, Department of Health and Human Services, Food and Drug Administration, Office of Health Affairs (HFY-20), 5600 Fishers Lane, Rockville, MD 20857, 301 443-1382

RIN: 0905-AC52

## 718. ● MENSTRUAL TAMPONS; PROPOSED USER LABELING

Significance: Regulatory Program

**Legal Authority:** 21 USC 321; 21 USC 352; 21 USC 360; 21 USC 371; 21 USC 374

**CFR Citation: 21 CFR 801.430** 

Legal Deadline: None

Abstract: FDA is considering a proposal to require tampon manufacturers to include on the package label information to describe absorbency of the tampon. The NPRM would also propose requiring that absorbency be determined in accordance with a specific test method.

#### Timetable:

Date		FR	Cite
09/23/88	53	FR	37250
12/22/88			
	09/23/88	09/23/88 53	09/23/88 53 FR

Small Entitles Affected: None

**Government Levels Affected: None** 

Agency Contact: Les Weinstein, Office of Standards and Regulations, Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health (HFZ-84), 5600 Fishers Lane, Rockville, Maryland 20857, 301 443-4874

RIN: 0905-AC54

# 719. ● ACTION LEVELS FOR ADDED POISONOUS OR DELETERIOUS SUBSTANCES IN FOOD (INCLUDING ANIMAL FEED)

Significance: Regulatory Program Legal Authority: 21 USC 342(a)(1) CFR Citation: 21 CFR 109; 21 CFR 509

Legal Deadline: None

Abstract: FDA is considering a proposed rule that would (1) amend its regulations creating and describing action levels for added poisonous or deleterious substances in food (including animal feed) to make clear that these action levels are prosecutorial guidelines rather than substantive rules, and (2) revoke the provisions for exceptions to action levels in 21 CFR Part 109 (human food) and 21 CFR Part 509 (animal feed).

#### Timetable:

Action	Date		FR	Cite	
Notice of Circuit Court Decision		53	FR	5043	
NPRM	10/00/88				

Small Entities Affected: Undetermined

**Government Levels Affected: None** 

Agency Contact: John R. Wessel, Director, Contaminants Policy Staff, Department of Health and Human Services, Food and Drug Administration, Office of Regulatory Affairs, 5600 Fishers Lane, Rockville, MD 20857, 301 443-1815

RIN: 0905-AC73

#### 720. ● PRESCRIPTION DRUG MARKETING ACT OF 1987; IMPLEMENTATION

Significance: Agency Priority

Legal Authority: PL 100-293 CFR Citation: 21 CFR 399

Legal Deadline: Final, Statutory, October 20, 1988.

Statutory date applies only to issuing guidelines for State licensing of wholesale drug distributors.

Abstract: The Prescription Drug Marketing Act of 1987 (the new law) amends the Federal Food, Drug, and Cosmetic Act to: (1) require State

#### HHS-PHS-FDA

**Proposed Rule Stage** 

licensing of wholesale distributors of prescription human drugs under Federal guidelines including minimum standards for storage, handling, and recordkeeping; (2) ban the reimportation of prescription human drugs produced in the United States, except when reimported by the manufacturer or for emergency use; (3) ban the sale, trade, or purchase of drug samples; (4) ban trafficking in or counterfeiting of drug coupons; (5) mandate storage, handling. and recordkeeping requirements for drug samples; (6) require practitioners to request drug samples in writing; (7) prohibit, with certain exceptions, the resale of prescription human drugs purchased by hospitals or health care facilities; and (8) set forth criminal and civil penalties for violations of these provisions. The new law requires that the guidelines under (1) above be promulgated as a regulation, through notice and comment rulemaking. It also provides that the prohibition against distribution of prescription drugs by

unlicensed wholesalers becomes effective two years (cont)

#### Timetable:

Action	Date	FR Cite
ANPRM Comment Period End	10/00/88	
Final Action Effective	10/00/90	
NPRM	00/00/00	
Final Decision on Further Regulations	00/00/00	
<b>Prescription Drug</b>	Marketing A	ct;

Prescription Drug Marketing Act; Information Letter Notice 08/08/88 (53 FR 29776)

Reimportation of Prescription Drugs; Import Aiert Notice 07/26/88 (53 FR 28069)

Wholesale Drug Distributors; Guidelines for State Licensing

NPRM 09/13/88 (53 FR 35325) NPRM Public Comment Period End 10/13/88 Final 10/00/88

Small Entities Affected: Undetermined

#### Government Levels Affected: Undetermined

Additional Information: ABSTRACT CONT: after the final regulation is published by the agency in the FEDERAL REGISTER. FDA has developed guidance information respecting other sections of the new law. After seeking comments from the regulated industry and other interested persons, the agency will decide what, if any, regulations are necessary for implementing the other sections and will establish timeframes for the development of those regulations.

Agency Contact: Richard Arkin, Regulatory Counsel, Division of Regulatory Affairs, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (HFD-362), 5600 Fishers Lane, Rockville, MD 20857. 301 295-8046

RIN: 0905-AC81

# DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) Public Health Service (PHS)—Food and Drug Administration (FDA)

Final Rule Stage

## 721. OVER-THE-COUNTER (OTC) DRUG REVIEW

Significance: Agency Priority

Legal Authority: 21 USC 321(p) Federal Food, Drug, and Cosmetic Act; 21 USC 352 Federal Food, Drug, and Cosmetic Act; 21 USC 355 Federal Food, Drug, and Cosmetic Act; 21 USC 371(a) Federal Food, Drug, and Cosmetic Act

**CFR Citation:** 21 CFR 310; 21 CFR 330; 21 CFR 333; 21 CFR 334; 21 CFR 335; 21 CFR 336; 21 CFR 336; 21 CFR 336; 21 CFR 340; 21 CFR 340; 21 CFR 341; 21 CFR 342; 21 CFR 343; 21 CFR 344; 21 CFR 345; ...

#### 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. NOTE: NPRM for "Antidotes, Toxic Ingestion Products" to be combined with NPRM for "Emetic Products" and reproposed as "Poison Treatment Products." NPRM for

"Astringent (Wet Dressings) Products" to be included in NPRMs for "External Analgesic" & "Skin Protectant Products." NPRM for "Diaper Rash Products" to be included in NPRMs for "Antifungal," "Antimicrobial," "External Analgesic" and "Skin Protectant Products." NPRM for "Fever Blister/Cold Sore Products (External)" to be included in NPRMs for "External Analgesic" and "Skin Protectant Products." NPRM for "Insect Bites and Stings (Relief) Products" to be included in NPRMs for "External Analgesic" and "Skin Protectant Products." "Poison Ivy/Oak/Sumac Prevention" to be included in NPRMs for "External Analgesic" and "Skin Protectant Products." NPRM for "Mercurial (Topical) Products" to be included in NPRM (cont)

#### Timetable:

#### Acne (Topical) Products

ANPRM 03/23/82 (47 FR 12430) NPRM 01/15/85 (50 FR 2172) Final Action 00/00/00

Aicohoi (Topical) Products (To be merged w/other rulemkg)

### ANPRM 05/21/82 (47 FR 22324) Anorectal Products

ANPRM 05/27/80 (45 FR 35576) NPRM 08/15/88 (53 FR 30756). **Antacid Drug Products** 

ANPRM 04/05/73 (38 FR 8714) NPRM 11/12/73 (38 FR 31260) Final Action 06/04/74 (39 FR 9862)

Anthelmintic Products

ANPRM 09/09/80 (45 FR 59541) NPRM 08/24/82 (47 FR 37062) Final Action 08/01/86 (51 FR 27756)

Antibiotic First Aid Products
ANPRM 04/01/77 (42 FR 17642)
NPRM 07/09/82 (47 FR 29986)
Final Action 12/11/87 (52 FR 47312)

Anticaries Products

ANPRM 03/28/80 (45 FR 20666)

NPRM 09/30/85 (50 FR 39854)

NPRM 06/15/88 (53 FR 22430)

Final Action 00/00/00

Antidiarrheal Products
ANPRM 03/21/75 (40 FR 12924)
NPRM 04/30/86 (51 FR 16138)
Final Action 00/00/00

Antidotes, Toxic Ingestion Prdts (Now Poison Treatment Prdts) ANPRM 01/05/82 (47 FR 444)

**Antiemetic Products** 

ANPRM 03/21/75 (40 FR 12934) NPRM 07/13/79 (44 FR 41064) Final Action 04/30/87 (52 FR 15886)

Antiflatulent Drug Products
NPRM 11/12/73 (38 FR 31260)
Final Action 06/04/74 (39 FR 19877)
NPRM (Amendment) 01/29/88 (53 FR 2716)

Antifungal (Topical) Products ANPRM 03/23/82 (47 FR 12480) NPRM 12/00/88 Antimicrobial Products

ANPRM 09/13/74 (39 FR 33103)

NPRM 01/06/78 (43 FR 1210)

Revised NPRM 02/00/89

Antiperspirant Products
ANPRM 10/10/78 (43 FR 46694)
NPRM 08/20/82 (47 FR 36492)
Final Action 00/00/00

Aphrodisiac Products
ANPRM 10/01/82 (47 FR 43572)
NPRM 01/15/85 (50 FR 2168)
Final Action 04/00/89

Astringent (Wet Dressings) Prdts (To be merged w/other ruiemkg) ANPRM 09/07/82 (47 FR 39436)

Benign Prostatic Hypertrophy Products ANPRM 10/01/82 (47 FR 43566) NPRM 02/20/87 (52 FR 5406) Final Action 00/00/00

Boil OIntments

ANPRM 06/29/82 (47 FR 28306)
NPRM 01/26/88 (53 FR 2198)
Final Action 00/00/00

Camphorated Oii Drug Products
ANPRM 09/26/80 (45 FR 63869)
Final Action 09/21/82 (47 FR 41716)

Cholecystokinetic Products

ANPRM 02/12/80 (45 FR 9286)
NPRM 08/24/82 (47 FR 37068)
Final Action 06/10/83 (48 FR 27004)
NPRM (Amendment) 08/15/88 (53 FR 30786)

Corn and Callus Remover Products ANPRM 01/05/82 (47 FR 522) NPRM 02/20/87 (52 FR 5412) Final Action 00/00/00

Cough/Cold (Anticholinergic) Products ANPRM 09/09/76 (41 FR 38312) NPRM 07/09/82 (47 FR 30002) Final Action 11/08/85 (50 FR 46582)

Cough/Cold (Antihistamine) Products ANPRM 09/09/76 (41 FR 38312) NPRM 01/15/85 (50 FR 2200) NPRM (Amendment) 08/24/87 (52 FR 31892)

Final Action 00/00/00 Cough/Cold (Antitussive) Products ANPRM 09/09/76 (41 FR 38312) NPRM 10/19/83 (48 FR 48576) Final Action 08/12/87 (52 FR 30042)

Cough/Cold (Bronchodilator) Products
ANPRM 09/09/76 (41 FR 38312)
NPRM 10/26/82 (47 FR 47520)
Final Action 10/02/86 (51 FR 35326)

Cough/Cold (Combination) Products ANPRM 09/09/76 (41 FR 38312) NPRM 08/25/88 (53 FR 30522) Final Action 00/00/00

Cough/Coid (Expectorant) Products ANPRM 09/09/76 (41 FR 38312) NPRM 07/09/82 (47 FR 30002) Final Action 04/00/89

Cough/Cold (Nasal Decongestant)
Products
ANPRM 09/09/76 (41 FR 38312)
NPRM 01/15/85 (50 FR 2220)

Final Action 04/00/89

Dandruff, Seborrheic Dermatitis and Psoriasis Control Products

ANPRM 12/03/82 (47 FR 54646)

NPRM 07/30/86 (51 FR 27346)

Final Action 00/00/00

Daytime Sedatives
ANPRM 12/08/75 (40 FR 57292)
NPRM 06/13/78 (43 FR 25544)
Final Action 06/22/79 (44 FR 36378)

Diaper Rash Products (To be merged w/other rulemkg) ANPRM 09/07/82 (47 FR 39406)

Digestive Aid Products
ANPRM 01/05/82 (47 FR 454)
NPRM 01/29/88 (53 FR 2706)
Final Action 00/00/00

Emetic Products ANPRM 03/21/75 (40 FR 12939) NPRM 09/05/78 (43 FR 39544)

Exocrine Pancreatic Insufficiency Products ANPRM 12/21/79 (44 FR 75666) NPRM 11/08/85 (50 FR 46594) Final Action 00/00/00

External Anaigesic Products

ANPRM 12/04/79 (44 FR 69768)

NPRM 02/08/83 (48 FR 5852)

NPRM (Amendment) 07/30/86 (51 FR 27360)

NPRM (Amendment) 08/25/88 (53 FR

32592) Final Action 00/00/00

Fever Blister Products (Internal) ANPRM 01/05/82 (47 FR 502) NPRM 06/17/85 (50 FR 25156) Final Action 00/00/00

Fvr Blister/Coid Sore Prdts (Ext.) (To be merged w/other rulemkg) ANPRM 09/07/82 (47 FR 39436)

Hair Grower and Hair Loss Prevention
Products

ANPRM 11/27/80 (45 FR 73955) NPRM 01/15/85 (50 FR 2190) Final Action 00/00/00

Hormone (Topical) Products ANPRM 01/05/82 (47 FR 430) NPRM 04/00/89

Hypo/Hyperphosphatemia Products ANPRM 12/09/80 (45 FR 81154) NPRM 01/15/85 (50 FR 2160) Final Action 00/00/00

Ingrown Toenail Relief Products ANPRM 10/17/80 (45 FR 69128) NPRM 09/03/82 (47 FR 39120) Final Action 00/00/00

Insect Bite & Sting (Relief) Prdts (To be merged w/other rulemkg) ANPRM 09/07/82 (47 FR 39412)

Insect Repellent Drug Products (Internal) ANPRM 01/05/82 (47 FR 424) NPRM 06/10/83 (48 FR 26986) Final Action 06/17/85 (50 FR 25170)

Internal Analgesic Products
ANPRM 07/08/77 (42 FR 35346)
NPRM 12/00/88

Internal Deodorant Products
ANPRM 01/05/82 (47 FR 512)
NPRM 06/17/85 (50 FR 25162)
Final Action 00/00/00

Laxative Products

ANPRM 03/21/75 (40 FR 12902)

NPRM 01/15/85 (50 FR 2124)

NPRM (Amendment) 10/01/86 (51 FR 35136)

Final Action 00/00/00

Leg Muscie Cramps (Nocturnal Relief)
Products
ANPRM 10/01/82 (47 FR 43562)
NPRM 11/08/85 (50 FR 46588)
Final Action 00/00/00

Male Genital Desensitizer Products ANPRM 09/07/82 (47 FR 39412) NPRM 10/02/85 (50 FR 40260) Final Action 00/00/00

Menstrual Products ANPRM 12/07/82 (47 FR 55075) NPRM 12/00/88

Mercuriai (Topical) Products (To be merged w/other rulemkg)
ANPRM 01/05/82 (47 FR 436)

Naiibiting/Thumbsucking Deterrent Products

ANPRM 10/17/80 (45 FR 69122) NPRM 09/03/82 (47 FR 39096) Final Action 00/00/00

Nighttime Sleep Ald Products ANPRM 12/08/75 (40 FR 57292) NPRM 06/13/78 (43 FR 25544) Final Action 10/00/88

Ophthalmic Products
ANPRM 05/06/80 (45 FR 30002)
NPRM 06/28/83 (48 FR 29788)
Final Action 03/04/88 (53 FR 7076)

Orai Discomfort (Relief) Products ANPRM 05/25/82 (47 FR 22712) NPRM 00/00/00

Oral Health Care Products

ANPRM 05/25/82 (47 FR 22760)

NPRM 01/27/88 (53 FR 2436)

Final Action 00/00/00

Orai Mucosal Injury Products (Merged w/Orai Health Care)
ANPRM 11/02/79 (44 FR 63270)
NPRM 07/26/83 (48 FR 33984)

Oral Wound Healing Products

ANPRM 11/02/79 (44 FR 63270)

NPRM 07/26/83 (48 FR 33984)

Final Action 07/18/86 (51 FR 26112)

Otic Products (Earwax) NPRM 07/09/82 (47 FR 30012) Final Action 08/08/86 (51 FR 28656)

Otic Products (Swimmers Ear) NPRM 07/30/86 (51 FR 27366) Final Action 00/00/00

Overinduigence Remedies
ANPRM 10/01/82 (47 FR 43540)
NPRM 00/00/00
Overinduigence Remedies/Prevention of

Inebriation ANPRM 10/01/82 (47 FR 43540) Final Action 07/19/83 (48 FR 32872)

Pediculicide Products
ANPRM 06/29/82 (47 FR 28312)
NPRM 12/00/88

Polson ivy/Oak/Sumac Prevention (To be merged w/other rulemkg) ANPRM 09/07/82 (47 FR 39412)

Poison Treatment Products NPRM 01/15/85 (50 FR 2244) Final Action 00/00/00

Skin Bleaching Products
ANPRM 11/03/78 (43 FR 51546)
NPRM 09/03/82 (47 FR 39108)
Final Action 02/00/89

Skin Protectant Products
ANPRM 08/04/78 (43 FR 34628)
NPRM 02/15/83 (48 FR 6820)
Final Action 00/00/00

# Smoking Deterrent Products ANPRM 01/05/82 (47 FR 490) NPRM 07/03/85 (50 FR 27552) Final Action 00/00/00

Stimulant Products
ANPRM 12/08/75 (40 FR 57292)
NPRM 06/13/78 (43 FR 25544)
Final Action 02/29/88 (53 FR 6100)

Stomach Acidifier Products

ANPRM 10/19/79 (44 FR 60316)

NPRM 01/15/85 (50 FR 2184)

Final Action 08/17/88 (53 FR 31270)

Sunscreen Products
ANPRM 08/25/78 (43 FR 38206)
NPRM 00/00/00

Sweet Spirits of Nitre ANPRM 02/22/80 (45 FR 11846) Final Action 06/27/80 (45 FR 43400)

Vaginai Contraceptive Products ANPRM 12/12/80 (45 FR 82014) NPRM 00/00/00

Vaginal Drug Products ANPRM 10/13/83 (48 FR 46694) NPRM 00/00/00

Vitamin/Minerai Products
ANPRM 03/16/79 (44 FR 16126)
Withdrawai 11/27/81 (46 FR 57914)

Wart Remover Products
ANPRM 10/03/80 (45 FR 65609)
NPRM 09/03/82 (47 FR 39102)
NPRM (Amendment) 03/27/87 (52 FR 9992)

Final Action 00/00/00
Weight Control Products
ANPRM 02/26/82 (47 FR 8466)
NPRM 00/00/00

#### Small Entities Affected: None

#### Government Levels Affected: None

Additional Information: ABSTRACT CONT: for "Antimicrobial Products." NPRM for "Alcohol (Topical) Products" to be included in revised NPRM for "Antimicrobial Products." The NPRM for "Antimicrobial Products" is being revised because it is being updated and split into two sections: first aid products and health care products.

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

Agency Contact: William E. Gilbertson, Director, Division of OTC Drug Evaluation, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (HFD-210), 5600 Fishers Lane, Rockville, MD 20857, 301 295-8000

RIN: 0905-AA06

#### 722. AVAILABILITY OF BULK NEW ANIMAL DRUG SUBSTANCES FOR USE BY LICENSED VETERINARIANS

Significance: Regulatory Program

Legal Authority: 21 USC 360b Federal Food, Drug, and Cosmetic Act

CFR Citation: 21 CFR 514.1

Legal Deadline: None

Abstract: This proposed rule would permit veterinarians to obtain bulk new animal drug substances for compounding products for use in their own practice. A number of veterinarians have requested that the regulations be revised in order that bulk new animal drug substances may be legally obtained by them for use in their practices. Seventeen comments were received in response to the proposed rule, five from pharmaceutical companies, six from trade/professional associations, three from consultants, two from veterinary practitioners, and one from a Federal agency. Only three of those commenting supported the proposal. The remaining 14 comments opposed the proposal. The agency is reevaluating the proposal in light of the comments received. In December 1987, a district court held that veterinarians may obtain and compound bulk drugs for use in their practices without approval by FDA. The Federal government has appealed this decision which has been stayed by the court of appeals.

#### Timetable:

Action	Date		FR	Cite
NPRM	07/01/85	50	FR	27016
NPRM Comment Period End	09/30/85	50	FR	27016
Final Action	11/00/88			

#### Small Entities Affected: None

#### **Government Levels Affected: None**

Agency Contact: Donald A. Gable, Director, Division of Therapeutic Drugs for Food Animals, Department of Health and Human Services, Food and Drug Administration, Center for Veterinary Medicine (HFV-130), 5600 Fishers Lane, Rockville, MD 20857, 301 443-1414

RIN: 0905-AB01

## 723. PROVISIONALLY LISTED COLOR ADDITIVES

Significance: Agency Priority

Legal Authority: 21 USC 371 Federal Food, Drug, and Cosmetic Act; 21 USC

376(b) to 376(d) Federal Food, Drug, and Cosmetic Act; 21 USC 376 note Federal Food, Drug, and Cosmetic Act

**CFR Citation:** 21 CFR 81.1; 21 CFR 81.27

Legal Deadline: None

Abstract: Substantial progress has been made in reducing the number of provisionally listed additives and only 1 color additive remains on the provisional list. The agency is presently reviewing petitions to list the color additive permanently. Because FD&C Red No. 3 animal feeding studies have shown a treatment-related increased incidence of tumor bearing animals, the agency considered the use of quantitative risk assessment as a basis for assessing the safety of this color additive in external drugs and cosmetics. As a preliminary step in its consideration of this approach, the agency formed a scientific peer review panel of government scientists to consider whether it is possible to quantify the risk presented by the use of FD&C Red No. 3 based on the scientific data available to the agency and, if so, what level of risk is presented by the use of this color additive. The agency has received the report from the scientific review panel in which the panel estimates the risk of cancer from use of FD&C Red No. 3 in external drugs and cosmetics. Furthermore, for FD&C Red No. 3 the industry has postulated a secondary mechanism for the observed tumorigenic response in the animal feeding (cont)

#### Timetable:

#### D&C Red No. 33

Final Action 08/30/88 (53 FR 33110)

#### D&C Red No. 36

Final Action 08/02/88 (53 FR 29024)

#### FD&C Red No. 3

Final Action 00/00/00

### FD&C Red No. 3; Extension of Provisional Listing

NPRM 08/30/88 (53 FR 33147)

### FD&C Red No. 3; Request for Data for Specific Uses

Notice 11/19/87 (52 FR 44485) FD&C Red No. 3; Request for Data for Specific Uses; Postponement Notice 12/21/87 (52 FR 48326)

#### Small Entitles Affected: None

#### **Government Levels Affected: None**

Additional Information: ABSTRACT CONT: study. The agency asked a second scientific peer review panel of government scientists to consider data relating to the issue of a possible secondary mechanism and implications for risk assessment. The panel was also asked to determine what, if any, further studies or analyses may be necessary to resolve the issues. The panel submitted its report to the Commissioner in July 1987. The report was made available to the public in August 1987.

Agency Contact: Donna A. Dennis, Supervisor, Division of Food and Color Additives, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition (HFF-330), 200 C Street, SW, Washington, DC 20204, 202 426-9463

RIN: 0905-AB60

# 724. FOOD LABELING INFORMATION REGARDING GOOD NUTRITION AND HEALTH

Significance: Regulatory Program

Legal Authority: 15 USC 1453 Fair Packaging and Labeling Act; 15 USC 1455 Fair Packaging and Labeling Act; 21 USC 321 Federal Food, Drug, and Cosmetic Act; 21 USC 343 Federal Food, Drug, and Cosmetic Act; 21 USC 348 Federal Food, Drug, and Cosmetic Act; 21 USC 371 Federal Food, Drug, and Cosmetic Act

CFR Citation: 21 CFR 101 Legal Deadline: None

Abstract: In the FEDERAL REGISTER of August 4, 1987, the Food and Drug Administration (FDA) discussed an initiative concerning health-related claims or information on food labeling and the criteria it will apply in evaluating the propriety of such labeling. Consistent with this initiative, FDA proposed to amend certain regulations on food labeling to codify and to clarify its policy on the appropriate use of health-related messages. The agency also announced its intention to form a Public Health Service (PHS) committee that will attempt to develop "health messages" appropriate for use on food labeling.

FDA recognizes that this initiative represents a substantive change in past agency policy, and because of the complexity of the matter and the broad public interest, wishes to proceed cautiously and deliberately in its regulatory approach.

Pending this rulemaking proceeding, the agency will employ the criteria discussed in the preamble to the notice in evaluating the propriety of bringing enforcement action against products bearing health messages on food labeling.

#### Timetable:

Action	Date	FR	Cite
NPRM	08/04/87	52 FR	28843
NPRM - Comment Period Ends	11/02/87	52 FR	28843
NPRM - Extension of Comment Period	11/02/87	52 FR	42003
NPRM - Correction of Extension of Comment Period	11/16/87	52 FR	43772
NPRM - Extension of Comment Period Ends	01/04/88	52 FR	43772
Final Action	10/00/88		

#### Small Entitles Affected: None

#### Government Levels Affected: None

Agency Contact: David G. Hattan, Chief, Regulatory Affairs Staff, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition (HFF-204), 200 C Street, SW, Washington, DC 20204, 202 245-3117

RIN: 0905-AB67

725. FOOD LABELING: DEFINITIONS OF CHOLESTEROL FREE, LOW CHOLESTEROL, AND REDUCED CHOLESTEROL

Significance: Regulatory Program

Legal Authority: 21 USC 343 Federal Food, Drug, and Cosmetic Act; 21 USC 321(n) Federal Food, Drug, and Cosmetic Act; 21 USC 371 Federal Food, Drug, and Cosmetic Act

CFR Citation: 21 CFR 101.9; 21 CFR 101.25

Legal Deadline: None

Abstract: In the FEDERAL REGISTER of November 25, 1986, the agency published a proposed rule that would provide a mechanism to allow relevant, truthful, and nonmisleading claims about cholesterol and fatty acid on product labeling for consumers. This proposed rule resulted from the medical

and consumer interest in the association between dietary fat and cholesterol and the occurrence of coronary heart disease, the leading cause of death and disability in the United States today. The proposed rule would allow industry voluntarily to provide consumers with cholesterol and fatty acid information currently prohibited by regulations by permitting the use of meaningful descriptors of the cholesterol content of foods as established by regulation (e.g., "cholesterol free," "low cholesterol," and "reduced cholesterol"). Additionally, the proposal would allow the use of comparative claims (e.g., 50 percent less cholesterol than our original product), provided quantitative cholesterol content information is supplied. Public comments submitted in response to the proposed rule are being reviewed.

#### Timetable:

Action	Date		FR	Cite
NPRM	11/25/86	51	FR	42584
NPRM Extension of Comment Period	01/23/87	52	FR	2558
NPRM Comment Period End	03/27/87	52	FR	2558
Final Action	03/00/89			

#### Small Entities Affected: None

#### **Government Levels Affected: None**

Agency Contact: David G. Hattan, Chief, Regulatory Affairs Staff, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition (HFF-204), 200 C Street, SW, Washington, DC 20204, 202 245-3117

RIN: 0905-AB68

#### 726. METHYLENE CHLORIDE

Significance: Agency Priority

Legal Authority: 21 USC 361 Federal Food, Drug, and Cosmetic Act; 21 USC 362 Federal Food, Drug, and Cosmetic Act; 21 USC 371(a) Federal Food, Drug, and Cosmetic Act

CFR Citation: 21 CFR 700.19

Legal Deadline: None

Abstract: Methylene chloride is used as a solvent in aerosol cosmetic products (hair sprays). Recent carcinogenicity bioassay studies, however, have shown that methylene chloride is an animal carcinogen. These studies indicate that the continued use of methylene chloride, in functional amounts, in such cosmetic products may pose a significant risk to the public health, especially in specific segments of the population that are continually exposed to aerosol cosmetics containing methylene chloride. The agency has been informed of voluntary efforts by the cosmetic industry to replace methylene chloride but believes that prohibiting its use in cosmetics is the only approach that will assure that the public health will be fully safeguarded from all such products, both foreign and domestic. FDA announced in the December 18, 1985, NPRM its conclusion that methylene chloride used as a solvent to extract caffeine from green coffee beans was not a danger under the Delanev Clause to the Food Additives Amendment because the risk was so miniscule as to be considered de minimis. FDA is reconsidering this conclusion in light of a recent appeals court (cont)

#### Timetable:

imetable.				
Action	Date	F	R	Cite
NPRM	12/18/85	50 F	R	51551
NPRM - Comment Period Ends	02/18/86	50 F	R	51551
NPRM - Comment Period Extended	02/24/86	51 F	R	6494
NPRM - Extended Comment Period Ends	04/04/86	51 F	R	6494
NPRM - Comment Period Reopened	12/05/86	51 F	R	43935
NPRM - Reopened Comment Period Ends	01/05/87	51 F	R	43935
Final Action	11/00/88			

Small Entities Affected: None

Government Levels Affected: None

Additional Information: ABSTRACT CONT: decision that struck down a similar interpretation of the color additive Delaney Clause.

Agency Contact: Terry C. Troxell, Division of Regulatory Guidance, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition (HFF-312), 200 C Street, SW, Washington, DC 20204, 202 485-0229

RIN: 0905-AC00

#### 727. INFANT FORMULA ACT

Significance: Regulatory Program

Legal Authority: 21 USC 371(a) Federal Food, Drug, and Cosmetic Act; PL 99-570 Infant Formula Act of 1986

CFR Citation: 21 CFR 7; 21 CFR 106

Legal Deadline: None

Abstract: The agency is preparing two proposals and one final rule which will implement the Infant Formula Act of 1986. The final rule will amend FDA's Infant Formula Recall regulations. These amended regulations will mandate the recall of infant formulas that are in violation of the Act and which have been determined by the Secretary to pose a health hazard. The first proposal will establish current good manufacturing practice regulations and strengthen the agency's existing quality control procedures for infant formulas. The second proposal will establish infant formula microbiological testing, consumer complaints, and record retention requirements.

#### Timetable:

Infant Form Cons Comp, Micro Test & Recd Retention Reg NPRM 12/00/88

Infant Formula Current Good Practices; Qual Control Proc NPRM 00/00/00

**Infant Formula Recall** 

NPRM 08/14/87 (52 FR 30171) Comment Period Ends 10/13/87 (52 FR 30171) Final Action 10/00/88

Small Entities Affected: None

Government Levels Affected: None

Additional Information: AGENCY CONTACT CONT: For Information Concerning Infant Formula, Microbiological Testing, Consumer Complaints, Record Retention Requirements, Good Manufacturing Practices, and Quality Control Procedures Contact: Nicholas Duy, Consumer Safety Officer, Center for Food Safety and Applied Nutrition (HFF-204), Department of Health and Human Services, Food and Drug Administration, 200 C Street, SW, Washington, DC 20204, (202) 245-3117

Agency Contact: Curtis Coker, Consumer Safety Officer, (For Info Concerning Infant Formula Recalls). Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition (HFF-314), 200 C Street, SW, Washington, DC 20204, 202 485-0024

RIN: 0905-AC46

728. COMMON OR USUAL NAME FOR DILUTED FRUIT OR VEGETABLE JUICE BEVERAGES OTHER THAN DILUTED ORANGE JUICE BEVERAGES

Significance: Regulatory Program

Legal Authority: 21 USC 321(n) Federal Food, Drug and Cosmetic Act; 21 USC 343 Federal Food, Drug and Cosmetic Act; 21 USC 371(a) Federal Food, and Cosmetic Act

CFR Citation: 21 CFR 102.33

Legal Deadline: None

Abstract: In 1980, FDA published a regulation (21 CFR 102.33) to require the declaration of the percent of juice contained in all diluted juice beverages. This regulation was published to extend the percent juice declaration required for diluted orange juice beverages (21 CFR 102.32) to all other diluted juice beverages. These two regulations were developed to provide consumers with information as to the various amounts of juice in the diluted juice beverages offered for sale. The regulation regarding percentage juice declaration for diluted orange juice beverages had been in effect for several years and functioning well before the regulation addressing all other diluted juice beverages was published. With publication of 21 CFR 102.33, a controversy developed over the applicability of the regulation to diluted cranberry juice beverages. The controversy centered around the fact that cranberry juice is a high acid juice and is not normally consumed as a single strength juice. Due to this unresolved controversy, 21 CFR 102.33 has not been made effective. In the FEDERAL REGISTER of July 16, 1987 (52 FR 26690), the agency proposed to revoke the common or usual (cont)

#### Timetable:

Action	Date		FR	Cite
NPRM - To Revoke Regulation	07/16/87	52	FR	26690

Action	Date		FR	Cite
NPRM - Comment Period Ends	09/14/87	52	FR	26690
NPRM - Extension of Comment Period	09/25/87	52	FR	36046
NPRM - Extended Comment Period Ends	12/13/87	52	FR	36046
NPRM - Comment Period Reopened	01/22/88	53	FR	1795
NPRM - Reopened Comment Period Ends	01/27/88	53	FR	1795
Final Action	10/00/88			

Small Entities Affected: None

Government Levels Affected: None

Additional Information: ABSTRACT CONT: name regulation (21 CFR 102.33) for diluted fruit or vegetable juice beverages other than diluted orange juice beverages. The revocation of this regulation will allow voluntary percentage labeling of these diluted juice beverages at the discretion of the manufacturer and according to the demands of the marketplace. Diluted orange juice beverages would continue to be subject to the percentage labeling requirement that has been in effect for diluted orange juice beverages since

1973. This proposed action also withdraws the proposed rule published in the FEDERAL REGISTER of June 1, 1984 (49 FR 22831), which, among other things, exempted cranberry juice products from percentage ingredient labeling requirements.

Agency Contact: Evelyn Osman, Division of Regulatory Guidance, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition (HFF-312), 200 C Street, SW, Washington, DC 20204, 202 485-0229

729. TAMPER-RESISTANT
PACKAGING REQUIREMENTS FOR
OVER-THE-COUNTER (OTC) DRUGS

Significance: Regulatory Program

**Legal Authority:** 21 USC 321(n); 21 USC 351; 21 USC 352; 21 USC 355; 21 USC 356; 21 USC 357; 21 USC 371

CFR Citation: 21 CFR 211.132

Legal Deadline: None

RIN: 0905-AC48

Abstract: The agency is considering amending the current tamper-resistant packaging regulations and updating information it previously made available on tamper-resistant packaging technologies. Under this approach, the agency is considering revisions to require special precautions against

tampering for two-piece, hard, gelatin capsules, the dosage form that has been the subject of fatal tamperings.

The agency is also considering other measures to provide additional guidance to manufacturers regarding tamper-resistant packaging technology and public education to improve consumer's alertness to tampering.

Any action taken would reflect the Administration policy that the consumer is the key to tamper resistance, and the ultimate goal of tamper-resistant packaging is that it should offer a signal to consumers about tampering.

#### Timetable:

Action	Date		FR	Cite
NPRM	05/05/88	53	FR	16150
NPRM Comment Period End	07/05/88	53	FR	16150
Final Action	10/00/88			

Small Entities Affected: Undetermined

Government Levels Affected: None

Agency Contact: Diane Goyette, Consumer Safety Officer, Division of Regulatory Affairs, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (HFD-362), 5600 Fishers Lane, Rockville, MD 20857, 301 295-8046

RIN: 0905-AC70

# DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) Public Health Service (PHS)—Food and Drug Administration (FDA)

**Completed Actions** 

730. PROPOSED USER CHARGE; NEW DRUG APPLICATIONS, ABBREVIATED NEW DRUG APPLICATIONS, NEW DEVICE APPLICATIONS, AND ANTIBIOTIC APPLICATIONS REVIEW

Significance: Agency Priority CFR Citation: 21 CFR 314

Completed:

Reason	Date	FR Cite
Withdrawn Withdrawn pending Congressional action.	08/31/88	

**Small Entities Affected: None** 

Government Levels Affected: None

Agency Contact: Marilyn Watson 301 295-8038

RIN: 0905-AB56

731. PATENT TERM RESTORATION FOR CERTAIN REGULATED PRODUCTS (TITLE II OF "DRUG PRICE COMPETITION AND PATENT TERM RESTORATION ACT OF 1984")

Significance: Regulatory Program

CFR Citation: 21 CFR 60

Completed:

Reason	Date		FR	Cite	
Final Action	03/07/88	53	FR	7298	
Final Action	05/06/88	53	FR	7298	

**Small Entities Affected: None** 

Government Levels Affected: None Agency Contact: Philip L. Chao 301

RIN: 0905-AB65

443-1382

732. MENSTRUAL TAMPONS; PROPOSED USER LABELING

Significance: Regulatory Program CFR Citation: 21 CFR 801.430

Completed:

Reason	Date	FR	Cite
RiN has been changed to 0905-AC54	08/26/88		

Smail Entitles Affected: Undetermined Government Levels Affected: None

#### HHS-PHS-FDA

**Completed Actions** 

Agency Contact: Les Weinstein 301 443-4874

RIN: 0905-AC58

### DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

**Proposed Rule Stage** 

Public Health Service (PHS)—Health Resources and Services Administration (HRSA)

733. HEALTH EDUCATION
ASSISTANCE LOAN (HEAL)
PROGRAM: IMPLEMENTATION OF
PUB. L. 99-129

**Legal Authority:** 42 USC 216; 42 USC 294 to 294l

CFR Citation: 42 CFR 60

Legal Deadline: None

Abstract: This rule proposes to implement provisions of the Health Professions Training Assistance Act of 1985 (Pub. L. 99-129) which require public comment before being published as final regulations.

#### Timetable:

Action	Date	FR	Cite
NPRM	11/30/88		

Small Entitles Affected: None

**Government Levels Affected:** None

Agency Contact: Ms. Peggy Washburn, Chief, Program Devel. Br., DSA, BHPr, Department of Health and Human Services, Health Resources and Services Administration, Room 8-48, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857, 301 443-4540

RIN: 0905-AC28

## 734. POST-BACCALAUREATE FACULTY FELLOWSHIP PROGRAM

**Legal Authority: 42 USC 216; 42 USC 297-2** 

CFR Citation: 42 CFR 57

Legal Deadline: None

Abstract: These proposed regulations would implement section 830 (b) of the Public Health Service Act relating to post-baccalaureate fellowships for faculty to conform with the Nurse Education Amendments of 1985 (Pub. L. 99-92).

#### Timetable:

Action	Date	FR	Cite
NPRM	11/30/88		

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Ms. Jo Eleanor Elliott, R.N., M.A., Director, Division of Nursing, BHPr, Department of Health and Human Services, Health Resources and Services Administration, Room 5C-26, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857, 301 443-5786

RIN: 0905-AC34

735. GRANTS FOR COMMUNITY
HEALTH SERVICES: CRITERIA AND
PROCEDURE FOR DETERMINING
MEDICALLY UNDERSERVED
POPULATIONS (MUP)

Legal Authority: PL 99-280, Sec 2; 42 USC 254c(b)

CFR Citation: 42 CFR 51c

Legal Deadline: None

Abstract: Section 330(b) of the Public Health Service Act was amended by Section 2 of the Health Services Amendments Act of 1986 (P.L. 99-280). The amendment requires the Secretary to publish, in regulation, criteria for the designation of areas or population groups with shortages of personnel health services. These designated areas are eligible for the award of grants for planning and operating Community Health Centers. The amendment requires that the Secretary consult with the Chief Executive Officer of a State and local officials in publishing MUP designation criteria and in designating or dedesignating MUP. The amendment also requires the Secretary to consult with State organizations representing a majority of Community Health Centers in the State.

#### Timetable:

Action	Date	FR	Cite
NPRM	10/00/88		

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: James P. Purvis, Director, Office of Program and Policy, Development, Department of Health and Human Services, Health Resources and Services Administration, 5600 Fishers Lane, Room 7-15, Rockville, MD 20857, 301 443-1034

RIN: 0905-AC35

## 736. AREA HEALTH EDUCATION CENTER (AHEC) PROGRAM

Legal Authority: 42 USC 216; 42 USC 295g-l

CFR Citation: 42 CFR 57

Legal Deadline: None

Abstract: This NPRM proposes to amend the existing regulations governing the Area Health Education Center (AHEC) Program, under section 781 of the Public Health Service Act, to incorporate provisions that would: 1) limit involvement by the Federal Government in the support of any new project to a maximum of 5 years; 2) require an applicant to submit a plan describing how the center will continue operations after a maximum of 5 years of support by the Federal Government; and 3) add an evaluation criteria to include the extent to which minorities or low-income individuals reside in the area served by the Center.

#### Timetable:

I lilietable.			
Action	Date	FR	Cite
NPRM	03/31/89		

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Donald L. Weaver, M.D., Director, Division of Medicine, BHPr, Department of Health and Human Services, Health Resources and Services Administration, Room 4C-25, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857, 301 443-6190

RIN: 0905-AC67

# 737. DESIGNATION OF MENTAL HEALTH MANPOWER SHORTAGE

Legal Authority: 42 USC 216; 42 USC 254e

CFR Citation: 42 CFR 5 Legal Deadline: None

#### HHS-PHS-HRSA

#### **Proposed Rule Stage**

Abstract: This notice proposes an amendment to the existing regulations governing the Designation of Health Manpower Shortage Areas authorized by section 332 of the Public Health Service Act, which would replace the current criteria for designations of areas having shortages of psychiatrists with criteria for mental health manpower shortage areas to include not only psychiatrists but also other core mental health professionals (clinical psychologists, psychiatric social workers and psychiatric nurses) in a geographic area.

#### Timetable:

Action	Date	FR Cite
NPRM	12/00/88	

#### Small Entitles Affected: None

#### Government Levels Affected: None

Agency Contact: Richard C. Lee, Chief, Shortage Analysis Staff, BHCDA, Department of Health and Human Services, Health Resources and Services Administration, Room 8-57, Parklawn Building, Rockville, MD, 20857, 301 443-6932

RIN: 0905-AC68

# 738. GRANTS FOR FACULTY TRAINING PROJECTS IN GERIATRIC MEDICINE AND DENTISTRY

Legal Authority: 42 USC 216; 42 USC 295g-8

CFR Citation: 42 CFR 57 Legal Deadline: None

Abstract: These proposed rules would govern grants made to schools of medicine, schools of osteopathy, teaching hospitals and graduate medical education programs for the purpose of providing support, including traineeships and fellowships, for geriatric medicine training projects to train physicians and dentists who plan to teach geriatric medicine or geriatric dentistry, in accordance with PL 100-177, the Public Health Amendments of 1987.

#### Timetable:

Action	Date	FR Cite
NPRM	10/00/88	

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Donald L. Weaver, M.D., Director, L'vision of Medicine, BHPr, Departmer of Health and Human Services, Public Health Service, Room 4c-25 Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857, 301 443-6190

RIN: 0905-AC71

# 739. ● HEALTH EDUCATION ASSISTANCE LOAN (HEAL) PROGRAM: BANKRUPTCY REVISIONS

**Legal Authority:** 42 USC 216; 42 USC 294 to 2941

CFR Citation: 42 CFR 60 Legal Deadline: None

Abstract: This NPRM would amend existing regulations governing the Health Education Assistance Loan (HEAL) Program, as authorized by sections 727-739 of the Public Health Service Act, to include revised procedures for handling HEAL bankruptcies.

#### Timetable:

Action	Date	FR	Cite
NPRM	03/31/89		

Small Entitles Affected: None

**Government Levels Affected: None** 

Agency Contact: Peggy Washburn, Chief, Program Development Br., DSA, BHPr, Department of Health and Human Services, Health Resources and Services Administration, Room 8-48 Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, 301 443-4540

RIN: 0905-AC75

#### 740. ● NURSING STUDENT LOAN (NSL) PROGRAM: CASH MANAGEMENT

Legal Authority: 42 USC 216; 42 USC 297a to 297h

CFR Citation: 42 CFR 57

Legal Deadline: None

Abstract: This NPRM would revise the existing regulations governing the Nursing Student Loan (NSL) Program to improve the cash management practices of schools participating in the program. The revisions address recommendations made by the General Accounting Office in its report on debts owed by health professionals, including nurses, and the Office of the Inspector General as a result of several major cash management audits.

#### Timetable:

I III CUDIC.				
Action	Date	FR	Cite	
NPRM	11/30/88			

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Peggy Washburn, Chief, Program Development Br., DSA, BHPr, Department of Health and Human Services, Health Resources and Services Administration, Room 8-48, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, 301 443-4540

RIN: 0905-AC76

#### 741. ● CENTERS FOR EXCELLENCE

Legal Authority: 42 USC 295g-8a CFR Citation: 42 CFR 57

Legal Deadline: None

Abstract: This NPRM proposes to establish regulations for Grants for Centers for Excellence, authorized by section 788A of the Public Health Service Act, to make grants to health professions schools to assist such schools in supporting programs of excellence in health professions education for minority individuals.

#### Timetable:

Action	Date	Cite
NPRM	10/00/88	

Small Entitles Affected: None

Government Levels Affected: None

Agency Contact: Clay E. Simpson, Jr.,Ph.D., Director, Division of Disadvantaged, Assistance, BHPr, Department of Health and Human Services, Health Resources and Services Administration, Room 8A-09, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, 301 443-2100

RIN: 0905-AC77

#### 742. ● HEALTH PROFESSIONS STUDENT LOAN (HPSL) PROGRAM: CASH MANAGEMENT

**Legal Authority:** 42 USC 216; 42 USC 294m to 294q

CFR Citation: 42 CFR 57 Legal Deadline: None

Abstract: This NPRM would revise the existing regulations governing the Health Professions Student Loan program to improve the cash management practices of schools participating in the program. The

#### HHS-PHS-HRSA

**Proposed Rule Stage** 

revisions address recommendations made by the General Accounting Office in its report on debts owed by health professionals, and the Office of Inspector General as a result of several major cash management audits.

Timetable:			
Action	Date	FR Cite	
NPRM	11/30/88		
Constitution	- A44A		

Small Entities Affected: None Government Levels Affected: None Agency Contact: Peggy Washburn, Chief, Program Development Branch, DSA, BHPr, Department of Health and Human Services, Health Resources and Services Administration, Room 8-48, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, 301 443-4540 RIN: 0905–AC78

#### DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Final Rule Stage

Public Health Service (PHS)—Health Resources and Services Administration (HRSA)

743. GRANTS FOR RESIDENCY TRAINING AND FACULTY DEVELOPMENT IN GENERAL INTERNAL MEDICINE AND/OR GENERAL PEDIATRICS

**Legal Authority:** 42 USC 216; 42 USC 295g-4

CFR Citation: 42 CFR 57 Legal Deadline: None

Abstract: These regulations propose to amend the existing regulations for residency training in general internal medicine and general pediatrics and to implement section 784 (a)(3) and (4) to plan, develop, and operate a program and provide financial assistance to physicians who plan to teach in general internal medicine and general pediatrics.

#### Timetable:

Action	Date	FR Cite
NPRM	05/03/88	53 FR 15710
NPRM Comment Period End	07/05/88	
Final Action	12/30/88	

Small Entities Affected: None

**Government Levels Affected: None** 

Agency Contact: Donald L. Weaver, M.D., Director, Division of Medicine, BHPr, Department of Health and Human Services, Health Resources and Services Administration. Public Health Service, 5600 Fishers Lane, Room 4C-25, Rockville, MD 20857, 301 443-6190

RIN: 0905-AB50

744. GRANTS FOR NURSE PRACTITIONER AND NURSE MIDWIFERY TRAINEESHIP PROGRAMS

Legal Authority: 42 USC 216; 42 USC 296m

CFR Citation: 42 CFR 57 Legal Deadline: None Abstract: These proposed regulations would implement the provisions of the Nurse Education Amendments of 1985 (Pub. L. 99-92) and add debt management provisions of the Debt Collection Act of 1982 (Pub. L. 97-365).

#### Timetable:

Action	Date	FR Cite	•
NPRM		53 FR 161	58
NPRM Comment Period End	07/05/88		
Final Action	12/30/88		

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Jo Eleanor Elliott, R.N., M.A., Director, Division of Nursing, BHPr, Department of Health and Human Services, Health Resources and Services Administration, Room 5C-26, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857, 301 443-5786

RIN: 0905-AC30

745. NURSING STUDENT LOAN (NSL) PROGRAM: IMPLEMENTATION OF THE LAW (PUB. L. 99-92)

**Legal Authority:** 42 USC 216; 42 USC 297a to 297h

CFR Citation: 42 CFR 57

Legal Deadline: None

Abstract: These regulations propose to implement provisions of the Nurse Education Amendments of 1985 (Pub. L. 99-92) which require public comment before being published in final regulations.

#### Timetable:

Action	Date		FR	Cite
NPRM	06/05/87	52	FR	21486
NPRM Comment Period End	07/20/87			
Final Action	10/00/88			
Small Entities	Affected: N	Jon	e	

**Government Levels Affected: None** 

Agency Contact: Ms. Peggy Washburn, Chief, Program Devel. Br., DSA, BHPr, Department of Health and Human Services, Public Health Service, Room 8-48, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857, 301 443-4540

RIN: 0905-AC31

746. HEALTH PROFESSIONS STUDENT LOAN (HPSL) PROGRAM: IMPLEMENTATION OF THE LAW (PUB. L. 99-129)

**Legal Authority:** 42 USC 216; 42 USC 294m to 294q

CFR Citation: 42 CFR 57 Legal Deadline: None

Abstract: These regulations propose to implement provisions of the Health Professions Training Assistance Act of 1985 (Pub. L. 99-129) which require public comment before they can be published in final regulations.

#### Timetable:

Action	Date		FR	Cite
NPRM	06/03/87	52	FR	20989
NPRM Comment Period End	07/20/87			
Final Action	10/00/88			

Small Entities Affected: None
Government Levels Affected: None

Agency Contact: Ms. Peggy Washburn, Chief, Program Devel. Br., DSA, BHPr, Department of Health and Human Services, Health Resources and Services Administration, Room 8-48,Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857, 301 443-4540

RIN: 0905-AC32

# 747. GRANTS FOR HEALTH PROFESSIONS PROJECTS IN GERIATRICS

Legal Authority: 42 USC 216; 42 USC

295g-8

CFR Citation: 42 CFR 57

Legal Deadline: None

Abstract: These proposed regulations would implement provisions for 788 (d) of the Public Health Service Act relating to geriatric education of the Health Professions Training Assistance Act of 1985 (Pub. L. 99-129).

#### Timetable:

Action	Date		FR	Cite
NPRM	05/06/88	53	FR	16293
NPRM Comment Period End	07/05/88			
Final Action	12/30/88			

Small Entities Affected: None

**Government Levels Affected:** None

Agency Contact: Thomas L. Louden, D.D.S., Director, Div. of Associated and Dental Health Professions, BHPr, Department of Health and Human Services, Health Resources and Services Administration, Room 8-101, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857, 301 443-6853

RIN: 0905-AC33

#### 748. HEALTH MANPOWER SHORTAGE AREA DESIGNATION CRITERIA FOR CORRECTIONAL FACILITIES

Legal Authority: 42 USC 216; 42 USC 254e

CFR Citation: 42 CFR 5

Legal Deadline: None

Abstract: This notice proposes an amendment to the existing regulations governing the criteria for Designation of Health Manpower Shortage Areas required by Section 332 of the P.H.S. Act. This amendment would revise the definition for the term "internees" used in the criteria for designating those Federal and State correctional institutions which have a shortage of primary medical care, dental care, or psychiatric manpower.

#### Timetable:

Action	Date		FR	Cite
NPRM	10/29/87	52	FR	41594
NPRM Comment Period End	12/28/87			
Final Action	10/00/88			

Small Entitles Affected: None

Government Levels Affected: None

Agency Contact: Richard C. Lee, Chief, Shortage Analysis Staff, BHCDA, Department of Health and Human Services, Public Health Service, Room 8-57, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, 301

RIN: 0905-AC50

749. IMPLEMENTATION OF HEALTH CARE QUALITY IMPROVEMENT ACT OF 1986 (TITLE IV, PUBLIC LAW 99-660)

Significance: Regulatory Program

Legal Authority: 42 USC 11136; 42 USC 11137

CFR Citation: 45 CFR 60 Legal Deadline: None

Abstract: This rule proposes to implement the Health Care Quality Improvement Act of 1986, Title IV of PL 99-660, specifically related to section 426 for the disclosure and correction of information and section 427(b) for confidentiality of information.

#### Timetable:

Action	Date		FR	Cite	
NPRM	03/21/88	53	FR	9260	
NPRM Comment Period End	05/20/88				
Final Action	12/30/88				

**Small Entities Affected: None** 

**Government Levels Affected: None** 

Agency Contact: J. Jarrett Clinton, M.D., Director, Bureau of Health Professions, Department of Health and Human Services, Public Health Service, Room 8-05, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, 301 443-5796

RIN: 0905-AC51

#### 750. NATIONAL HEALTH SERVICE CORPS, STATE LOAN REPAYMENT AND SPECIAL REPAYMENT PROGRAMS

Significance: Regulatory Program

Legal Authority: PL 100-177

**CFR Citation:** 42 CFR 62.21 to 62.27; 42 CFR 62.51 to 62.56; 42 CFR 62.71 to 62.76

Legal Deadline: Final, Statutory, May 28, 1988.

Abstract: The National Health Service Corps Amendments of 1987, PL 100-177 amends the Public Health Service Act adding a new section at 338B of the Act authorizing the Secretary to establish the NHSC Loan Repayment Program. PL 100-177 also amends the PHS Act by adding a new section 338H authorizing the Secretary to establish a program of matching grants to support state loan repayment programs similar to the Federal Loan Repayment Program. PL 100- 177 also establishes a new program which is not part of the PHS Act which provides a time limited opportunity for persons in default of their scholarship obligation as of November 1, 1987 to repay these obligations through service or through a combination of service and monetary payment. The publication of the regulations beyond the statutory date will not have any impact on the funding or implementation of the programs affected by these regulations.

#### Timetable:

Action	Date	FR Cite
Interim Final Rule	10/15/88	

Small Entities Affected: None

**Government Levels Affected: None** 

Agency Contact: James P. Purvis, Director, Office Of Program and Policy, Development, BHCDA, Department of Health and Human Services, Health Resources and Services Administration, 5600 Fishers Lane, Room 7-05, Rockville, MD 20857, 301 443-1034

RIN: 0905-AC65

# 751. HEALTH EDUCATION ASSISTANCE LOAN (HEAL): LITIGATION

Legal Authority: 42 USC 216; 42 USC 2941

CFR Citation: 42 CFR 60

Legal Deadline: None

Abstract: This NPRM would amend the HEAL regulations, 42 CFR Part 60, to clarify the litigation requirement for all lenders and holders and to clarify the applicability of various sections of the regulations.

#### Timetable:

Action	Date		FR	Cite
NPRM	07/25/88	53	FR	27950
NPRM Comment Period End	08/24/88			
Final Action	02/28/89			

#### HHS-PHS-HRSA

Final Rule Stage

Small Entitles Affected: None
Government Levels Affected: None

Agency Contact: Ms. Peggy Washburn, Chief, Program Development Branch, DSA, BHPr, Department of Health and Human Services, Health Resources and Services Administration, Room 8-48, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857, 301 443-4540

#### DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

**Completed Actions** 

Public Health Service (PHS)—Health Resources and Services Administration (HRSA)

## 752. GRANTS FOR NURSE ANESTHETIST TRAINEESHIPS

CFR Citation: 42 CFR 57

#### Completed:

Reason	Date		FR	Cite	
Final Action Final Action Effective	03/21/88 03/21/88	53	FR	9114	

#### Small Entitles Affected: None

**Government Levels Affected:** None

Agency Contact: Dr. Thomas P. Phillips 301 443-6333

RIN: 0905-AB33

#### 753. HEALTH PROFESSIONS STUDENT LOAN (HPSL) PROGRAM: DEFERMENT REVISIONS

Significance: Agency Priority

CFR Citation: 42 CFR 57 Completed:

Reason	Date		FR	Cite
Final Action Final Action Effective	02/29/88 02/29/88	53	FR	6090

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Ms. Peggy Washburn 301 443-4540

RIN: 0905-AC06

# 754. HEALTH EDUCATION ASSISTANCE LOAN (HEAL) PROGRAM: DEFERMENT REVISIONS

Significance: Agency Priority CFR Citation: 42 CFR 60

Completed:

Reason	Date		FR	Cite	
Final Action Final Action	02/29/88 02/29/88	53	FR	6094	

Small Entitles Affected: None

**Government Levels Affected: None** 

Agency Contact: Ms. Peggy Washburn 301 443-4540

RIN: 0905-AC07

## 755. NURSING SPECIAL PROJECT GRANTS

CFR Citation: 42 CFR 57

#### Completed:

Reason	Date	FR Cite
Final Action Final Action Effective	04/26/88 04/26/88	53 FR 14792

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Ms. Jo Eleanor Elliott, R.N., M.A. 301 443-5786

RIN: 0905-AC18

## 756. AREA HEALTH EDUCATION CENTERS (AHEC)

CFR Citation: 42 CFR 57

#### Completed:

Completed.				
Reason	Date	FR Cite		
Withdrawn AC 22-AHEC final will be merged with AC67- AHEC (NPRM)	08/01/88			

Small Entitles Affected: None

**Government Levels Affected: None** 

Agency Contact: Donald L. Weaver, M.D. 301 443-6190

RIN: 0905-AC22

# 757. GRANTS FOR CONSTRUCTION OF TEACHING FACILITIES, EDUCATIONAL IMPROVEMENTS, SCHOLARSHIPS, AND STUDENT LOANS

CFR Citation: 42 CFR 57

#### Completed:

Reason	Date		FR	Cite
Final Action	04/26/88	53	FR	14789
Final Action	04/26/88			

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Ms. Rosemary Havill 301 443-1530

RIN: 0905-AC66

# 758. ● REMOVAL OF OBSOLETE REGULATIONS ON HEMOPHILIA TREATMENT CENTERS AND GENETIC DISEASE TESTING AND COUNSELING PROGRAMS

Legal Authority: PL 97-35; 42 USC 702(a)

CFR Citation: 42 CFR 51d; 42 CFR 51f

Legal Deadline: None

Abstract: This rule removes obsolete regulations governing grants for hemophilia treatment centers and grants for genetic disease testing and counseling programs. These regulations have been replaced by unified regulations governing the maternal and child health project grant program including the hemophilia and genetic programs. This action will eliminate duplicative regulations applicable to the maternal and child health project grant program.

#### Timetable:

Action	Date		FR	Cite
Final Action Final Action Effective	07/25/88 07/25/88	53	FR	27859

Small Entities Affected: None

**Government Levels Affected: None** 

Agency Contact: Dr. Roger McClung, Chief, Legislation, Regulations and Planning, Branch, BMCHRD, Department of Health and Human Services, Public Health Service, Room 9A33, 5600 Fishers Lane, Rockville, Maryland 20857, 301 443-4273

RIN: 0905-AC82

## DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) Public Health Service (PHS)—National Institutes of Health (NIH)

**Prerule Stage** 

FR Cite

#### 759. MISCONDUCT IN SCIENCE

Significance: Regulatory Program

Legai Authority: 42 USC 241; 42 USC 289b

CFR Citation: 42 CFR 50 Legal Deadline: None

Abstract: Recipients of Public Health Service research and research training funds do not presently have sufficient guidance regarding their responsibility to investigate and report possible misconduct in PHS-funded research or research training. While many institutions have voluntarily established procedures for dealing with misconduct in science, they are not required to do so and in many recent instances the lack of defined procedures has delayed

or compromised awardees' investigations. Institutional policies regarding reports to funding agencies vary considerably. The proposed regulation will define the point at which funding agencies are notified and will require awardees to develop procedures for dealing with misconduct in science. Section 493 of the PHS Act requires that the HHS Secretary issue regulations.

#### Timetable:

Period End

Action	Date		FR	Cite
ANPRM	09/19/88	53	FR	36344
NPRM	09/19/88	53	FR	36347
ANPRM	11/18/88			

Bethesda, MD 20892, **301 496-5356** RIN: 0905-AB91

Action

		01.0
NPRM Comment Period End	11/18/88	
Final Action	06/00/89	
Small Entities A	Affected: No	one
Government Le	evels Affect	ted: None
Agency Contact Ph.D., Associate Extramural Affa Health and Hun Health Service,	e Director fo nirs, Depart nan Service	or ment of s, Public
Bldg. 1, Rm. 111	, 9000 Rock	

Date

# DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) Public Health Service (PHS)—National Institutes of Health (NIH)

760. CHANGES IN NIH PROGRAM REGULATIONS DUE TO P.L. 99-158,P.L. 99-499 AND TITLE X OF P.L.

**Legai Authority:** PL 99-158, Sec 2; PL 99-499, Sec 126; PL 99-499, Sec 209; PL 99-660, Title X

CFR Citation: 42 CFR 4; 42 CFR 52 to 52h; 42 CFR 59a; 42 CFR 64; 42 CFR 66

Legai Deadline: None

99-660

Abstract: The regulations of the National Institutes of Health will be revised to show changed section numbers in the PHS Act and reflect program changes under the Health Research Extension Act of 1985 (P.L. 99-158), the Superfund Amendments and Reauthorization Act of 1986 (P.L. 99-499), and the provisions of Title X of P.L. 99-660 concerning Alzheimer's Disease and Related Dementias Research.

#### Timetable:

Action	Date	 Cite
NPRM	00/00/00	

Small Entities Affected: Undetermined

Government Leveis Affected: Local, State, Federal

Agency Contact: Lowell D. Peart, NIH Regulations Officer, Department of Health and Human Services, National Institutes of Health, 9000 Rockville Pike, 31/3B07, Bethesda, MD 20892, 301 496-4606

RIN: 0905-AC02

#### 761. NATIONAL INSTITUTES OF HEALTH CENTER GRANTS 42 CFR PART 52A

Legai Authority: 42 USC 216; 42 USC 285a-3; 42 USC 285b-4; 42 USC 285c-5; 42 USC 285d-6; 42 USC 285e-2

CFR Citation: 42 CFR 52a

#### Legal Deadline: None

Abstract: The NIH Center Grants Regulations will be revised to incorporate changes necessitated by the Health Research Extension Act of 1985 (P.L. 99-158).

**Proposed Rule Stage** 

#### Timetable:

Action	Date	FR	Cite
NPRM	12/00/88		

Smail Entities Affected: None

#### **Government Leveis Affected: None**

Agency Contact: Lowell D. Peart, NIH Regulations Officer, Department of Health and Human Services, National Institutes of Health, 9000 Rockville Pike, 31/3B07, Bethesda, MD 20892, 301 496-4606

RIN: 0905-AC27

## DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) Public Health Service (PHS)—National Institutes of Health (NIH)

Final Rule Stage

762. NATIONAL LIBRARY OF MEDICINE PROGRAMS. REVISION OF GENERAL RULES FOR THE NATIONAL LIBRARY OF MEDICINE AND NATIONAL LIBRARY OF MEDICINE GRANTS

**Legal Authority:** 42 USC 216; 42 USC 286; 42 USC 286b-2; 42 USC 286b-3; 42 USC 286b-5; 42 USC 286b-6; 42 USC 284

**CFR Citation:** 42 CFR 4; 42 CFR 59a; 42 CFR 63; 42 CFR 64

Legal Deadline: None

**Abstract:** All of the regulations are being substantially clarified and reduced in size by eliminating out of date or otherwise available information.

The regulations at 42 CFR Part 4 pertain to the access of facilities and library collections. Those at 42 CFR Part 59a deal with NLM extramural programs. Part 59a is being amended to remove the requirement that photocopies of biomedical material be provided without charge to users. The regulations at 42 CFR Part 63 deal with both NIH and NLM traineeships. Part 63 is proposed to be revised to reflect authority in section 405, PHS Act. The regulations at 42 CFR Part 64 govern the training grants of NIH and NLM.

Action	Date		FR	Cite
NPRM	02/11/85	50	FR	05638
Final Action	12/00/88			

Small Entities Affected: None
Government Levels Affected: None

Agency Contact: Kenneth Carney, Executive Officer, Department of Health and Human Services, Public Health Service, National Library of Medicine, Bethesda, MD 20894, 301 496-6491

RIN: 0905-AA66

## DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) Health Care Financing Administration (HCFA)

**Proposed Rule Stage** 

763. ADMINISTRATIVE APPEALS
PROCESS FOR PROVIDER PAYMENT
DISPUTES INCLUDING AMENDING
COST REPORTS & REOPENING
INTERMEDIARY PAYMENT
DETERMINATIONS &
ADMINISTRATIVE REVIEW
DECISIONS

Legal Authority: 42 USC 1302; 42 USC 1395f(b); 42 USC 1395g; 42 USC 1395l; 42 USC 1395x(v); 42 USC 1395hh; 42 USC 1395rr; 42 USC 1395ww; 42 USC 1395xx; 42 USC 405; 42 USC 1395ii; 42 USC 1395o

**CFR Citation:** 42 CFR 405.453; 42 CFR 405.1833; 42 CFR 405.1885; 42 CFR 405.1887; 42 CFR 405.1803; 42 CFR 405.1811(a); 42 CFR 405.1813; 42 CFR 405.1837; 42 CFR 405.1841; 42 CFR 405.1863; 42 CFR 405.1877; 42 CFR 405.1869; 42 CFR 405.1869; 42 CFR 405.1869; 42 CFR 412.72(b)

Legal Deadline: None

Abstract: This proposal would clarify and establish rules governing the administrative appeals process for providing appeals of payment disputes including rules distinguishing between the amending of cost reports and the reopening of Medicare intermediary payment determinations and administrative review decisions. This proposal would provide guidance to intermediaries and the Provider Reimbursement Review Board concerning the circumstances under which those actions may be taken.

#### Timetable:

Action	Date	FR	Cite
NPRM	00/00/00		

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Paul Olenick, Division Director, Department of Health and Human Services, Health Care Financing Administration, Division of Medicare Eligibility Policy, Room 323 EHR, 6325 Security Blvd., Baltimore, MD 21207, 301 966-4472

RIN: 0938-AA33

#### 764. MEDICAID ELIGIBILITY

**Legal Authority:** 42 USC 1396a(a)(10); 42 USC 1302; 42 USC 1396a(f); 42 USC 1396a(a)(17); 42 USC 1396b(f)(1); 42 USC 1396d(a)

CFR Citation: 42 CFR 435; 42 CFR 436

Legal Deadline: None

Abstract: This regulation would conform the current regulations to changes with respect to Medicaid eligibility groups and coverage criteria made primarily by Pub.L. 97-248. Most of these changes affect the provisions of September 30, 1981 regulations concerning Medicaid eligibility for the optional categorically needy and the medically needy, published as a result of the Omnibus Budget Reconciliation Act of 1981. The regulations would also respond to public comments received on the September 30 regulations and make some administrative changes to

clarify policy and enhance the efficient operation of the Medicaid program (for example, clarification of policy on establishing the medically needy income level for one person).

#### Timetable:

Action	Date	Cite
NPRM	11/00/88	

Small Entities Affected: None

Government Levels Affected: Local, State

Agency Contact: Marinos Svolos, Division Director, Department of Health and Human Services, Health Care Financing Administration, Div of Medicaid Eligibility, Room 416, East High Rise Bldg, 6325 Security Blvd, Baltimore, MD 21207, 301 966-4451

RIN: 0938-AA58

#### 765. MMIS: DEFINITION OF "MECHANIZED CLAIMS PROCESSING AND INFORMATION RETRIEVAL SYSTEM"

**Legal Authority:** 42 USC 1302; 42 USC 1396b(a)(3); 42 USC 1396b(r)

**CFR Citation:** 42 CFR 433.111; 42 CFR 433.112; 42 CFR 433.113; 42 CFR 433.119; 42 CFR 433.120; 42 CFR 433.121; 42 CFR 433.122; 42 CFR 433.131

Legal Deadline: None

Abstract: This rule will change the definition of "mechanized claims processing and information retrieval systems" to clarify under what

circumstances we will pay Federal financial participation at a percentage higher than 50 percent for a Medicaid Management Information System.

#### Timetable:

Action	Date		FR	Cite
NPRM	08/11/88	53	FR	30317
NPRM Comment Period End	10/11/88	53	FR	30317
Final Action	00/00/00			

Small Entities Affected: None

**Government Levels Affected: State** 

Agency Contact: Guy Harriman, Director, Division of Payment Systems, Department of Health and Human Services, Health Care Financing Administration, Division of Medicaid Procedures, 233 EHR, 6305 Security Boulevard, Baltimore, MD 21207, 301 966-3292

RIN: 0938-AA63

## 766. DEDUCTION OF INCURRED MEDICAL EXPENSES (SPENDDOWN)

Significance: Agency Priority

Legal Authority: 42 USC 1302; 42 USC 1396a(a)(10); 42 USC 1396a(a)(17)

**CFR Citation:** 42 CFR 435.732; 42 CFR 435.831; 42 CFR 436.831

#### Legal Deadline: None

Abstract: These regulations permit States to revise the process by which medical expenses are considered in determining Medicaid eligibility. This process applies when an individual's income level during a budget period would ordinarily preclude eligibility except that incurred medical expenses reduce income to the eligibility level.

#### Timetable:

Action	Date		FR	Cite
NPRM	09/02/83	48	FR	39959
NPRM Comment Period End	11/01/83			
Developing detailed study of issues	00/00/00			

Small Entities Affected: Undetermined Government Levels Affected: State

Agency Contact: Marinos Svolos, Director, Div. of Medicaid Eligibility, Department of Health and Human Services, Health Care Financing Administration, Room 416 East High Rise Bldg., 6325 Security Boulevard, Baltimore, MD 21207, 301 966-4451

RIN: 0938-AB07

# 767. PAYMENT FOR CLINICAL DIAGNOSTIC LABORATORY SERVICES

Legal Authority: 42 USC 1395l(a)(1)(D); 42 USC 1395l(a)(2)(D); 42 USC 1395l(b)(3); 42 USC 1395l(h); 42 USC 1395c(a)(2)(A); 42 USC 1396b(i)(7); 42 USC 1302; 42 USC 1395hh; PL 100-203, Sec 4064

CFR Citation: 42 CFR 405.439; 42 CFR 405.501; 42 CFR 405.502; 42 CFR 405.505; 42 CFR 405.511; 42 CFR 405.516; 42 CFR 405.1672; 42 CFR 405.1684; 42 CFR 405.1684; 42 CFR 407.10; 42 CFR 447.300; 42 CFR 447.321; 42 CFR 447.342

#### Legal Deadline: None

Abstract: These regulations would implement provisions of Pub.L. 98-369, 99-272, 99-509 and 100-203 regarding payment and "assignment" for diagnostic clinical laboratory tests, establishing in regulations the methods for implementing fee schedules. This rule would set forth the methods by which the fee schedules would be updated and would allow certain adjustment or exceptions to the fee schedules. In accordance with the statute, the regulations would provide that on January 1, 1990 and thereafter, fees will be determined on a nationwide basis.

#### Timetable:

Innetable.				
Action	Date	FR	Cite	
NPRM	00/00/00			

Small Entities Affected: Undetermined

## Government Levels Affected: Undetermined

Agency Contact: Bernard Patashnik, Division Director, Department of Health and Human Services, Health Care Financing Administration, Division of Medical Services Reimbursement, Room 1-A-5 ELR, 6325 Security Blvd., Baltimore, MD 21207, 301 966-4497

RIN: 0938-AB50

#### 768. PAYMENT FOR THE SERVICES OF PHYSICIANS FURNISHED IN TEACHING SETTINGS AND OTHER PROVIDERS

**Legal Authority:** 42 USC 1395u; 42 USC 1395x; 42 USC 1395xx; 42 USC 1302; 42 USC 1395l(a); 42 USC 1395hh

CFR Citation: 42 CFR 405.465; 42 CFR 405.466; 42 CFR 405.480; 42 CFR 405.481; 42 CFR 405.482; 42 CFR 405.522; 42 CFR 405.523; 42 CFR 405.524; 42 CFR 405.550; 42 CFR 405.551; 42 CFR 405.552; 42 CFR 405.552; 42 CFR 405.553; 42 CFR 405.554; 42 CFR 405.555; ...

#### Legal Deadline: None

Abstract: These regulations would implement provisions of section 948 of P.L. 96-499 and section 2307 of P.L. 98-369. This legislation deals with certain problems that have arisen in the Medicare program with respect to payment for physicians in the teaching setting. Specifically addressed by Congress is the problem of distinguishing between the services a physician furnishes to individual patients as a teaching physician and services furnished to the provider, as well as the method of reimbursement for these services. This proposed rule sets forth the conditions under which physicians in teaching settings would be reimbursed on a reasonable cost basis or, alternatively, on a reasonable charge basis. It also describes the methods used to determine the customary charges for the services of those physicians. This rule would also clarify related issues of physician reimbursement.

#### Timetable:

Action	Date	FR	Cite
NPRM	11/00/88		

Small Entitles Affected: None

#### Government Levels Affected: None

Agency Contact: Bernard Patashnik, Director, Division of Medical Services Reimbursement, Department of Health and Human Services, Health Care Financing Administration, Room 1-H-5 ELR, 6325 Security Blvd., Baltimore, MD 21207, 301 966-4497

RIN: 0938-AB61

**Proposed Rule Stage** 

769. REVISION OF THE CLINICAL LABORATORY REGULATIONS FOR THE MEDICARE, MEDICAID, AND CLINICAL LABORATORIES IMPROVEMENT ACT OF 1967 PROGRAMS

Significance: Regulatory Program

**Legal Authority:** 42 USC 1395x; 42 USC 1302; 42 USC 1395hh; 42 USC 263a

CFR Citation: 42 CFR 405.1310 to 405.1317; 42 CFR 482.27; 42 CFR 74

Legal Deadline: None

Abstract: Currently, hospital-based and independent laboratories are subject to varying State Licensure requirements and to Medicare regulations that vary from requirements of private accreditation entities and from regulations governing laboratories performing tests under interstate commerce. One consequence is that the quality of laboratories' services is adjudged using different standards. Inconsistent standards not only create confusion regarding necessary performance levels, but may permit laboratories with substandard performance to continue furnishing covered services. This proposed rule would establish better measures of performance and amend requirements to improve the quality of laboratory services.

#### Timetable:

Action	Date		FR	Cite
NPRM	08/05/88	53	FR	29590
NPRM Comment Period End	11/03/88	53	FR	29590
Final Action	00/00/00			

Small Entitles Affected: Businesses

**Government Levels Affected: State** 

Additional information: Taken from the Regulatory Program of the United States Government 1987 - 1988 which projected final action in October 1987.

Agency Contact: Wayne Smith, Director, Office of Survey and Certification, Department of Health and Human Services, Health Care Financing Administration, 2-D-2 ME, 6300 Security Blvd., Baltimore, MD 21207, 301 966-6763

RIN: 0938-AB96

770. CHANGES IN PAYMENT POLICY FOR DIRECT GRADUATE MEDICAL EDUCATION COSTS

Significance: Regulatory Program

Legal Authority: 42 USC 1395ww(h); PL 99-272, Sec 9202; PL 99-509, Sec 9314

**CFR Citation:** 42 CFR 405.521; 42 CFR 405.522; 42 CFR 412.113; 42 CFR 413.85; 42 CFR 413.86; 42 CFR 413.170

Legal Deadline: None

Abstract: This rule will set forth changes in Medicare Policy concerning payment for direct graduate medical education costs of providers associated with approved residency programs. These changes are necessary in order to implement section 1886(h) of the Social Security Act which was added by section 9202 of the Consolidated Omnibus Budget Reconciliation Act of 1985 and amended by section 9314 of the Omnibus Budget Reconciliation Act of 1986. The changes in this rule are effective for cost reporting periods beginning on or after July 1, 1985.

#### Timetable:

Action	Date		FR	Cite
NPRM	09/21/88	53	FR	36589
NPRM Comment Period End	11/21/88			
Final Action	00/00/00			

Small Entities Affected: Businesses

**Government Levels Affected: State** 

Agency Contact: Linda Magno, Director, Div. of Hospital Payment Policy, Office of Reimbursement Policy, Department of Health and Human Services, Health Care Financing Administration, 1-H-1 ELR, 6325 Security Blvd., Baltimore, MD 21207, 301 966-4529

RIN: 0938-AC27

771. USE OF THE HCFA HOSPITAL WAGE INDEX FOR DETERMINING PAYMENT TO HOSPICES

Legal Authority: 42 USC 1395f(i) CFR Citation: 42 CFR 418.306(c)

Legal Deadline: None

Abstract: This notice would replace the current wage index used to determine payment for hospice care furnished to Medicare beneficiaries with the HCFA survey-based hospital wage index.

#### Timetable:

	 			-
Action		Date	FR	Cite

Proposed Notice 00/00/00

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Anthony Lovecchio, Director, Div. of Alternative Reimbursement Systems, Department of Health and Human Services, Health Care Financing Administration, 1-A-3 East Low Rise, 6325 Security Blvd., Baltimore, MD 21207, 301 966-4575

RIN: 0938-AC49

#### 772. HOSPICE/CASE MANAGEMENT

Legal Authority: 42 USC 1396d(a)(18); 42 USC 1396d(o); 42 USC 1396b(a)(13)(C); 42 USC 1396o(a)(2)(E); 42 USC 1396o(b)(2)(E); 42 USC 1302; 42 USC 1396n(g); PL 99-509; PL 99-514; PL 99-272

**CFR Citation:** 42 CFR 418.32; 42 CFR 431.50; 42 CFR 435.218; 42 CFR 435.231; 42 CFR 440.185; 42 CFR 440.190; 42 CFR 440.250; 42 CFR 441; 42 CFR 447.53; 42 CFR 447.327; 42 CFR 447.381 to 384; 42 CFR 435.726; 42 CFR 435.735; 42 CFR 436.231; 42 CFR 441.18; ...

Legal Deadline: None

Abstract: These regulations would implement 3 provisions of Pub. L. 99-272: (1) under section 9505, Medicaid coverage of hospice care at State option, the regulations would establish eligibility requirements, covered services, reimbursement procedures and conditions of participation; (2) under section 9508, Medicaid coverage of case management services, at State option case management services may be furnished to specific Medicaid groups or geographic areas within a State; (3) under section 9123 there is an indefinite extension of the Medicare hospice benefit, which was scheduled to end on 09/30/86. These regulations would also implement sections 9411, 9412, and 9435d of Pub. L. 99-509, and section 1895(c) of Pub. L. 99-514, all relating to optional State coverage of case management and hospice services for the Medicaid population.

#### Timetable:

Action	Date	FR Cite
NPRM	00/00/00	
Small Entiti	as Affantade O	gonizations

Small Entities Affected: Organizations
Government Levels Affected: State

Agency Contact: Thomas Hoyer, Director, Div. of Provider Services & Coverage Policy, Department of Health and Human Services, Health Care Financing Administration, Room 405

**Proposed Rule Stage** 

EHR, 6325 Security Blvd., Baltimore, MD 21207, **301 966-4607** 

RIN: 0938-AC52

### 773. MEDICARE BENEFICIARY APPEALS

Legal Authority: 42 USC 1302; 42 USC 1395ff; 42 USC 1395hh; 42 USC 1395 et seq; 42 USC 1395ii; 42 USC 1395pp; 42 USC 1395u; 42 USC 405(a); 42 USC 1395i; 42 USC 1395i; 42 USC 1395c; PL 100-203, Sec 4307

CFR Citation: 42 CFR 405.701; 42 CFR 405.708; 42 CFR 405.716; 42 CFR 405.717; 42 CFR 405.718a through d; 42 CFR 405.729; 42 CFR 405.720; 42 CFR 405.722; 42 CFR 405.724; 42 CFR 405.730; 42 CFR 405.801; 42 CFR 426; 42 CFR 405.702

Legal Deadline: None

Abstract: These regulations would establish a new Part 426, setting forth the procedures under which HCFA Administrative Law Judges (ALJs) would conduct hearings of certain Medicare appeals, which are now heard by ALIs of the Social Security Administration. These hearings involve appeals under section 1869 and 1879 of the Social Security Act concerning the amount of benefits payable under Part A and Part B. Prior to enactment of the Omnibus Reconciliation Act of 1986, ALJ hearings were not available for appeals of Part B payments, except for certain matters arising under section 1876 of the Act (payment to health maintenance organizations and competitive medical plans). Part 426 also would establish procedures for a Medicare Review Board, judicial review, reopening of ALJ and Board decisions, representation of parties and payment of certain travel expenses.

#### Timetable:

Action	Date	FR	Cite
NPRM	00/00/00		

Small Entities Affected: Undetermined

Government Levels Affected: Undetermined

Agency Contact: Harold Shaffer, Special Assistant, AAO, Department of Health and Human Services, Health Care Financing Administration, Room 784 EHR Bldg., 6325 Security Blvd., Baltimore, MD 21207, 301 966-5765

RIN: 0938-AC81

#### 774. DENIAL OF PAYMENT FOR SUBSTANDARD QUALITY CARE, REVIEW OF BENEFICIARY COMPLAINTS

Significance: Regulatory Program

Legal Authority: 42 USC 1320c-3(a); 42 USC 1395cc(a)(1)(K); 42 USC 1395u; 42 USC 1395pp(b); PL 99-272, Sec 9403; PL 99-509, Sec 9353(c); PL 100-203, Sec 4096(a)(1)(A)

CFR Citation: 42 CFR 462.105; 42 CFR 466.70; 42 CFR 466.74; 42 CFR 466.83; 42 CFR 466.88; 42 CFR 466.93; 42 CFR 466.94; 42 CFR 466.98; 42 CFR 466.100; 42 CFR 466.106; 42 CFR 473.12; 42 CFR 473.14; 42 CFR 473.40; 42 CFR 476.133; 42 CFR 489.21; ...

Legal Deadline: None

Abstract: The purpose of this proposed rule is to implement section 9403 of PL 99-272 and 9353(c) of PL 99-509 and PL 100-203, section 4096(a)(1)(A). Under section 9403 of PL 99-272, Peer Review Organizations (PROs) are authorized to deny Medicare payment to a physician or hospital for services furnished that are of substandard quality. The PRO determinations to deny Medicare payment for these services would be made on the basis of criteria that are consistent with guidelines established by the Secretary. Under section 9353(c) of PL 99-509, PROs would conduct an appropriate review of all written complaints from beneficiaries or their representatives about the quality of services not meeting professionally recognized standards of health care. Under PL 100-203 beneficiaries are protected from liability for the cost of physician services where payment is denied because services were of substandard quality.

#### Timetable:

Action	Date	FR Cite	
NPRM	10/00/88		

Small Entitles Affected: Businesses

Government Levels Affected: Undetermined

Agency Contact: Patricia Booth, Director, Division of Review Program. Department of Health and Human Services, Health Care Financing Administration, 2-D-2 Meadows East Bldg., 6300 Security Blvd., Baltimore, MD 21207, 301 966-6880

RIN: 0938-AC84

# 775. REVISED EFFECTIVE DATE OF MEDICARE/MEDICAID PROVIDER AGREEMENT AND SUPPLIER PARTICIPATION

**Legal Authority:** 42 USC 1302; 42 USC 1395cc; 42 USC 1393ff(c); 42 USC 1395hh; 42 USC 1396i

**CFR Citation:** 42 CFR 440.10; 42 CFR 440.70; 42 CFR 442.13; 42 CFR 488.40; 42 CFR 489.13; 42 CFR 498.3

Legal Deadline: None

Abstract: This proposed rule would revise Medicare and Medicaid rules to provide for a 60-day conditional certification period for facilities seeking participation in the Medicare and Medicaid program to apply uniform effective rules to all Medicare or Medicaid providers, including Medicare Suppliers, and Medicaid only hospitals and home health agencies; and to specify that effective date decisions are precluded from Medicare reconsiderations and hearings.

#### Timetable:

Action	,	Date	FR	Cite
NPRM		00/00/00		

Small Entitles Affected: Businesses. Governmental Jurisdictions

Government Levels Affected: State, Federal

Agency Contact: Alfreda Stanton, Program Analyst, Office of Survey and Certification, Department of Health and Human Services, Health Care Financing Administration, Room 2-D-2 Meadows East Bldg., 6300 Security Blvd., Baltimore, MD 21207, 301 966-6770

RIN: 0938-AC88

#### 776. RECOGNITION OF COLLEGE OF AMERICAN PATHOLOGISTS LABORATORY ACCREDITATION PROGRAM

Legal Authority: 42 USC 1395bb

CFR Citation: 42 CFR 405.1310; 42 CFR 482.27

Legal Deadline: None

Abstract: This notice proposes that the Health Care Financing Administration recognize the accreditation program of the College of American Pathologists for clinical laboratories participating in the Medicare program. As a result of HCFA's recognition, these laboratories would not ordinarily be subject to an inspection by State survey agencies to

**Proposed Rule Stage** 

determine their compliance with Federal requirements. They would be "deemed" to meet the Medicare Conditions of Participation for Hospital-Based Laboratories or conditions for coverage of services of independent laboratories.

#### Timetable:

Action	Date	FR Cite
Final Notice	00/00/00	
Proposed Notice	00/00/00	

#### Small Entitles Affected: None

#### **Government Levels Affected: None**

Agency Contact: Mike Goldman, Chief, Laboratory and Ambulatory Services Branch, Department of Health and Human Services, Health Care Financing Administration, 2-D-2 Meadows East Building, 6300 Security Boulevard, Baltimore, MD 21207, 301 966-6813

#### RIN: 0938-AC89

# 777. PRO REVIEW OF SURGICAL PROCEDURES AND REQUIREMENTS FOR SECOND OPINIONS

**Legal Authority:** 42 USC 1320c-13; 42 USC 1302; 42 USC 1395hh; 42 USC 1395pp

**CFR Citation:** 42 CFR 466.150 to 190; 42 CFR 473.12; 42 CFR 473.14; 42 CFR 473.40; 42 CFR 405.332

#### Legal Deadline: None

Abstract: This proposed rule would implement section 9401 of Pub.L. 99-272, which provides that, under Medicare, a physician must request from the Peer Review Organization (PRO) preadmission review for certain surgical procedures. Under section 9401, if the PRO determines that the procedure is not appropriate and medically necessary, the PRO will deny payment under Medicare. If the PRO cannot determine whether a surgical procedure is medically necessary and appropriate, the beneficiary would obtain an opinion from a second physician, or where the opinion of the second physician differs from the first physician, the beneficiary may obtain an opinion from a third physician. In addition, as required by section 409ô(b) of Pub. L.100-203, if an assigned claim by a physician or supplier or any claim by a provider is denied because the services furnished are not reasonable and necessary or constitute custodial care and the physician, suppler or provider, but not the beneficiary, knew, or reasonably

could be expected to know, that the services were not covered by Medicare, (Continued under Additional Information)

#### Timetable:

Action	Date	FR	Cite
NPRM	10/00/88		

Small Entities Affected: Undetermined

#### Government Levels Affected: Undetermined

Additional Information: (Abstract Continued): the physician, supplier or provider would not be entitled to collect and retain payment from the beneficiary for those services.

Agency Contact: Richard Husk, Director, Office of Medical Review, Department of Health and Human Services, Health Care Financing Administration, Room 2-D-2 Meadows East Bldg., 6300 Security Blvd., Baltimore, MD 21207, 301

#### RIN: 0938-AC90

# 778. PAYMENT FOR THE COST OF MALPRACTICE INSURANCE FOR HOSPITALS EXCLUDED FROM THE PROSPECTIVE PAYMENT SYSTEM

Legal Authority: 42 USC 1302; 42 USC 1395f(b); 42 USC 1395g; 42 USC 1395l(a); 42 USC 1395x(v); 42 USC 1395hh; 42 USC 1395rr; 42 USC 1395ww; 42 USC 1395vc; 42 USC 1395vc

#### CFR Citation: 42 CFR 413.56

#### Legal Deadline: None

Abstract: Medicare's share of payment for the cost of a hospital's malpractice insurance is determined in part through the use of a scaling factor formula. In this notice, we are undertaking to develop a separate set of values for use in the scaling factor formula for hospitals excluded from the prospective payment system.

#### Timetable:

Action	Date	FR	Cite
Notice	00/00/00		

Small Entitles Affected: Undetermined

## **Government Levels Affected:** Undetermined

Agency Contact: Paul Trimble, Special Assistant, Office of Reimbursement Policy, Department of Health and Human Services, Health Care Financing Administration, 1-F-5 East Low Rise Bldg., 6325 Security Blvd., Baltimore, MD 21207, **301 966-4509** 

#### RIN: 0938-AC97

#### 779. CHANGES CONCERNING SUSPENSION OF MEDICARE PAYMENTS, INTEREST RATES CHARGED ON OVERPAYMENTS AND UNDERPAYMENTS, AND DETERMINATIONS OF ALLOWABLE INTEREST EXPENSE

Legal Authority: 42 USC 1320b-4; 42 USC 1395g; 42 USC 1395u; 42 USC 1395x(v)(1)(A); 42 USC 1395hh; 42 USC 1302; 42 USC 13951

**CFR Citation:** 42 CFR 413.153; 42 CFR 405.370; 42 CFR 405.376; 42 CFR 413.5(c)(3)

#### Legal Deadline: None

Abstract: This rule will change the Medicare regulations to provide for the following: (1) elimination of the requirement that in case of overpayments to health care providers, the contractor makes a determination that a suspension of payment is needed to protect the program against financial loss before the payment can be suspended; (2) elimination of the requirement that investment income of providers from gifts, grants, and endowments be offset against allowable interest expenses if that investment income is not held separately (that is, commingled with other funds); and (3) extension of the list of exceptions to the interest expense reduction provision to include investment income from deferred compensation plans and self-insurance funds; and (4) permitting interest on overpayments and underpayments to be assessed at the higher of the private consumer rate or the current value of funds rate.

#### Timetable:

***************************************					
	Action	Date		FR	Cite
	NPRM	08/22/88	53	FR	31888
	NPRM Comment Period End	10/21/88			
	Final Action	00/00/00			

#### Small Entities Affected: None

#### Government Levels Affected: None

Agency Contact: William Goeller, Director, Division of Payment and Reporting Policy, Department of Health and Human Services, Health Care Financing Administration, 1-F-5 East

**Proposed Rule Stage** 

Low Rise Building, 6325 Security Blvd., Baltimore, MD 21207, 301 966-4513

RIN: 0938-AC99

# 780. CHANGES CONCERNING THE DEFINITION OF ACCRUAL BASIS OF ACCOUNTING

Legal Authority: 42 USC 1395x(v) CFR Citation: 42 CFR 413.24

Legal Deadline: None

Abstract: This rule proposes to revise the Medicare regulations to clarify the definition of "accrual basis of accounting" to indicate that expenses must be incurred by provider of health care services before Medicare will pay its share of those expenses. This change is intended to conform the regulations with the law and to promote economy and efficiency in the administration of the Medicare program.

#### Timetable:

Action	Date	FR	Cite
NPRM	00/00/00		

Small Entities Affected: None

**Government Levels Affected:** None

Agency Contact: William Goeller, Director, Division of Payment and Reporting Policy, Department of Health and Human Services, Health Care Financing Administration, Room 1-F-5 ELR, 6325 Security Blvd., Baltimore, MD 21207, 301 966-4513

RIN: 0938-AD01

#### 781. OPTIONAL PAYMENT SYSTEM FOR LOW MEDICARE VOLUME SKILLED NURSING FACILITIES

Significance: Regulatory Program Legal Authority: 42 USC 1395yy(d)

CFR Citation: 42 CFR 413.200; 42 CFR 413.202; 42 CFR 413.204; 42 CFR 413.208; 42 CFR 413.210; 42 CFR 413.212; 42 CFR 413.214; 42 CFR 413.216; 42 CFR 413.220; 42 CFR 413.221; 42 CFR 413.1; 42 CFR 413.24

Legal Deadline: None

Abstract: This rule proposes to establish optional prospective payment rates for routine services furnished by certain skilled nursing facilities. The prospective rate would be on a per diem basis and would include payment for the cost of furnishing general inpatient routine services and associated capital-related costs. As

specified in the Conference Committee Report accompanying PL 99-272, the rates paid to proprietary SNFs would include a component for the routine service portion of the return on equity capital. As specified in section 1861(v)(1)(B) of the Act, the return on equity component would only be included in the rate paid to proprietary SNFs. This rule would propose instructions for determining eligibility for payment under this system, and the methodology for calculating the prospective payment rates.

#### Timetable:

Action	Date	FR	Cite
NPRM	00/00/00		

Small Entities Affected: None

Government Levels Affected: Undetermined

Agency Contact: William Goeller, Director, Division of Payment and Reporting Policy, Department of Health and Human Services, Health Care Financing Administration, Room 1-F-5 ELR, 6325 Security Blvd., Baltimore, MD 21207. 301 966-4513

RIN: 0938-AD02

#### 782. CRITERIA AND PROCEDURES FOR MEDICAL SERVICES COVERAGE DECISIONS

Significance: Regulatory Program

**Legal Authority:** 42 USC 1395y; 42 USC 1302; 42 USC 1395hh; 42 USC 1395xx

**CFR Citation:** 42 CFR 400.200; 42 CFR 400.202; 42 CFR 405.380; 42 CFR 405.381; 42 CFR 405.382; 42 CFR 405.383

Legal Deadline: None

Abstract: The proposed rule would establish in regulations generally applicable standards and procedures for HCFA determinations as to whether and under what circumstances specific medical items and services should be paid for under Medicare. It establishes and explains the criteria relied upon for determining whether an item or service is "reasonable and necessary." The objective of the criteria and procedures set forth in this proposed rule is to assure that Federal funds are expended only for medical services that are covered under the Medicare program.

#### Timetable:

Action	Date	FR	Cite
NPRM	10/00/88		

Small Entities Affected: Undetermined

Government Levels Affected: None

Agency Contact: Sam DellaVecchia, Chief, Special Coverage Issues Branch. Department of Health and Human Services, Health Care Financing Administration, 455 East High Rise Bldg., 6325 Security Blvd., Baltimore. MD 21207, 301 966-5316

RIN: 0938-AD07

783. RECOGNITION OF JOINT COMMISSION ON ACCREDITATION OF HEALTHCARE ORGANIZATIONS' HOME CARE PROGRAM STANDARDS AND THE NATIONAL LEAGUE FOR NURSING'S STANDARDS FOR HOME HEALTH AGENCIES

Significance: Agency Priority

Legal Authority: 42 USC 1395bb(a); 42 USC 1302; 42 USC 1395hh

CFR Citation: Not applicable

Legal Deadline: None

Abstract: Under this final notice, hospital-based home health agencies accredited by the Joint Commission on Accreditation for Healthcare Organizations' and home health agencies accredited by the National League for Nursing are considered or "deemed" to meet the Medicare conditions of participation. Thus, these agencies will not ordinarily be subject to an inspection by State survey agencies to determine their compliance with Federal requirements. As a result of the home health agency's deemed status, a State also can choose to permit the agency to participate as a provider under the Medicaid program.

#### Timetable:

Action	Date		FR	Cite
Proposed Notice	12/31/87	52	FR	49510
Public Comment Period End	02/29/88			
Final Notice	00/00/00			

Small Entities Affected: None

**Government Levels Affected: State** 

Agency Contact: Anita Heygster, Program Analyst, Long Term Care Branch, Department of Health and Human Services, Health Care Financing Administration, Room 431 EHR, 6325

**Proposed Rule Stage** 

Security Blvd., Baltimore, MD 21207, 301 966-5667

RIN: 0938-AD13

## 784. ELIGIBILITY OF ALIENS FOR MEDICAID

Significance: Regulatory Program

Legal Authority: 42 USC 1396b(u); PL 99-603, Sec 201; PL 99-509

CFR Citation: 42 CFR 435.402; 42 CFR 436.402; 42 CFR 440.200; 42 CFR 440.250; 42 CFR 436.406; 42 CFR 436.406; 42 CFR 436.408; 42 CFR 436.2; 42 CFR 440.255; 42 CFR 435.139; 42 CFR 435.406; 42 CFR 435.408; 42 CFR 435.1; 42 CFR 435.3; 42 CFR 436.128; ...

#### Legal Deadline: None

Abstract: This proposed rule would revise Medicaid regulations applicable for aliens who meet eligibility requirements as categorically needy or medically needy. It would establish in the regulations that aliens lawfully admitted for permanent residence or permanently residing in the United States under color of law may be eligible for all Medicaid services. It also would identify those aliens who may be eligible only for limited services.

#### Timetable:

Action	Date	FR	Cite
NPRM	10/00/88		

Small Entities Affected: None

**Government Levels Affected: State** 

Agency Contact: Marinos T. Svolos, Director, Division of Medicaid Eligibiltiy Policy, Department of Health and Human Services, Health Care Financing Administration, Room 400 East High Rise Bldg., 6325 Security Blvd., Baltimore, MD 21207, 301 966-4451

RIN: 0938-AD15

785. MEDICAID: ELIGIBILITY GROUPS EXTENDED COVERAGE OF SERVICES, AND CONDITIONS OF ELIGIBILITY: OBRA '87, COBRA, AND TEFRA

Legal Authority: 42 USC 1396a(a)(10); 42 USC 1302; 42 USC 1396d(a); 42 USC 1396k(a); 42 USC 1396s; 42 USC 1383c; 42 USC 673; 42 USC 675; 42 USC 672; 42 USC 1396a(a)(25)(b); 42 USC 1396a(e)(3)

CFR Citation: 42 CFR 435; 42 CFR 436

Legal Deadline: None

Abstract: This proposed rule would amend the Medicaid regulations to incorporate numerous eligibility groups for Medicaid coverage: pregnant women; children in adoption and foster care; certain disabled widows and widowers; certain disabled children being cared for at home; and qualified children. The rule would also provide for extended care for pregnant women after termination of pregnancy and add a condition of eligibility relating to third party liability. The amendments would conform the regulations to provisions of the Omnibus Budget Reconciliation Act of 1987, the Consolidated Omnibus Budget Reconciliation Act of 1985, and the Tax Equity and Fiscal Responsibility Act of 1982. States have been informed that these provisions of the statute are self-implementing. Manual instructions containing procedures for States to implement the requirements have been issued.

#### Timetable:

Action	Date	FR Cite
NPRM	10/00/88	

Small Entitles Affected: None

**Government Levels Affected:** Local, State

Agency Contact: Marinos Svolos, Director, Division of Medicaid Eligibility Policy, Department of Health and Human Services, Health Care Financing Administration, Room 416 East High Rise Bldg., 6325 Security Blvd., Baltimore, MD 21207, 301 966-

RIN: 0938-AD16

# 786. MEDICAID ELIGIBILITY OF POVERTY LEVEL GROUPS AND EXTENDED COVERAGE OF SERVICES

Legal Authority: 42 USC 1396a(a)(10); 42 USC 1396a(l); 42 USC 1396a(f); 42 USC 1396a(b)(2); 42 USC 1302; 42 USC 1396a(m); 42 USC 1396a(n); 42 USC 1396b(f); 42 USC 1396b(u); 42 USC 1396d(p); 42 USC 1396r-1; 42 USC 1396a(a)(47); 42 USC 1396a(e)(6); 42 USC 1396a(e)(8); 42 USC 1396a(a)(17)

**CFR Citation:** 42 CFR 431; 42 CFR 435; 42 CFR 436; 42 CFR 440; 42 CFR 447

Legal Deadline: None

Abstract: This proposed rule would amend the Medicaid regulations to incorporate changes relating to Medicaid eligibility groups and coverage of services made by the Medicare Catastrophic Coverage Act (P.L. 100-360), the Omnibus Budget Reconciliation Acts of 1987 and 1986.(P.L. 100-203 and P.L. 99-509), and the Homeless Eligibility Clarification Act of 1986 (P.L. 99-570). This rule would add eligibility groups of pregnant women, infants and children, and aged and disabled individuals with incomes up to a specified percentage of the Federal poverty line; provide for Medicaid coverage of Medicare costsharing expenses for qualified Medicare beneficiaries with incomes at or below the Federal poverty line; clarify eligibility of homeless individuals; add provisions for a presumptive eligibility period for pregnant women who, based on preliminary information, appear to meet income requirements under Medicare, and clarify coverage of and services to pregnant women and children.

#### Timetable:

Action	Date	FR Cite
NPRM	00/00/00	

Small Entities Affected: None

**Government Levels Affected:** Local, State

Agency Contact: Marinos Svolos, Director, Division of Medicaid Eligibility, Department of Health and Human Services, Health Care Financing Administration, Room 416 East High Rise, 6325 Security Blvd., Baltimore, MD 21207, 301 966-4452

RIN: 0938-AD17

#### 787. TRANSFER OF ASSETS

**Legal Authority:** PL 100-360, Sec 303(b) **CFR Citation:** 42 CFR 435; 42 CFR 436

Legal Deadline: None

Abstract: These regulations would implement the provisions of section 303(b) of Pub.L.100-360, which require that State Medicaid agencies, in determining an institutionalized individual's eligibility for Medicaid, to include as a resource the uncompensated value of assets such as cash or property that the individual has transferred to someone else for less than fair market value within the 30 months preceding a Medicaid application.

#### Timetable:

Action	Date	FR	Cite
NPRM	00/00/00		

Small Entities Affected: Undetermined

Government Levels Affected: Local, State

Agency Contact: Marinos Svolos, Director, Division of Medicaid Eligibility, Department of Health and Human Services, Health Care Financing Administration, Room 416 East High Rise, 6325 Security Blvd., Baltimore, MD 21207. 301 966-4451

RIN: 0938-AD18

#### 788. PAYMENT FOR SERVICES OF CERTIFIED REGISTERED NURSE ANESTHETISTS

Legal Authority: 42 USC 1395x(s)(ll); 42 USC 1395l(l); 42 USC 1395x(bb); 42 USC 1302; 42 USC 1395hh

CFR Citation: 42 CFR 405.553; 42 CFR 405.502; 42 CFR 413.80

Legal Deadline: NPRM, Statutory, January 1, 1989. Final, Statutory, January 1, 1989.

Abstract: Section 9320 of Pub. L. 99-509 provides for payment on a fee schedule basis for services of certified registered nurse anesthetists (CRNAs) furnished to Medicare beneficiaries on or after January 1, 1989. The payment amount would be equal to the least of 80 percent of a fee schedule established by the Secretary (and adjusted annually by the change in the Medicare economic index), 80 percent of the prevailing charge for an anesthesiologist; or 80 percent of the actual charge. CRNAs would be required to accept assignment for all Medicare services and civil monetary penalties could be imposed for violations of this requirement. Alternatively, the hospital or physician could bill for and receive payment for services of CRNAs where an employment relationship or contract so stipulates. The hospital or physician could not bill more for CRNA services than the amount the CRNA could bill directly.

#### Timetable:

Action	Date	FR Cite
NPRM	10/00/88	
Final Action	12/00/88	

**Small Entities Affected: Businesses** 

Government Levels Affected: None

Agency Contact: Bernard Patashnik, Director, Division of Medical Services, Reimbursement, Department of Health and Human Services, Health Care Financing Administration, 6325 Security Blvd., Baltimore, MD. 21207, 301 956-4497

RIN: 0938-AD25

#### 789. WITHDRAWAL OF COVERAGE OF SINGLE PHOTON ABSORPTIOMETRY

Legal Authority: 42 USC 1395y; 42 USC 1302; 42 USC 1395hh

CFR Citation: Not applicable

Legal Deadline: None

Abstract: This notice announces the Medicare program's intent to withdraw Medicare coverage (including coverage under the End-Stage Renal Disease (ESRD) program) for single photon absorptiometry and radiographic absorptiometry for measuring bone mineral density for either diagnostic or treatment purposes, and to continue noncoverage of dual photon absorptiometry.

#### Timetable:

Action	Date		FR	Cite
Proposed Notice	09/08/88	53	FR	34898
Public Comment Period End	11/07/88			
Final Action	00/00/00			

#### Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Sam DellaVecchia, Chief, Special Coverage Issue Branch, Office of Coverage Policy, Department of Health and Human Services, Health Care Financing Administration, Rm. 455 EHR, 6325 Security Blvd., Baltimore, MD. 21207, 301 966-5316

RIN: 0938-AD28

# 790. MODIFICATION OF CERTAIN REQUIREMENTS FOR HEALTH INSURING ORGANIZATIONS

**Legal Authority:** 42 USC 1302; 42 USC 1396b(m)(2)(A); PL 99-272, Sec 9517(c); PL 99-514, Sec 1895(c)(4); PL 99-509, Sec 9435(e)

**CFR Citation:** 42 CFR 434.14; 42 CFR 434.20; 42 CFR 434.40; 42 CFR 434.42; 42 CFR 434.44; 42 CFR 434.2

#### Legal Deadline: None

Abstract: The final rule will describe the conditions under which a Health Insuring Organization (HIO) is subject to Medicaid Health Maintenance Organization (HMO) regulations. It would require that an HIO which becomes operational on or after January 1, 1986 and arranges for the delivery of services to recipients be subject to HMO requirements. The regulations would specify that exemptions from certain HMO requirements are permitted for HIOs which began operations on or after January 1, 1986 if the HIOs obtained a section 1915(b) waiver prior to that date, or if an HIO is otherwise identified in the law. The exemptions last only until the expiration of a section 1915(b) waiver.

#### Timetable:

Action	Date		FR	Cite
NPRM	08/25/88	53	FR	32406
NPRM Comment Period End	10/24/88			
Final Action	00/00/00			

Small Entities Affected: None

Government Levels Affected: Undetermined

Agency Contact: Robert E. Wren, Office Director, Department of Health and Human Services, Health Care Financing Administration, Office of Coverage Policy, Rm. 401 EHR, 6325 Security Blvd., Baltimore, MD. 21207, 301 968-5661

RIN: 0938-AD31

## 791. OCCUPATIONAL THERAPY, PHYSICIAN ASSISTANTS

Legal Authority: 42 USC 1302; 42 USC 1395x(g); 42 USC 1395cc; 42 USC 1395k; 42 USC 1395l; 42 USC 1395x; 42 USC 1395x(r); 42 USC 1395x(s); 42 USC 1395x(cc); 42 USC 1395x(s); 42 USC 1395r; 42 USC 1395r; 42 USC 1395r; 42 USC 1395x; 42 USC 1395aa

**CFR Citation:** 42 CFR 405.1634; 42 CFR 410.150; 42 CFR 486.1; 42 CFR 486.2; 42 CFR 486.3; 42 CFR 486.13; 42 CFR 486.14; 42 CFR 486.21; 42 CFR 486.22; 42 CFR 486.23; 42 CFR 486.24; 42 CFR 486.15; 42 CFR 486.16; 42 CFR 486.17; 42 CFR 486.19; ...

#### Legal Deadline: None

Abstract: This proposed rule would implement sections 9337 and 9338 of Pub.L 99-509 which provide Medicare coverage for outpatient occupational therapy services furnished by providers and independent practitioners, identical to the coverage for outpatient physical

therapy, and for physician assistant services.

#### Timetable:

Action	Date	FR	Cite	
NPRM	00/00/00			

Small Entities Affected: Undetermined

#### Government Levels Affected: Undetermined

Agency Contact: Sheridan Gladhill, Program Analyst, Department of Health and Human Services, Health Care Financing Administration, Rm. 403, EHR, 6325 Security Blvd., Baltimore, MD. 21207. 301 966-4605

RIN: 0938-AD32

# 792. PROHIBITION ON UNBUNDLING OF HOSPITAL OUTPATIENT SERVICES

Legal Authority: 42 USC 1302; 42 USC 1395y(a)(14); 42 USC 1395cc(a)(1)(H); 42 USC 1395cc(g); 42 USC 1395hh

**CFR Citation:** 42 CFR 405; 42 CFR 410; 42 CFR 489; 42 CFR 1003

#### Legal Deadline: None

Abstract: This rule, issued jointly by HCFA and OIG, will prohibit Medicare payment for nonphysician services furnished to a hospital outpatient by a provider or supplier other than the hospital, unless the services are furnished under an arrangement with the hospital. The hospital will be obligated by its provider agreement to furnish the services directly or under an arrangement. These regulations also authorize OIG to impose a civil money penalty, not to exceed \$2,000, against any individual who knowingly and willfully presents, or causes to be presented, a bill or request for payment for a hospital outpatient service under Part B of Medicare in violation of an arrangement. These regulations would sections 9343(c)(1), (c)(2), and (c)(3) of the Omnibus Budget Reconciliation Act of 1986.

#### Timetable:

Action	Date		FR	Cite	
NPRM	08/05/88	53	FR	29486	
NPRM Comment Period End	10/04/88	53	FR	29486	
Final Action	00/00/00				

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Tom Hoyer, Director, Division of Provider Services and,

Coverage Policy, Department of Health and Human Services, Health Care Financing Administration, Rm. 405 EHR, 6325 Security Blvd., Baltimore, MD. 21207, 301 966-4607

RIN: 0938-AD33

#### 793. PHYSICIAN LIABILITY ON NON-ASSIGNED CLAIMS

**Legal Authority:** PL 99-509, Sec 9332; 42 USC 1395u; 42 USC 1302; 42 USC 1395hh

CFR Citation: 42 CFR 405.339

Legal Deadline: None

Abstract: This regulation would implement Section 9332(c) of the Omnibus Budget Reconciliation Act of 1986 under which nonparticipating physicians who provide on an unassigned basis services which are determined to be medically unnecessary are required to refund to the beneficiary any amounts collected for such services. Exceptions to the refund requirement would be granted only if the physician did not know and could not reasonably have been expected to know that the service was not covered, or if the beneficiary, after being informed that Medicare will not pay for the service, agrees to pay.

#### Timetable:

Action	Date	FR	Cite
NPRM	10/00/88		

#### Small Entities Affected: None

#### Government Levels Affected: None

Agency Contact: Elmer Smith, Director, Office of Eligibility Policy, Department of Health and Human Services, Health Care Financing Administration, Rm. 400 EHR, 6325 Security Blvd., Baltimore, MD. 21207, 301 966-5648

RIN: 0938-AD34

## 794. STATE SHARE OF FINANCIAL PARTICIPATION

Significance: Regulatory Program Legal Authority: 42 USC 1302 CFR Citation: 42 CFR 433

Legal Deadline: None

Abstract: This rule revises the current regulations concerning State's use of donations and certain taxes in determining the State share of financial participation in Medicaid.

		e:

Action	Date	FR	Cite
NPRM	11/00/88		

Small Entities Affected: Undetermined

Government Levels Affected: State

Agency Contact: Tzvi Heftner, Program Analyst, Department of Health and Human Services, Health Care Financing Administration, Room 1-A-3, ELR, 6325 Security Blvd., Baltimore, MD. 21207, 301 966-4580

RIN: 0938-AD36

# 795. PRO DISCLOSURE TO LICENSING AND CERTIFICATION BODIES

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

**CFR Citation:** 42 CFR 400; 42 CFR 412; 42 CFR 476; 42 CFR 498; 42 CFR 1001

#### Legal Deadline: None

Abstract: This proposed rule would revise and clarify HCFA's authority with respect to corrective action procedures and procedures for program payment denial against those hospital providers who circumvent PPS.

#### Timetable:

Action	Date	FR Cite
NPRM	00/00/00	

Small Entities Affected: None

#### Government Levels Affected: None

Agency Contact: Richard Husk, Director, Office of Medical Review, Health Standards and Quality Bureau, Department of Health and Human Services, Health Care Financing Administration, 2-D-2 Meadows East, 6325 Security Boulevard, Baltimore, MD 21207, 301 966-6850

RIN: 0938-AD42

## 796. REVISION OF THE MEDICARE ECONOMIC INDEX

Legal Authority: 42 USC 1302; 42 USC 1395hh; 42 USC 1395u(b)(3)

CFR Citation: 42 CFR 405.504

Legal Deadline: None

Abstract: This proposed rule would establish in regulations the revised proxy measures which we believe have a sounder economic foundation than the current ones and meet the requirements of the statute.

**Proposed Rule Stage** 

## Timetable: Action Date FR Cite

**Next Action Undetermined** 

Small Entities Affected: Undetermined

Government Levels Affected: Undetermined

Agency Contact: Ross H. Arnett, III, Chief, Economics and Actuarial Analysis Branch, Department of Health and Human Services, Health Care Financing Administration, 1705 Equitable Building Room 100, 6325 Security Blvd, Baltimore, MD 21207, 301 966-7934

RIN: 0938-AD43

# 797. UPDATE OF AMBULATORY SURGICAL CENTER PAYMENT RATES FOR JULY 1, 1988

Significance: Agency Priority

**Legal Authority:** 42 USC 1395l(a)(4); 42 USC 1395l(i); 42 USC 1395k(a)(2)(F)

**CFR Citation: 42 CFR 416.130** 

Legal Deadline: NPRM, Statutory, July 1, 1988.

Abstract: We will state the methodology used to determine the payment amounts for ambulatory surgical services and update payment rates, effective July 1, 1988.

#### Timetable:

Action	Date		FR	Cite
Proposed Notice	08/18/88	53	FR	31468
Public Comment Period End	10/17/88			
Final Notice	12/00/88			

Small Entitles Affected: Businesses

Government Levels Affected: None

Agency Contact: Charles Booth, Director, Office of Reimbursement Policy, Department of Health and Human Services, Health Care Financing Administration, Room 181 EHR, 6325 Security Blvd., Baltimore, MD 21207, 301 966-4487

RIN: 0938-AD44

798. SCHEDULE OF LIMITS FOR SKILLED NURSING FACILITY INPATIENT ROUTINE SERVICE COSTS FOR REPORTING PERIODS BEGINNING ON OR AFTER OCTOBER 1, 1988

Significance: Agency Priority

**Legal Authority:** 42 USC 1395x(v)(1); 42 USC 1395yy; 42 USC 1302; 42 USC 1305hb

CFR Citation: 42 CFR 413.30

Legal Deadline: None

Abstract: This notice would set forth a revised schedule of limits on skilled nursing facility inpatient routine service costs that are reimbursed under Medicare. This schedule would apply to cost reporting periods beginning on or after October 1, 1988.

#### Timetable:

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Action	Date	 Cite
Notice	10/00/88	

Small Entitles Affected: Undetermined

**Government Levels Affected: None** 

Agency Contact: William Goeller, Director, Division of Payment and Reporting Policy, Department of Health and Human Services, Health Care Financing Administration, 1-F-5 ELR, 6325 Security Blvd., Baltimore, MD 21207, 301 966-4513

RIN: 0938-AD48

# 799. APPLICATION OF THE COMPARABLE SERVICES LIMITATION IN DETERMINING REASONABLE CHARGES

**Legal Authority:** 42 USC 1395u(b)(3)(B); 42 USC 1302; 42 USC 1395hh

CFR Citation: 42 CFR 405.508

Legal Deadline: None

Abstract: This proposed rule would clarify the circumstances under which Medicare carriers are to apply the comparable services limitation in making their determination of a reasonable charge for Medicare Part B services. Under section 1842(b)(3)(B) of the Act, carriers are prohibited from making a determination of a reasonable charge that would be higher than the charge upon which it would base payment to its own policyholders for a comparable service under comparable circumstances. Currently, there is a great deal of confusion among the carriers as to what constitutes comparable services and comparable circumstances, the result of which is that very few carriers are applying the comparable services limitation in their reasonable charge determination. We would revise the regulations to more clearly state how the comparable

services limitation should be implemented by the carriers.

#### Timetable:

Action	Date	FR	Cite
NPRM	00/00/00	-	

Small Entities Affected: Undetermined

Government Levels Affected: Undetermined

Agency Contact: Bernard Patashnik, Director, Division of Medical Services Reimbursement, Department of Health and Human Services, Health Care Financing Administration, 1-H-5 ELR, 6325 Security Blvd., Baltimore, MD 21207, 301 966-4497

RIN: 0938-AD50

## 800. HOME AND COMMUNITY-BASED SERVICES FOR THE ELDERLY

Legal Authority: 42 USC 1396n(d); 42 USC 1302

CFR Citation: 42 CFR 441

Legal Deadline: NPRM, Statutory, October 1, 1989. Final, Statutory, July 1, 1989.

Regulation must be promulgated containing methodology.

Abstract: This regulation would implement section 1915(d) of the Act. These rules would allow a State to provide skilled nursing facility (SNF), intermediate care facility (ICF), and home and community-based services to individuals 65 years of age and older, in exchange for a "cap" on the amount of money for which Medicaid Federal financial participation would be available. The program would be administered by means of waivers which a State could request. As currently constructed, the statute allows for waivers of statewideness, comparability, and income deeming. Home and community-based services could be made available to individuals age 65 or older who are shown by an evaluation to be likely to require the level of care provided in an SNF or ICF, the cost for which could be paid by Medicaid. For States electing this option, the waiver would replace the home and community-based services waivers available under section 1915(c) of the Act, for individuals in this age category.

**Proposed Rule Stage** 

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Action	Date	FR	Cite
NPRM	00/00/00		

Small Entities Affected: Undetermined Government Levels Affected: Local,

Agency Contact: Thomas Hoyer, Director, Division of, Provider Services Coverage Policy, Department of Health and Human Services, Health Care Financing Administration, Room 405 EHR., 6325 Security Blvd., Baltimore, MD 21207, 301 966-4607

RIN: 0938-AD55

## 801. REVISIONS TO THE FREEDOM OF INFORMATION REGULATIONS

**Legal Authority:** 42 USC 1306; 5 USC 552; 42 USC 1302

CFR Citation: 42 CFR 401.101; 42 CFR 401.102; 42 CFR 401.103; 42 CFR 401.104; 42 CFR 401.111; 42 CFR 401.112; 42 CFR 401.130 to 401.138; 42 CFR 401.140 to 401.145; 42 CFR 401.150 to 401.154; 42 CFR 401.120 to 401.155

#### Legal Deadline: None

Abstract: This rule proposes changes to the regulations implementing the Freedom of Information Act. The regulations would be brought up-to-date in light of HCFA's experience with the FOIA and would conform HCFA's FOIA rules to the new HHS FOIA regulations, the guidelines from OMB and the Department of Justice, a Presidential Order, and the Freedom of Information Reform Act of 1986.

#### Timetable:

Action	Date	FR	Cite
NPRM	00/00/00		

Small Entities Affected: Undetermined

## Government Levels Affected: Undetermined

Agency Contact: Rosario Cirrincione, Chief, Freedom of Information Branch, Department of Health and Human Services, Health Care Financing Administration, Room 100 Professional Bldg., 6660 Security Blvd., Baltimore, MD 21207, 301 966-5352

RIN: 0938-AD60

## 802. FEE SCHEDULES FOR RADIOLOGIST SERVICES

Significance: Regulatory Program

**Legal Authority:** 42 USC 1395l(a)(1)(J); 42 USC 1395m(b); 42 USC 1302; 42 USC 1395hh; PL 100-203, Sec 4049

**CFR Citation:** 42 CFR 405.501; 42 CFR 405.530; 42 CFR 405.531; 42 CFR 405.532; 42 CFR 405.533; 42 CFR 405.550; 42 CFR 405.551; 42 CFR 405.554; 42 CFR 405.555

**Legal Deadline:** NPRM, Statutory, August 1, 1988. Effective for services performed on or after 01/01/89.

Abstract: As a result of provisions included in section 4049 of PL 100-203, we are proposing a fee schedule for radiology services furnished by a board-certified or board eligible radiologist or by a physician whose charges for radiology services account for 50 percent or more of his or her total Medicare charges. These physicians would be paid at 80 percent of the lower of the actual charge or the appropriate fee schedule amount. The fee schedule amount for a nonparticipating physician would be 95 percent of the amount applicable to a participating physician. In addition, a nonparticipating physician's charges to beneficiaries would be capped. The proposed fee schedule would result in overall amount of payment to physicians for radiology services of 3 percent less than would have occurred without a fee schedule. The fee schedule would be updated annually in accordance with the annual increase in the Medicare Economic Index.

#### Timetable:

Action	Date	FR Cite
NPRM	10/00/88	
Final Action	12/01/88	
Fee schedule in place for services	01/01/89	
performed on or after		

Small Entities Affected: Businesses

#### Government Levels Affected: None

Agency Contact: Bernard Patashnik, Director, Division of Medical Services Reimbursement, Department of Health and Human Services, Health Care Financing Administration, Room 1-H-5 ELR, 6325 Security Blvd., Baltimore, MD 21207. 301 966-4497

RIN: 0938-AD62

## 803. ESTABLISHMENT OF MEDICARE ECONOMIC INDEX FOR 1989

Legal Authority: 42 USC 1395u(b)(3); 42 USC 1395u(b)(4); 42 USC 1302; 42 USC 1395hh

CFR Citation: Not applicable

Legal Deadline: None

Abstract: This notice updates the Medicare economic index which is used to calculate the prevailing charge levels that help to determine reasonable charges for physician services under Medicare. For physician services furnished, on or after January 1, 1989 and before January 1, 1990, the increase for primary care services will be 3.0 percent, and for other services it will be 1.0 percent.

#### Timetable:

Action	Date	FR	Cite
Notice	11/00/88		

Small Entitles Affected: None

## Government Levels Affected: Undetermined

Agency Contact: Paul Riesel, Technical Assistant, Office of Reimbursement Policy, Department of Health and Human Services, Health Care Financing Administration, Room 1-H-5 ELR, 6325 Security Blvd., Baltimore, MD 21207, 301

RIN: 0938-AD64

#### 804. PAYMENT FOR DURABLE MEDICAL EQUIPMENT AND ORTHOTIC AND PROSTHETIC DEVICES

**Legal Authority:** 42 USC 1302; 42 USC 1395hh; 42 USC 1395m; 42 USC 1395zz

CFR Citation: 42 CFR 405.502; 42 CFR 405.514; 42 CFR 414.200; 42 CFR 414.202; 42 CFR 414.210; 42 CFR 414.220; 42 CFR 414.222; 42 CFR 414.224; 42 CFR 414.226; 42 CFR 414.228; 42 CFR 414.230

Legal Deadline: None

Abstract: This final rule with comment period implements section 4062 of PL 100-203. It establishes fee schedules and payment methodologies that govern payments for six categories of durable medical equipment and orthotic and prosthetic devices as required by section 4062 of PL 100-203. The new payment rates are to be effective for items provided on or after January 1, 1969.

#### Timetable:

Action	Date	FR Cite
NPRM	00/00/00	
Final with comment period	00/00/00	

Small Entities Affected: Undetermined

## Government Levels Affected: Undetermined

Agency Contact: Bernard Patashnik, Director of Medical Services Reimbursement, Office of Reimbursement Policy, Department of Health and Human Services, Health Care Financing Administration, Room 1-H-5 ELR, 6325 Security Blvd., Baltimore, MD 21207, 301 966-4497

RIN: 0938-AD65

### 805. CHARGES TO RESIDENTS' FUNDS IN NURSING HOMES

**Legal Authority:** PL 100-203, Sec 4201(a)(3); PL 100-203, Sec 4211(a)(3); 42 USC 1302

CFR Citation: 42 CFR 405; 42 CFR 442

Legal Deadline: NPRM, Statutory, July 1, 1988. Final, Statutory, July 1, 1989.

Abstract: This proposed rule would define those costs which may be charged to the personal funds of Medicare and Medicaid patients in nursing facilities and the costs which are to be included in the payment amount for nursing facility services.

#### Timetable:

Action	Date	FR	Cite	
NPRM	00/00/00			

Small Entitles Affected: None

Government Levels Affected: None

Agency Contact: Samuel Kidder, Chief, Long Term Care Branch, Department of Health and Human Services, Health Care Financing Administration, 429 EHR Bldg., 6325 Security Blvd., Baltimore, MD 21207, 301 966-4620

RIN: 0938-AD66

#### 806. CRITERIA FOR STANDARD AND EXTENDED HOME HEALTH AGENCY SURVEYS

**Legal Authority:** 42 USC 1395bbb(c)(d); 42 USC 1395hh; PL 100-203, Sec 4022

CFR Citation: 42 CFR 488

Legal Deadline: NPRM, Statutory, January 1, 1989. Final, Statutory, July 1, 1989.

Abstract: This regulation would implement the requirements of PL 100-203, section 4022 which specify criteria for standard and extended home health agency surveys. The regulation would define each survey and the criteria for its use. It would additionally implement a new survey instrument and a home visit process. Finally, the regulation would require a Statewide 12 month average survey cycle.

#### Timetable:

Action	Date	FR	Cite
NPRM	00/00/00		

Small Entities Affected: Undetermined

### Government Levels Affected: Undetermined

Agency Contact: Walter Merten, Director, Division of Survey Procedures and Training, Department of Health and Human Services, Health Care Financing Administration, Meadows East Building, 6325 Security Blvd., Baltimore, MD 21207, 301 966-6767

RIN: 0938-AD67

# 807. ● OUTPATIENT SURGERY AND PRE-ADMISSION DIAGNOSTIC TESTING FOR INPATIENT SURGERY UNDER MEDICAID

Significance: Regulatory Program

Legal Authority: 42 USC 1302; 42 USC 1396a(30)(A)

CFR Citation: 42 CFR 431

Legal Deadline: None

Abstract: This proposed rule would amend current Medicaid rules to require that State Medicaid plans include programs requiring preadmission review and approval for selected surgical procedures and medical treatment; identify surgical procedures that can be safely performed on an ambulatory basis; require diagnostic testing prior to admission; and schedule hospital admission on the same day as surgery.

#### Timetable:

Action	Date	FR Cite
NPRM	11/00/88	
Final Action	04/00/80	

Small Entitles Affected: Businesses Government Levels Affected: State Agency Contact: Ernestine Jones, Program Analyst, Department of Health and Human Services, Health Care Financing Administration, Room 463, EHR, 6325 Security Boulevard, Baltimore, Maryland 21207, 301 966-4646

RIN: 0938-AD70

# 808. ● CHANGES TO THE REASONABLE COST REGULATION CONCERNING INVESTMENT INCOME

Legal Authority: 42 USC 1395x(v)

**CFR Citation:** 42 CFR 413.153; 42 CFR 413.17; 42 CFR 413.130

Legal Deadline: None

Abstract: This rule proposes to revise 42 CFR 413.153(b)(2), which requires that "necessary interest" be offset by investment income. Rather than to offset interest expense by investment income, we propose to reduce (dollar for dollar) allowable debt principal related to patient care by the principal amount of investment funds generated from operations related to patient care and subsequently invested in nonpatient care activities or in another provider's patient care activities.

#### Timetable:

Action	Date	FR	Cite
NPRM	00/00/00		

Small Entities Affected: Undetermined

## Government Levels Affected: Undetermined

Agency Contact: William J. Goeller, Director, Division of Payment and Reporting Policy, Department of Health and Human Services, Health Care Financing Administration, Room 1-F-5, ELR, 6325 Security Boulevard, Baltimore, Maryland 21207, 301 966-4513

RIN: 0938-AD72

# 809. ● MEDICARE SECONDARY PAYER FOR DISABLED ACTIVE INDIVIDUALS

**Legal Authority:** 42 USC 1302; 42 USC 1395y(b); 42 USC 1395hh

CFR Citation: 42 CFR 411

Legal Deadline: None

Abstract: These rules would establish limitations on Medicare payment for services furnished to disabled "active individuals" who are also covered under a large group health plan (LGHP), and prohibit discrimination by an LGHP against such individuals.

**Proposed Rule Stage** 

Ti	m	e	ta	bl	e:

Action	Date	FR	Cite	
NPRM	11/00/88			

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Herbert Pollock, Branch Chief, Department of Health and Human Services, Health Care Financing Administration, Medicare Claims Payment Policy Branch, Room 323, EHR, 6325 Security Boulevard, Baltimore, Maryland 21207, 301 966-4474

#### 810. ● INHERENT REASONABLENESS FOR HOME DIALYSIS SUPPLIES AND EQUIPMENT

Legal Authority: 42 USC 1395u(b)(8)

CFR Citation: None

RIN: 0938-AD73

Legal Deadline: None

Abstract: This notice would establish a special reasonable charge payment limit for home dialysis equipment and supplies to prevent excessive payment for these items.

#### Timetable:

Action	Date	FR Cite
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Proposed Notice 11/00/88

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Bob Niemann, Program Analyst, Department of Health and Human Services, Health Care Financing Administration, Div. of Dialysis & Transplant Payment Policy, 1-A-5, ELR, 6325 Security Boulevard, Baltimore, Maryland 21207, 301 966-4569

RIN: 0938-AD74

# 811. ● CLARIFICATION OF DURABLE MEDICAL EQUIPMENT COVERAGE UNDER MEDICARE

Legal Authority: 42 USC 1395x; 42 USC 1395hh; 42 USC 1395k; 42 USC 1395l

CFR Citation: Not yet determined

Legal Deadline: None

Abstract: These regulations would codify longstanding policies that concern the coverage, limitations, and exclusions applicable to durable medical equipment (DME). It would describe how all items of DME must be ordered by a physician and explain the requirements necessary for an item to be considered durable.

#### Timetable:

Action	Date	FR	Cite
NPRM	00/00/00		

Small Entitles Affected: Undetermined

Government Levels Affected: Undetermined

Agency Contact: James Hannon, Chief, Physician and Other Medical, Services Branch, Department of Health and Human Services, Health Care Financing Administration, Room 479, EHR, 6325 Security Boulevard, Baltimore, Maryland 21207, 301 966-4636

RIN: 0938-AD77

#### 812. ● MEDICARE COVERAGE OF HOME HEALTH SERVICES, MEDICARE CONDITIONS OF PARTICIPATION AND HOME AIDE SUPERVISION AND DISCHARGE PLANNING

**Legal Authority:** 42 USC 1302; 42 USC 1395u; 42 USC 1395x; 42 USC 1395y; 42 USC 1395hh

**CFR Citation:** 42 CFR 405; 42 CFR 409; 42 CFR 418

Legal Deadline: None

Abstract: This proposed rule would establish home health aid supervision and duty requirements applicable to all HHA's that provide services under Medicare. In addition, these regulations would codify longstanding policies that concern the limitations and exclusions applicable to home health services under Medicare.

#### Timetable:

Action	Date	FR	Cite
NPRM	00/00/00		

Small Entities Affected: Undetermined
Government Levels Affected: None

Agency Contact: Tom Hoyer, Director, Div. of Provider Services Coverage Policy, Department of Health and Human Services, Health Care Financing Administration, 6325 Security Blvd., Room 405 EHR, Baltimore, Maryland 21207, 301 966-4607

RIN: 0938-AD78

#### 813. ● PREPAID HEALTH CARE PLANS: BENEFICIARY AND OTHER RELATED PROVISIONS

**Legal Authority:** 42 USC 1395mm; 42 USC 1302; 42 USC 1395hh; 42 USC 1395l(a)(1)(A)

**CFR Citation:** 42 CFR 405; 42 CFR 417; 42 CFR 482

Legal Deadline: None

Abstract: This proposed rule would make a number of changes to the regulations governing health maintenance organizations, competitive medical plans, and health care prepayment plans that furnish Medicare covered services to Medicare beneficiaries. These proposed changes relate to the provision of services, beneficiary and plan rights and liabilities, and contracts. Most of the changes would clarify or establish policy in areas in which operational experiences have demonstrated a need for revision. Several of the changes would implement provisions of the Omnibus Budget Reconciliation Act of

#### Timetable:

Action	Date	FR	Cite
NPRM	01/00/89		

Small Entities Affected: Undetermined

Government Levels Affected: Undetermined

Agency Contact: Joan Mahanes, Program Analyst, Div of Medical Services Coverage Policy, Department of Health and Human Services, Health Care Financing Administration, Room 463 EHR, 6325 Security Boulevard, Baltimore, Maryland 21207, 301 966-4642

RIN: 0938-AD79

# 814. ● PROHIBITIONS ON FFP FOR EDUCATIONAL AND VOCATIONAL TRAINING FOR INSTITUTIONALIZED INDIVIDUALS

**Legal Authority:** 42 USC 1302; 42 USC 1396a(a)(17)(B); 42 USC 1396a(a)(25); 42 USC 1396b(c)

CFR Citation: 42 CFR 441

Legal Deadline: None

Abstract: This proposed rule would revise and clarify the meaning of the prohibition against Federal financial participation for vocational training and educational activities in intermediate care facilities for the mentally retarded and in psychiatric facilities, or in programs providing psychiatric services to individuals under age 21.

#### Timetable:

Action	Date	 Cite
NPRM	12/00/88	

#### Small Entities Affected: None

#### Government Levels Affected: State

Agency Contact: Samuel W. Kidder, Chief, Long Term Care Branch, Department of Health and Human Services, Health Care Financing Administration, 428 EHR, 6325 Security Boulevard, Baltimore, Maryland, 301 966-4620

RIN: 0938-AD80

# 815. ● OBRA '87 LONG TERM CARE FACILITIES CONDITIONS OF PARTICIPATION

Significance: Agency Priority

Legal Authority: 42 USC 1395x; 42 USC 1395aa; 42 USC 1395i-3; PL 100-203, Sec 4201; 42 USC 1396r; PL 100-203, Sec 4211

#### CFR Citation: 42 CFR 483

#### Legal Deadline: None

Abstract: This proposed rule would implement provisions of the Omnibus Budget Reconciliation Act of 1987 (OBRA '87), PL 100-203, which long term care facilities would be required to meet to participate in the Medicare and Medicaid programs effective October 1, 1000

#### Timetable:

Action	Date	FR Cite	
NPRM	12/00/88		

Small Entities Affected: Undetermined

### Government Levels Affected: Undetermined

Agency Contact: Samuel Kidder, Chief, Long Term Care Branch, Department of Health and Human Services, Health Care Financing Administration, Room 300, EHR, 6325 Security Boulevard, Baltimore, Maryland 21207, 301 966-4620

RIN: 0938-AD81

# 816. • MEDIGAP POLICY STANDARDS - DIRECT TRANSMITTAL OF CLAIMS FROM MEDICARE CARRIERS TO MEDIGAP INSURERS AND RELATED USER FEES

Legal Authority: 42 USC 1302; 42 USC 1395ss; 42 USC 1395hh

**CFR Citation:** 42 CFR 403.206; 42 CFR 403.218; 42 CFR 403.222; 42 CFR 403.232

Legal Deadline: None

Abstract: These proposed regulations would add requirements for the direct transmittal of bills submitted for services to Part B beneficiaries by participating physicians and suppliers from Medicare carriers to Medigap insurers.

#### Timetable:

Action	Date	FR	Cite
NIDRM	11/00/88		

Small Entities Affected: Undetermined

#### Government Levels Affected: Undetermined

Agency Contact: Thomas E. Hoyer, Director, Div. of Provider Services & Coverage Policy, Department of Health and Human Services, Health Care Financing Administration, Room 405, EHR, 6325 Security Boulevard, Baltimore, Maryland 21207, 301 966-4607

RIN: 0938-AD82

#### 817. ● COVERAGE OF PSYCHOLOGISTS' SERVICES FURNISHED AT RURAL HEALTH CLINICS

Legal Authority: 42 USC 1395k(a); 42 USC 1395x(s); 42 USC 1395x(aa); 42 USC 1395hh; 42 USC 1395h

#### CFR Citation: 42 CFR 405

#### Legal Deadline: None

Abstract: This proposed notice would provide a fee schedule for services furnished by a clinical psychologist at a rural health clinic even if not furnished under the supervision of a physician. Medicare payment would be made on an assignment related basis only.

#### Timetable:

Time table.			
Action	Date		Cite
Notice	00/00/00		

Small Entities Affected: Businesses. Organizations

#### Government Levels Affected: None

Agency Contact: Stanley Katz, Director, Div. of Medical Services Coverage Policy, Department of Health and Human Services, Health Care Financing Administration, Room 489, EHR, 6325 Security Boulevard, Baltimore, Maryland 21207, 301 966-4637

RIN: 0938-AD84

## 818. ● COVERAGE OF SCREENING MAMMOGRAPHY

Legal Authority: 42 USC 1395x; 42 USC 1395m; 42 USC 1395z; 42 USC 1395aa(a); 42 USC 1395(a)(2)(E); 42 USC 1395hh; 42 USC 1395f; 42 USC 1395bb; 42 USC 1395y; 42 USC 1396a; 42 USC 1302; 42 USC 1396n

CFR Citation: Not yet determined

#### Legal Deadline: None

Abstract: This regulation would implement section 204 of Pub.L. 100-360 by providing coverage and payment standards for screening mammography, information on the frequency of coverage, and certification of quality standards.

#### Timetable:

Action	Date	FR Cite
NPRM	05/00/89	· · · · · · · · · · · · · · · · · · ·

Small Entities Affected: Undetermined

## Government Levels Affected: Undetermined

Agency Contact: Stanley Katz, Director, Div. of Medical Services Coverage Policy, Department of Health and Human Services, Health Care Financing Administration, Room 489, EHR, 6325 Security Boulevard, Baltimore, Maryland 21207, 301 966-4637

RIN: 0938-AD88

# 819. ● COVERAGE OF HOME INTRAVENOUS DRUG THERAPY SERVICES

Legal Authority: 42 USC 1395k(a)[2](A); 42 USC 1395x; 42 USC 1395k(a)[2]; 42 USC 1320c to 3(a); 42 USC 1395hh; 42 USC 1395z; 42 USC 1395aa; 42 USC 1395w; 42 USC 1395b; 42 USC 1395b; 42 USC 1395y; 42 USC 1395b; 42 USC 1395y; 42 USC 1395b;

CFR Citation: Not yet determined

#### Legal Deadline: None

Abstract: This regulation would implement section 203 of Pub.L. 100-360. In particular it would define those services which could be covered as home intravenous drug therapy services, would provide payment guidelines and would require that all home intravenous therapy services be reviewed and approved by a Peer Review Organization.

**Proposed Rule Stage** 

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Action	Date	FR	Cite
NPRM	05/00/89		

Small Entities Affected: Undetermined

#### **Government Levels Affected:** Undetermined

Agency Contact: Sam Kidder, Chief, Long Term Care Branch, Department of Health and Human Services, Health Care Financing Administration, Room 429, EHR, 6325 Security Boulevard, Baltimore, Maryland 21207, 301 966-4620

RIN: 0938-AD89

#### 820. ● IN-HOME CARE FOR CHRONICALLY DEPENDENT INDIVIDUALS

Legal Authority: 42 USC 1395x; 42 USC 1395l(a); 42 USC 1395n(a)(2); 42 USC 1395y(a); 42 USC 1302

CFR Citation: 42 CFR 408; 42 CFR 480

Legal Deadline: None

Abstract: This regulation would implement sections 205(b) through 205(e). It would define under the Medicare program covered services, eligible persons, payment guidelines, certification guidelines and standards for utilization of services for in-home care of chronically dependent individuals.

#### Timetable:

Action	Date	FR	Cite
NPRM	03/00/89		

Small Entities Affected: Undetermined

#### **Government Levels Affected:** Undetermined

Agency Contact: Tom Hoyer, Director, Div. of Provider Services Coverage Policy, Department of Health and Human Services, Health Care Financing Administration, Room 405, EHR, 6325 Security Boulevard, Baltimore, Maryland 21207, 301 966-4607

RIN: 0938-AD90

#### 821. ● OUTPATIENT DRUG **COVERAGE AND REIMBURSEMENT**

Legal Authority: 42 USC 1395x; 42 USC 1395l(b); 42 USC 1395m; 42 USC 1395t; 42 USC 1395y(c); 42 USC 1395u(f); 42 USC 1395u(b)(3); 42 USC 1395u(h)(2); 42 USC 1395mm(e)(1); 42 USC 1395cc(a)(2)(A); 42 USC 1396b(i)(5); 42 USC 1395hh; 42 USC 1395x; 42 USC 1320a-7a

CFR Citation: Not yet determined Legal Deadline: None

Abstract: This regulation would implement Sec. 202 of Pub.L. 100-360 which adds outpatient drugs as a covered service under Medicare. This regulation would provide a description of covered outpatient drugs, deductible and payment amounts and give specific guidelines on the time period a prescription would be covered.

#### Timetable:

Action	Date	FR	Cite
NPRM	04/00/89		

Small Entities Affected: Undetermined

#### Government Levels Affected: Undetermined

Agency Contact: Stanley Katz, Director, Div. of Medical Services Coverage Policy, Department of Health and Human Services, Health Care Financing Administration, Room 489, EHR, 6325 Security Boulevard, Baltimore, Maryland 21207, 301 966-4637

RIN: 0938-AD91

#### 822. • SURVEY AND CERTIFICATION

Legal Authority: 42 USC 1395aa; 42 USC 1395i-3; PL 100-203, Sec 4202; 42 USC 1396r; PL 100-203, Sec 4212

CFR Citation: 42 CFR 488 Legal Deadline: None

Abstract: This proposed rule would implement provisions of the Omnibus **Budget Reconciliation Act of 1987** (OBRA '87), Pub.L. 100-203, which govern the process used by HCFA to survey long-term care facilities, and certify that the facilities meet the conditions of participation for the Medicare and Medicaid programs.

#### Timetable:

Action	Date	FR Cite
NPRM	00/00/00	

Small Entities Affected: Undetermined

#### **Government Levels Affected:** Undetermined

Agency Contact: Wayne Smith, Director, Office of Survey and Certification, Department of Health and Human Services, Health Care Financing Administration, 6325 Security Boulevard, Baltimore, Maryland 21207, 301 966-6763

RIN: 0938-AD94

#### 823. ● RECOVERY OF OVERPAYMENTS RESULTING FROM **COMPUTATIONAL ERRORS**

Legal Authority: 42 USC 1395gg; 42 USC 1302; 42 USC 1395hh

CFR Citation: 42 CFR 405.350(a)(2); 42 CFR 405.355(a)

Legal Deadline: None

Abstract: Due to a computational errors , some physicians and beneficiaries received substantial sums of incorrect payments. This proposed rule would clarify situations where being without fault relieves a recipient of the obligation to return incorrect payments.

#### Timetable:

Action	Date	FR	Cite
NPRM	00/00/00		

Small Entities Affected: Undetermined

#### **Government Levels Affected:** Undetermined

Agency Contact: Sam Guida, Director, Division of Overpayment Prevention, Department of Health and Human Services, Health Care Financing Administration, 6325 Security Boulevard, Baltimore, Maryland 21207, 301 966-7521

RIN: 0938-AD95

#### 824. ● GRACE PERIOD AND **TERMINATION FOR NON-PAYMENT** OF SUPPLEMENTARY MEDICAL **INSURANCE (PART B) PREMIUMS** FOR INSURED PERSONS

Legal Authority: 42 USC 1395j; 42 USC 1395q; 42 USC 1395hh; 42 USC 1302

**CFR Citation: 42 CFR 408.8; 42 CFR** 

Legal Deadline: None

Abstract: Under current rules, individuals who do not pay their Part B premiums will have their coverage terminated after a grace period that allows several months lateness. The grace period for individuals eligible for monthly social security cash payments is different from that of other individuals. This proposed rule would allow a uniform 3-month grace period to treat all individuals identically.

#### Timetable:

Action	Date	FR	Cite
NPRM	00/00/00		

Small Entities Affected: None

### **Government Levels Affected: None**

Agency Contact: Paul Boerschel, Program Analyst, Bureau of Program Operations, Department of Health and Human Services, Health Care Financing Administration, Room 233, EHR, 6325

Security Boulevard, Baltimore, Maryland 21207, 301 966-5941 RIN: 0938-AD97

#### DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) Health Care Financing Administration (HCFA)

Final Rule Stage

#### 825. MISCELLANEOUS MEDICARE AND MEDICAID AMENDMENTS

Legal Authority: 42 USC 1302; 42 USC 1395hh

CFR Citation: 42 CFR 405; 42 CFR 409; 42 CFR 410; 42 CFR 416; 42 CFR 421; 42 CFR 441; 42 CFR 489

#### Legal Deadline: None

Abstract: These rules amend existing Medicare and Medicaid regulations to conform them to statutory and policy changes that have occurred since those regulations were last published. The pertinent statutory changes are primarily those contained in the Omnibus Reconciliation Act of 1980 (P.L. 96-499).

#### Timetable:

Action	Date		FR	Cite
NPRM	12/18/87	52	FR	48127
NPRM Comment Period End	02/16/88			
Final Action	00/00/00			

#### Small Entities Affected: Undetermined

#### **Government Levels Affected:** Undetermined

Agency Contact: Luisa Iglesias, Technical Assistant, Department of Health and Human Services, Health Care Financing Administration, BERC Regulations Staff, Rm. 4243 North, 300 Independence Ave., S.W., Washington, DC 20201, 202 245-0383

RIN: 0938-AB05

#### 826. WAIVER OF CERTAIN **MEMBERSHIP REQUIREMENTS FOR CERTAIN HEALTH MAINTENANCE ORGANIZATIONS (HMOS) AND STATE** OPTION FOR DISENROLLMENT RESTRICTIONS FOR CERTAIN HMOS **UNDER MEDICAID**

Legal Authority: 42 USC 1302; 42 USC 1396a(e)(2); 42 USC 1396b(m)

CFR Citation: 42 CFR 434.26; 42 CFR 434.27; 42 CFR 434.20; 42 CFR 435.212; 42 CFR 435.326

Legal Deadline: None

Abstract: This rule revises current Medicaid rules to expand the waiver authority of the Secretary to permit certain health maintenance organizations (HMOs) meeting certain requirements, to exceed the composition of enrollment limit to allow certain organizations to contract on a risk basis, to permit continuation of benefits to recipients enrolled in certain organizations after they have lost entitlement to Medicaid, and give a State the option of restricting a Medicaid enrollee's right to disenroll from certain types of risk HMOs and other organizations. These regulations would conform our regulations with authority provided in section 2364 of Pub.L. 98-369, the Deficit Reduction Act of 1984, as amended by section 9517 of Pub.L. 99-272, the Consolidated Omnibus Budget Reconciliation Act of

#### Timetable:

Action	Date		FR	Cite	
NPRM	01/12/88	53	FR	744	
NPRM Comment Period End	03/14/88	53	FR	744	
Final Action	00/00/00				

#### Small Entities Affected: None

#### **Government Levels Affected: State**

Agency Contact: Robert E. Wren, Office Director, Department of Health and Human Services, Health Care Financing Administration, Office of Coverage Policy, Room 401 EHR, 6325 Security Blvd., Baltimore, MD 21207, 301 966-5661

RIN: 0938-AB54

#### 827, MEDICARE: HEALTH MAINTENANCE ORGANIZATIONS AND **COMPETITIVE MEDICAL PLANS:** COORDINATED OPEN ENROLLMENT

Significance: Agency Priority

Legal Authority: 42 USC 1395mm(c)(3)(A)(ii); 42 USC 1302; 42 USC 1395hh

CFR Citation: 42 CFR 417 Legal Deadline: None

Abstract: These regulations will implement section 2350 of Pub. L. 98-369 by requiring that HMOs and CMPs hold coordinated open enrollment periods for Medicare beneficiaries.

#### Timetable:

Action	Date		FR	Cite	
NPRM	06/09/88	53	FR	21696	
NPRM Comment Period End	08/08/88	52	FR	21697	
Final Action	10/00/88				

Small Entitles Affected: Undetermined

#### **Government Levels Affected:**

Undetermined

Agency Contact: Stanley Katz, Division Director, Department of Health and Human Services, Health Care Financing Administration, Div. of Medical Services Coverage Policy, Room 489 EHR, 6325 Security Blvd., Baltimore, MD 21207, 301 966-4637

RIN: 0938-AB57

#### 828. INDIRECT PART B PAYMENT **PROCEDURE**

Legal Authority: 42 USC 1395u(b)(6)(B); 42 USC 1395hh: 42 USC 1302

CFR Citation: 42 CFR 424.36; 42 CFR 424.60; 42 CFR 424.66

Legal Deadline: None

Abstract: This regulation would conform existing regulations to the provisions of Pub.L. 98-369 that allows payment for services furnished under Part B of Medicare to be made to a health benefits plan.

#### Timetable:

Action	Date		FR	Cite
NPRM	07/01/86	51	FR	23792
NPRM Comment Period End	07/31/86	51	FR	23792
Final Action	10/00/88			

Small Entities Affected None

Government Levels Affected: None

Agency Contact: Paul Olenick, Division Director, Department of Health and Human Services, Health Care

Final Rule Stage

Financing Administration, Division of Medicare Eligibility, Room 448 EHR, 6325 Security Blvd., Baltimore, MD 21207, **301** 966-4472

RIN: 0938-AB59

#### 829. HOSPITAL INSURANCE ENTITLEMENT AND SUPPLEMENTARY MEDICAL INSURANCE ENROLLMENT AND FNTITI FMENT

Legal Authority: 42 USC 426; 42 USC 426-1; 42 USC 426a; 42 USC 1395c; 42 USC 1395i-2; 42 USC 1395p; 42 USC 1395q; 42 USC 1395r; 42 USC 1395v; 42 USC 1302; 42 USC 1395h

**CFR Citation:** 42 CFR 405; 42 CFR 406; 42 CFR 407

Legal Deadline: None

Abstract: This regulation will revise the Medicare rules that deal with hospital insurance entitlement and with supplementary medical insurance (SMI) enrollment and entitlement, as required by amendments to the Social Security Act. It will also revise Medicaid rules that deal with State buy-in agreements, under which States secure SMI benefits for certain Medicaid-eligible individuals, by paying their SMI premiums.

#### Timetable:

Action	Date		FR	Cite
NPRM	02/19/88	53	FR	5008
NPRM Comment Period End	04/19/88	53	FR	5008
Final Action	00/00/00			

Small Entities Affected: Undetermined

Government Levels Affected: Undetermined

Agency Contact: Denis Garrison, Chief, Medicare Eligibility and, Technical Issues Branch, Department of Health and Human Services, Health Care Financing Administration, Division of Medicare Eligibility Policy, Room 357 EHR, 6325 Security Blvd., Baltimore, MD 21207, 301 966-5643

RIN: 0938-AB60

### 830. MEDICARE/MEDICAID REVALUATION OF ASSETS

Significance: Regulatory Program

**Legal Authority:** 42 USC 1302; 42 USC 1395hh; 42 USC 1395x(v)(1)(O); 42 USC 1396a(a)(13)(B)

**CFR Citation:** 42 CFR 413.130; 42 CFR 413.134; 42 CFR 447.250; 42 CFR 447.253

Legal Deadline: None

Abstract: This final rule implements changes to the regulations as required by section 2314 of Pub. L. 98-369 and sections 9110 and 9509 of Pub. L. 99-272. This rule imposes new limitation on the valuation of assets acquired as the result of changes in ownership occurring on or after July 18, 1984. These changes will affect hospitals and skilled nursing facilities under the Medicare program and hospitals, skilled nursing facilities, intermediate care facilities, and intermediate care facilities for the mentally retarded under the Medicaid program.

#### Timetable:

Action	Date		FR	Cite
NPRM	10/26/87	52	FR	39927
NPRM Comment Period End	12/28/87	52	FR	39927
Final Action	00/00/00			

Small Entities Affected: None

**Government Levels Affected: State** 

Agency Contact: William J. Goeller, Director, Division of Payment and Reporting Policy, Department of Health and Human Services, Health Care Financing Administration, Room 1-F-5 ELR, 6825 Security Blvd., Baltimore, MD 21207, 301 966-4513

RIN: 0938-AB64

# 831. CLARIFICATION OF POLICY ON ADJUSTING THE HOSPITAL-SPECIFIC PORTION OF THE PROSPECTIVE PAYMENT RATE

Significance: Agency Priority

**Legal Authority:** 42 USC 1395ww(d); 42 USC 1302; 42 USC 1395hh

CFR Citation: 42 CFR 412.72

Legal Deadline: None

Abstract: This final rule clarifies Medicare's policy on adjusting the hospital-specific portion of the prospective payment rate for inpatient hospital services as the result of adjustments to a hospital's target amount for events occurring in the year following its base year. It clarifies that exemptions, exceptions, or adjustments granted under section 1886(b)(4) of the Act or 42 CFR 413.30 or 413.40(e)-(h) for periods subsequent to the base year have no effect on the hospital-specific

portion of the prospective payment rates.

#### Timetable:

Action	Date		FR	Cite	
NPRM	03/10/86	51	FR	8208	
NPRM Comment Period End	04/19/86	51	FR	8208	
Final Action	00/00/00				

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Edward Rees, Branch Chief, Department of Health and Human Services, Health Care Financing Administration, Payment Determination Policy Branch, DHPP, R. 1-H-1 ELR, 6325 Security Blvd., Baltimore, MD 21207, 301 966-4536

RIN: 0938-AB71

#### 832. REVISION OF MEDICAID ELIGIBILITY QUALITY CONTROL (MEQC) PROGRAM REQUIREMENTS

Significance: Regulatory Program

Legal Authority: 42 USC 1396b; 42 USC 1302

**CFR Citation:** 42 CFR 431.800 to 431.808; 42 CFR 431.810 to 431.822; 42 CFR 431.830 to 431.836; 42 CFR 431.861 to 431.865

Legal Deadline: None

Abstract: This final rule revises the regulations governing the Medicaid eligibility quality control (MEQC) program to include more specified program requirements and to establish new time frames for completing and reporting MEQC case findings to HCFA. The final rule also establishes a performance-based threshold for States to meet before HCFA will consider good faith waiver requests of disallowance of Federal financial participation in erroneous Medicaid payments and provides more definitive criteria for evaluating States good faith efforts to meet the national standard error rate. In addition, the rule makes several technical changes and specifies that States may rebut their quarterly projected error rates when they can present evidence that the projected rates were based on erroneous data. The revisions will strengthen the MEQC program and provide flexibility and incentives to States to produce more accurate Medicaid eligibility determinations.

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Action	Date		FR	Cite
NPRM	01/26/87	52	FR	02733
NPRM Comment Period End	03/27/87	52	FR	02733
Final Action	00/00/00			

Small Entitles Affected: None

**Government Levels Affected: State** 

Agency Contact: Randolph Graydon, Acting Director, Division of Program Performance, Department of Health and Human Services, Health Care Financing Administration, Bureau of Quality Control, 207-L ELR, 6325 Security Blvd., Baltimore, MD 21207, 301 966-3294

RIN: 0938-AB85

# 833. MEDICARE SECONDARY PAYOR AND MEDICARE RECOVERY AGAINST THIRD PARTIES

Significance: Regulatory Program Legal Authority: 42 USC 1302; 42 USC 1395y(b); 42 USC 1395hh

**CFR Citation:** 42 CFR 405; 42 CFR 411; 42 CFR 489

Legal Deadline: None

Abstract: This rule revises regulations to reflect recent statutory provisions regarding HCFA's right to bring an action directly against certain third parties or to join or intervene in an action against a third party. It would also place certain requirements on hospitals regarding the identification and billing of potential Medicare secondary payor cases. Additionally, it would include requirements regarding timely refunds to Medicare when collections have been made from another insurer. It also clarifies rules for Medicare payment for services furnished to an end-stage renal disease (ESRD) patient who is also covered under an employer group health plan. It would include the changes pertaining to Medicare conditional payments for ESRD beneficiaries made by section 4036(a) of the Omnibus Budget Reconciliation Act of 1987. It would update policies pertaining to Medicare payment for services covered under a workers' compensation law or plan, or under no-fault or liability insurance. It would make Medicare secondary to all kinds of no-fault insurance, not just automobile no-fault insurance.

#### Timetable:

Action Date			FR	Cite
NPRM	06/15/88	53	FR	22335
NPRM Comment Period End	08/15/88			
Final Action	12/00/88			

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Herbert Pollock, Branch Chief, Department of Health and Human Services, Health Care Financing Administration, Medicare Claims Payment Policy Branch, Rm. 323 EHR, 6325 Security Blvd., Baltimore, MD 21207, 301 966-4474

RIN: 0938-AC05

834. MEDICARE COVERAGE OF HEPATITIS B VACCINE FOR HIGH AND INTERMEDIATE RISK INDIVIDUALS, HEMOPHILIA CLOTTING AND CERTAIN X-RAY SERVICES

Legal Authority: 42 USC 1395x(s)(2)(I); 42 USC 1395x(s)(10)(B); 42 USC 1395l(k); 42 USC 1395l(r); 42 USC 1395r(b)(11); 42 USC 1302; 42 USC 1395(g); 42 USC 1395l; 42 USC 1395u; 42 USC 1395u; 42 USC 1395c; 42 USC 1395c; 42 USC 1395p; 42 USC 1395h); 42 USC 1395pp

CFR Citation: 42 CFR 405.231(r); 42 CFR 405.232(b); 42 CFR 405.232(c); 42 CFR 405.310(a); 42 CFR 405.310(e); 42 CFR 405.310(k); 42 CFR 410.10; 42 CFR 410.29; 42 CFR 410.32; 42 CFR 410.63

Legal Deadline: None

Abstract: This final rule implements section 2323 of P.L 98-369 which provides Medicare coverage for hepatitis B vaccine for those individuals who are eligible for Medicare and at high or intermediate risk of contracting hepatitis B. It would implement section 2324 of P.L. 98-369 that provides coverage for the self-administration of hemophilia clotting factors and the items necessary for their administration to Medicare eligibles. The final rule would also clarify Medicare coverage of certain x-ray services.

#### Timetable:

Action	Date		FR	Cite
NPRM	09/10/87	52	FR	34244
NPRM Comment Period End	11/09/87	52	FR	34244
Final Action	00/00/00			

Small Entitles Affected: None

Government Levels Affected: None

Agency Contact: James Hannon, Chief, Physician and Other Medical Services Branch, Department of Health and Human Services, Health Care Financing Administration, Office of Coverage Policy, Rm. 479 EHR, 6325 Security Blvd., Baltimore, MD 21207, 301 966-4636

RIN: 0938-AC07

#### 835. MEDICAID: ELIGIBILITY DETERMINATIONS BASED ON DISABILITY

**Legal Authority:** 42 USC 1396a(a)(10); 42 USC 1396d(a); 42 USC 1302

**CFR Citation:** 42 CFR 435.541; 42 CFR 435.911; 42 CFR 436.541

Legal Deadline: None

**Abstract:** These regulations make explicit in the regulations HCFA's policy on the relationship between State Medicaid eligibility determinations based on disability and disability determinations by SSA under the Supplemental Security Income Program. The regulations incorporate the conditions under which the State agency must make independent determinations of disability and the effect of only SSA determination on Medicaid eligibility. The regulations also conform the Medicaid provisions on composition of medical review teams, required information, and the time limit for making determinations more closely to those used by SSA in making SSI determinations. Because of numerous questions raised and litigation, it is necessary to clarify our policy on the controlling nature of SSI disability determinations on Medicaid eligibility.

#### Timetable:

Action	Date		FR	Cite
NPRM	12/14/87	52	FR	47414
NPRM Comment Period End	02/12/88	52	FR	47414
Final Action	00/00/00			

**Small Entities Affected: None** 

Government Levels Affected: Local, State, Federal

Agency Contact: Marinos Svolos, Director, Division of Medicaid Eligibility Policy, Department of Health and Human Services, Health Care Financing Administration, 436 East High

Final Rule Stage

Rise Bldg., 6325 Security Blvd., Baltimore, MD 21207, 301 966-4451

RIN: 0938-AC31

836. EFFECT OF APPEALS ON HOSPITAL-SPECIFIC PORTION OF THE PROSPECTIVE PAYMENT RATE

Significance: Agency Priority

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

**CFR Citation:** 42 CFR 412.71; 42 CFR 412.72; 42 CFR 412.73; 42 CFR 412.76; 42 CFR 412.128

Legal Deadline: None

Abstract: This final rule amends and clarifies the prospective payment regulations governing administrative and judicial review of payment amounts in order to resolve confusion concerning interpretation of those regulations. In particular, the rule amends and clarifies the provisions pertaining to adjustment of the hospital-specific rate under the prospective payment system.

#### Timetable:

Action	Date		FR	Cite
NPRM	06/13/88	53	FR	22028
NPRM Comment Period End	08/12/88	53	FR	22028
Final Action	00/00/00			

Small Entities Affected: Businesses

Government Levels Affected: Local, State

Agency Contact: Edward Rees, Branch Chief, Department of Health and Human Services, Health Care Financing Administration, Payment Determination Policy Branch, Rm. 1-H-1 ELR, 6325 Security Blvd., Baltimore, MD 21207, 301 966-4536

RIN: 0938-AC40

837. ADDITIONS TO AND DELETIONS FROM CURRENT LIST OF COVERED SURGICAL PROCEDURES FOR AMBULATORY SURGICAL CENTERS

Significance: Regulatory Program

Legal Authority: 42 USC 1395l(i)(1)

CFR Citation: 42 CFR 416.65

Legal Deadline: None

Abstract: This notice announces additions to and deletions from the current list of surgical procedures for which facility services are covered when the procedures are performed in an ambulatory surgical center (ASC).

#### Timetable:

Action	Date	FR Cite
Proposed Notice Comment period ends	08/11/87 10/13/87	52 FR 29729
Final Notice	00/00/00	

Small Entitles Affected: None

Government Levels Affected: None

Agency Contact: Stan Katz, Director, Division of Medical Services Coverage Policy, Department of Health and Human Services, Health Care Financing Administration, 489 East High Rise Bldg., 6325 Security Blvd., Baltimore, MD 21207, 301 966-4637

RIN: 0938-AC45

838. EMPLOYERS CONTRIBUTION TO HEALTH MAINTENANCE ORGANIZATIONS OPTION

Significance: Regulatory Program Legal Authority: 42 USC 300e-9

CFR Citation: 42 CFR 417.157

Legal Deadline: None

Abstract: This final rule will revise the requirement regarding employer contributions to a Health Maintenance Organization employee benefit plans.

#### Timetable:

Action	Date		FR	Cite
NPRM	01/13/87	52	FR	01343
NPRM Comment Period End	03/16/87			
Final Action	12/00/88			

Small Entitles Affected: None

Government Levels Affected: None

Additional Information: \*The Regulatory Program of the United States Government 1987-1988 projected final publication in July, 1987.

Agency Contact: Larry Sobel, Legal Adviser, Office of Prepaid Health Care, Department of Health and Human Services, Health Care Financing Administration, 423H HHH Bldg., 200 Independence Ave., SW, Washington, DC 20201, 202 245-0197

RIN: 0938-AC48

839. HOME AND COMMUNITY-BASED SERVICES AND RESPIRATORY CARE FOR VENTILATOR-DEPENDENT INDIVIDUALS

Legal Authority: 42 USC 1302; 42 USC 1396n(c)

CFR Citation: 42 CFR 435.726; 42 CFR 435.735; 42 CFR 440.180; 42 CFR 441.301; 42 CFR 441.302; 42 CFR 441.303; 42 CFR 441.305; 42 CFR 441.306; 42 CFR 441.307; 42 CFR 441.308; 42 CFR 441.310; 42 CFR 440.185; 42 CFR 440.250

Legal Deadline: None

Abstract: This rule revises the regulations for home and community based services as required by section 9502 of Pub.L. 99-272 and sections 9408 and 9411 of Pub.L. 99-509. Also, this rule would provide for respiratory care services as medical assistance under the State plan, in accordance with section 9408 of Pub.L. 99-509.

#### Timetable:

Action	Date		FR	Cite	
NPRM	06/01/88	53	FR	19950	
NPRM Comment Period End	07/31/88	53	FR	19950	
Final Action	00/00/00				

Small Entities Affected: None

Government Levels Affected: Local, State

Agency Contact: Thomas Hoyer, Director, Division of Provider Services Coverage Pol., Department of Health and Human Services, Health Care Financing Administration, Room 405 EHR, 6325 Security Blvd., Baltimore, MD 21207, 301 966-4607

RIN: 0938-AC55

840. BILLING AND VERIFICATION ADD-ON RELATING TO HOME HEALTH AGENCIES COST PER VISIT

**Legal Authority:** 42 USC 1395x(v)(1)(A); 42 USC 1395x(v)(1)(L)

CFR Citation: 42 CFR 413.30

Legal Deadline: None

Abstract: This notice responds to the public comments we received concerning the billing and verification add-on factors that were included in the two schedules of limits on home health agency costs that were published in the Federal Register on July 7, 1987 (52 FR 25562). The first schedule of limits was applicable to cost reporting periods beginning on or after July 1,

1986 but before July 1, 1987, and the second to cost reporting periods beginning on or after July 1, 1987.

#### Timetable:

Action	Date		FR	Cite
Final notice for comments	07/07/87	52	FR	25562
Comment period ends	09/08/87	52	FR	25562
Final	10/00/88			

Small Entitles Affected: Undetermined

### Government Levels Affected: Undetermined

Agency Contact: William J. Goeller, Director, Division of Payment and Reporting Policy, Department of Health and Human Services, Health Care Financing Administration, Room 1-F-5 ELR, 6325 Security Blvd, Baltimore, MD 21207, 301 966-4513

RIN: 0938-AC56

#### 841. REIMBURSEMENT FOR PHYSICIAN'S OUTPATIENT MAINTENANCE DIALYSIS SERVICES

Legal Authority: 42 USC 1395rr; 42 USC 1302; 42 USC 1395hh

**CFR Citation:** 42 CFR 405.439(c)(5); 42 CFR 405.502(f)(1); 42 CFR 405.542(a); 42 CFR 405.542(b); 42 CFR 405.542(c)

#### Legal Deadline: None

Abstract: This rule is necessitated by a court decision requiring the Secretary to reinstate a modified version of the initial method of reimbursement for physician's dialysis services. We also are clarifying and modifying some of the principles of the monthly capitation payment method. In addition, we will clarify that physician's services reimbursable under both the initial method and the monthly capitation payment must meet the general program requirements for dialysis services furnished to patients.

#### Timetable:

Action	Date		FR	Cite
NPRM	10/05/87	52	FR	37176
NPRM Comment Period End	12/04/87	52	FR	37176
Final Action	00/00/00			

Small Entitles Affected: None

#### **Government Levels Affected: None**

Agency Contact: Robert Niemann, Program Analyst, Reimbursement Policy Branch, Department of Health and Human Services, Health Care Financing

Administration, 1-A-5 EHR Bldg., 6325 Security Blvd., Baltimore, MD 21207, 301 966-4569

RIN: 0938-AC57

#### 842. PARTICIPATION IN CHAMPUS AND CHAMPVA, HOSPITAL ADMISSIONS FOR VETERANS, DISCHARGE RIGHTS NOTICE, AND HOSPITAL RESPONSIBILITY FOR EMERGENCY CARE

Significance: Agency Priority

**Legal Authority:** 42 USC 1395x; 42 USC 1395cc; 42 USC 1395dd; 42 USC 1395hh; 42 USC 1302

CFR Citation: 42 CFR 405.1903; 42 CFR 489.20; 42 CFR 489.24; 42 CFR 489.25; 42 CFR 489.26; 42 CFR 489.27; 42 CFR 489.53; 42 CFR 1001.202; 42 CFR 1001.203; 42 CFR 1001.211; 42 CFR 1001.221; 42 CFR 1003.100; 42 CFR 1003.101; 42 CFR 1003.103; ...

#### Legal Deadline: None

Abstract: This final rule will implement sections 9121 and 9122 of PL 99-272 as amended by PL 100-203. Specifically, under section 9121, Medicare participating hospitals with emergency departments would be required to provide upon request medical examinations and treatments for individuals with emergency medical conditions and women in active labor. Hospitals failing to meet those requirements may have their Medicare provider agreements suspended or terminated. In addition, the hospital and the responsible physician may each be subject to a civil money penalty for each such violation. Under section 9122, Medicare participating hospitals would be required to accept CHAMPUS and CHAMPVA payment as payment in full for services provided to CHAMPUS and CHAMPVA beneficiaries. These regulations will also implement section 233 of PL 99-576, which requires Medicare hospitals to admit veterans. They will also implement section 9305(b)(1) of PL 99-509, which requires Medicare hospitals to give patients a notice of their discharge rights.

#### Timetable:

Action	Date	FR	Cite
NPRM	06/16/88	53 FR	22513
NPRM Comment Period End	08/15/88	53 FR	22513
Final Action	12/00/88		

Small Entitles Affected: Businesses

**Government Levels Affected: None** 

Agency Contact: Thomas Hoyer, Director, Div. of Provider Services & Coverage Policy, Department of Health and Human Services, Health Care Financing Administration, Room 405 EHR Bldg., 6325 Security Blvd., Baltimore, MD 21207, 301 966-4607

RIN: 0938-AC58

#### 843. PAYMENT FOR KIDNEYS SENT TO FOREIGN COUNTRIES OR TRANSPLANTED IN PATIENTS OTHER THAN MEDICARE BENEFICIARIES

Legal Authority: 42 USC 1395rr; 42 USC 1302; 42 USC 1395hh

**CFR Citation: 42 CFR 413.179** 

Legal Deadline: None

Abstract: These regulations will exclude from Medicare payments made to organ procurement organizations the costs associated with kidneys sent to foreign countries or transplanted in patients other than Medicare beneficiaries.

#### Timetable:

Action	Date		FR	Cite
NPRM	03/02/88	53	FR	6672
NPRM Comment Period End	05/02/88	53	FR	6672
Final Action	11/00/88			

Small Entitles Affected: None

**Government Levels Affected: None** 

Agency Contact: Mark Horney, Program Analyst, Office of Reimbursement Policy, Department of Health and Human Services, Health Care Financing Administration, 1-A-5 ELR, 6325 Security Boulevard, Baltimore, MD 21207, 301 966-4554

RIN: 0938-AC59

#### 844. STATE PLAN REQUIREMENTS AND OTHER PROVISIONS RELATING TO STATE THIRD-PARTY LIABILITY PROGRAMS

Significance: Agency Priority

**Legal Authority:** 42 USC 1396a(a)(25); 42 USC 1302

**CFR Citation:** 42 CFR 433.138; 42 CFR 433.139; 42 CFR 447.20; 42 CFR 447.21

Legal Deadline: Final, Statutory, October 7, 1986.

Section 9503 of Pub. L. 99-272 (April 7, 1986) requires that final regulations be

published within 6 months after date of enactment.

Abstract: This rule implements, in part, those portions of sec. 9503 of Pub. L. 99-272 that set forth State plan requirements and other provisions relating to State third-party liability (TPL) programs. The provisions deal with (1) the integration of a State's pursuit of third-party claims with its Mechanized Claims Processing and Information Retrieval Systems and the Secretary's responsibility to develop performance standards to assess TPL collection efforts with respect to this integration; (2) certain exceptions to the cost avoidance method of claims payment in TPL situations; and (3) provider restrictions and provider penalties related to attempts at collection of cost sharing or portions of those amounts from Medicaid recipients when third party liability has been established.

#### Timetable:

Action	Date		FR	Cite
NPRM	03/03/87	52	FR	06350
NPRM Comment Period End	04/02/87	52	FR	06350
Final Action	00/00/00			

Small Entities Affected: None

**Government Levels Affected: State** 

Agency Contact: Sue Knefley, Program Analyst, Bureau of Quality Control, Department of Health and Human Services, Health Care Financing Administration, Third Party Liability Branch, 233 EHR, 6325 Security Blvd., Baltimore, MD 21207, 301 966-3396

RIN: 0938-AC64

#### 845. MEDICAID ELIGIBILITY FOR QUALIFIED SEVERELY IMPAIRED INDIVIDUALS

Legal Authority: 42 USC 1302; 42 USC 1396a(f); 42 USC 1396a(10)(A)(i)(II); 42 USC 1396a(O); 42 USC 1396d(q); 42 USC 1382h: 42 USC 1382h note; 42 USC 1396a note

**CFR Citation:** 42 CFR 435.120; 42 CFR 435.121; 42 CFR 435.725; 42 CFR 435.733

Legal Deadline: None

Abstract: This final rule amends the Medicaid regulations to specify for Medicaid, mandatory categorically needy eligibility for individuals who, although severely impaired, work and demonstrate ability to perform substantial gainful activity and who are

considered to be Supplemental Security Income (SSI) beneficiaries by virtue of 1619 of the Act. It also specifies how States electing the option under Section 1902 to provide Medicaid under criteria more restrictive than SSI, will treat the "1619" individuals. It also specifies how SSI payments made to certain institutionalized individuals are to be disregarded as income under Medicaid for up to two months. The amendments conform the regulations to provisions of the Omnibus Budget Reconciliation Act of 1986 and the Employment Opportunities for Disabled Americans Act.

#### Timetable:

Action	Date		FR	Cite
NPRM	05/04/88	53	FR	15857
NPRM Commen Period End	t 07/05/88	53	FR	15857
Final Action	00/00/00			

Small Entities Affected: None

**Government Levels Affected:** Local. State

Agency Contact: Richard Strauss, Program Analyst, Division of Medicaid Eligibility Policy, Department of Health and Human Services, Health Care Financing Administration, Room 448 East High Rise Bldg., 6325 Security Blvd., Baltimore, MD 21207, 301 966-

RIN: 0938-AC82

#### 846. REFUNDING OF FEDERAL SHARE OF OVERPAYMENTS MADE TO MEDICAID PROVIDERS

Legal Authority: 42 USC 1396b(d)

**CFR Citation:** 42 CFR 433.32 to 35; 42 CFR 433.112; 42 CFR 433.116; 42 CFR 433.300 to 322

Legal Deadline: None

Abstract: These regulations specify the requirements and procedures under which States are allowed 60 days following the date of discovery of an overpayment to a Medicaid provider to recover or attempt to recover the overpayment before the Federal share must be credited to HCFA. The Federal Government will share in any overpayments that the State documents it is unable to recover because the debts of the provider have been discharged in bankruptcy or the provider is out-of-business. The regulations, which implement section 9512 of the Consolidated Omnibus

Budget Reconciliation Act of 1986, are intended to aid in recovering improperly spent Federal funds expeditiously.

#### Timetable:

Action	Date		FR	Cite
NPRM	12/21/87	52	FR	48290
NPRM Comment Period End	02/09/88			
Final Action	00/00/00			

Small Entities Affected: None

**Government Levels Affected: State** 

Agency Contact: David Greenberg, Program Analyst, Bureau of Quality Control, Department of Health and Human Services, Health Care Financing Administration, Room 300 Meadows East Bldg., 6300 Security Blvd., Baltimore, MD 21207, 301 966-3278

RIN: 0938-AC83

## 847. MEDICARE COVERAGE OF IMMUNOSUPPRESSIVE DRUGS

Significance: Regulatory Program

**Legal Authority:** 42 USC 1395x(s)(2)(J); 42 USC 1302

**CFR Citation:** 42 CFR 410.10; 42 CFR 410.29; 42 CFR 410.65

Legal Deadline: None

Abstract: This rule will implement section 9335(c) of Pub.L. 99-509 which authorizes Medicare coverage of immunosuppressive drugs for a period of 1-year following a Medicare-covered organ transplant. Current regulations reflect the statutory exclusion from Medicare Part B coverage of drugs or biologicals that can be selfadministered. The regulations will be amended to reflect the new statutory requirement. Final regulation will also implement section 4075 of P.L. 100-203. which expanded coverage from "immunosuppressive drugs" to "prescription drugs used in immunosuppressive therapy."

#### Timetable:

Action	Date		FR	Cite
NPRM NPRM Comment	01/19/88 03/21/88	53	FR	1383
Period End Final Action	00/00/00			

Small Entities Affected: Undetermined

Government Levels Affected: Undetermined

Final Rule Stage

Agency Contact: James Hannon, Chief, Physician & Other Medical Services Branch, Department of Health and Human Services, Health Care Financing Administration, Room 479 East High Rise, 6325 Security Blvd., Baltimore, MD 21207, 361 966-4636

RIN: 0938-AD09

848. REVISIONS TO CONDITIONS OF PARTICIPATION FOR HOSPITALS AND CONDITIONS FOR COVERAGE OF SERVICES OF INDEPENDENT LABORATORIES AND SUPPLIERS OF ESRD SERVICES

Significance: Regulatory Program

**Legal Authority:** 42 USC 1395x(e)(6)(B); PL 99-509, Sec 9339(d); 42 USC 1395x(ee); 42 USC 1302; 42 USC 1395hh

**CFR Citation:** 42 CFR 405.1312; 42 CFR 482.21; 42 CFR 405.2135; 42 CFR 405.2137; 42 CFR 482.27; 42 CFR 482.43

Legal Deadline: None

Abstract: These revisions will (a) require hospitals to provide a discharge planning process; and (b) allow a laboratory director to meet State standards for qualifications, rather than federal, if they differ. These revisions will conform our regulations with requirements of Pub.L. 99-509.

#### Timetable:

Action	Date		FR	Cite
NPRM	06/16/88	53	FR	22506
NPRM Comment Period End	08/15/88	53	FR	22506
Final Action	00/00/00			

Small Entitles Affected: None

Government Levels Affected: None

Agency Contact: Robert Wren, Director, Office of Coverage Policy, Department of Health and Human Services, Health Care Financing Administration, Room 401 East High Rise, 6325 Security Blvd., Baltimore, MD 21207, 301 966-5661

RIN: 0938-AD11

### 849. CONDITIONS OF PARTICIPATION FOR LONG TERM CARE FACILITIES

Significance: Regulatory Program

**Legal Authority:** 42 USC 1395x(j); 42 USC 1396a(a)(28); 42 USC 1396d(c); 42 USC 1302; 42 USC 1395hh

**CFR Citation:** 42 CFR 442.1; 42 CFR 442.30; 42 CFR 442.100; 42 CFR 442.101; 42 CFR 442.105; 42 CFR 442.300 to

442.346; 42 CFR 442.250 to 442.254; 42 CFR 483.1 to 483.75

Legal Deadline: None

Abstract: In this final rule we respond to comments on our proposal and incorporate a number of selfimplementing changes to the statute made by the Omnibus Budget Reconciliation Act of 1987, which was enacted after the proposed rule was published. These conditions would replace the existing separate conditions for SNFs participating in the Medicare program, and SNFs and ICFs participating in the Medicaid program. Although some essential distinctions imposed by the statute remain, these new conditions reflect common needs in SNFs and ICFs. The purpose of these revisions is to focus on actual facility performance in meeting residents' needs in a safe and healthful environment, rather than on the capacity of a facility to provide appropriate services. The results of this change in focus will be to enforce requirements from the perspective of quality of care and life for long term care patients, not only under Medicare and Medicaid, but generally since most of these requirements pertain to all patients of an SNF or ICF. These revisions are also expected to simplify Federal enforcement by using a single set of conditions for those activities we identify as common to all facilities.

#### Timetable:

Action	Date		FR	Cite
NPRM	10/16/87	52	FR	38582
NPRM Comment Period End	01/14/88	52	FR	38582
Final Action	10/00/88			

**Small Entitles Affected:** Businesses, Organizations

Government Levels Affected: Undetermined

Agency Contact: Samuel Kidder, Chief, Long Term Care Branch, Department of Health and Human Services, Health Care Financing Administration, Room 300 East High Rise, 6325 Security Blvd., Baltimore, MD 21207, 301 966-4620

RIN: 0938-AD12

## 850. EXPLANATION OF RIGHTS AND OTHER HMO/CMP PROVISIONS

**Legal Authority:** 42 USC 1395mm; PL 99-509, Sec 9312(a); 42 USC 1302; 42 USC 1395hh; PL 100-203, Sec 4011(b)

CFR Citation: 42 CFR 417.413; 42 CFR 417.428; 42 CFR 417.436; 42 CFR 417.436; 42 CFR 417.448; 42 CFR 417.460; 42 CFR 417.640; 42 CFR 417.494; 42 CFR 417.444; 42 CFR 417.597

Legal Deadline: None

Abstract: This rule revises Medicare regulations to repeal the "two-for-one" rule for Medicare enrollees; expand required information and require annual notice of HMO/CMP enrollees rights; and add a provision to terminate a contract for noncompliance pertaining to restrictions on waivers of 50 percent for Medicare enrollment. These revisions implement provisions of the Omnibus Budget Reconciliation Act of 1986, provisions of the Omnibus Budget Reconciliation Acts of 1986 and 1987.

#### Timetable:

Action	Date	FR Cite
NPRM	07/22/88	53 FR 27718
NPRM Comment Period End	09/20/88	53 FR 27718
Final Action	00/00/00	

Small Entities Affected: Businesses, Organizations

Government Levels Affected: None

Agency Contact: Joan Mahanes, Program Analyst, Office of Coverage Policy, Department of Health and Human Services, Health Care Financing Administration, Room 463 East High Rise Bldg., 6325 Security Blvd., Baltimore, MD 21207, 301 966-4642

RIN: 0938-AD14

#### 851. DISCONTINUATION OF PREVAILING CHARGE DIFFERENTIALS FOR SPECIALISTS

Legal Authority: 42 USC 1395u(b)(3) CFR Citation: 42 CFR 405.504(b)

Legal Deadline: None

Abstract: This notice requests comments on a possible change to the regulations that govern determinations of the reasonable charges that Medicare pays for physician services. We are considering discontinuing the establishment of separate prevailing charge screens for physicians' services based on specialty practice, with the possible exception of specified medical visits and consultations.

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Action	Date		FR	Cite
Notice of Request For Comments	04/12/88	53	FR	12037
Comment period ends	06/13/88	53	FR	12037

**Next Action Undetermined** 

Small Entities Affected: Undetermined

### Government Levels Affected: Undetermined

Agency Contact: Bernard Patashnik, Director, Division of Medical Services, Reimbursement, Department of Health and Human Services, Health Care Financing Administration, Rm. 1-H-5 ELR, 6325 Security Blvd., Baltimore, MD. 21207, 301 966-4497

RIN: 0938-AD26

### 852. CHANGES TO PEER REVIEW ORGANIZATION REGULATIONS

**Legal Authority:** 42 USC 1395y(a); 42 USC 1320(c); 42 USC 1395hh; 42 USC 1396a(a)(30)

**CFR Citation:** 42 CFR 405.310; 42 CFR 431.630; 42 CFR 433.15; 42 CFR 434.53; 42 CFR 456.2; 42 CFR 456.650; 42 CFR 462.101; 42 CFR 462.102; 42 CFR 462.106; 42 CFR 462.107; 41 CFR 466.71; 42 CFR 466.76; 42 CFR 466.78; 42 CFR 466.83; 42 CFR 466.93; ...

#### Legal Deadline: None

Abstract: This rule sets forth several changes to the Medicare regulations governing Peer Review Organizations. Some of these changes are the result of the passage of the Consolidated Omnibus Budget Reconciliation Act of 1985 and the Omnibus Budget Reconciliation Act of 1986. Other changes are of a technical nature and are intended to clarify and correct existing regulations on the Peer Review Organization Program. The rule also sets forth the policy for reimbursement of costs incurred by hospitals for photocopying medical records needed by PROs during offsite reviews.

#### Timetable:

Action	Date		FR	Cite	
NPRM	03/16/88	53	FR	8654	
NPRM Comment Period End	05/16/88	53	FR	8654	
Final Action	00/00/00				

Small Entitles Affected: None

#### Government Levels Affected: Undetermined

Agency Contact: Richard Husk, Director, Office of Medical Review, Department of Health and Human Services, Health Care Financing Administration, Rm. 2-D-2 Meadows East Bdlg., 6325 Security Blvd., Baltimore, MD. 21207, 301 966-6850

RIN: 0938-AD38

# 853. MEDICARE, MEDICAID, AND CLINICAL LABORATORIES IMPROVEMENT ACT (CLIA) PATIENT CONFIDENTIALITY RULES

**Legal Authority:** 42 USC 216; 42 USC 1302; 42 USC 1395x; 42 USC 1395hh

**CFR Citation:** 42 CFR 74; 42 CFR 405; 42 CFR 441

#### Legal Deadline: None

Abstract: This rule eliminates the requirement that a laboratory maintain the name and other identification of individuals undergoing testing to determine the presence of the Human Immunodeficiency Virus (HIV) antibody or causative agent, if the laboratory is not seeking Medicare or Medicaid payment for these tests.

#### Timetable:

Action	Date		FR	Cite
NPRM	03/31/88	53	FR	10404
NPRM Comment Period End	05/31/88	53	FR	10404
Interim Final Rule	00/00/00			

#### Small Entities Affected: None

#### Government Levels Affected: None

Agency Contact: Mike Goldman, Chief, Laboratory and Ambulatory Branch, Department of Health and Human Services, Health Care Financing Administration, 2D2 Meadows East, 6300 Security Blvd., Baltimore, MD 21207, 301 966-6813

RIN: 0938-AD40

#### 854. HOME HEALTH AGENCIES: CONDITIONS OF PARTICIPATION AND REDUCTION IN RECORDKEEPING REQUIREMENTS

Significance: Regulatory Program

**Legal Authority:** 42 USC 1302; 42 USC 1395x; 42 USC 1395hh; 42 USC 1395bbb

CFR Citation: 42 CFR 484

Legal Deadline: Final, Statutory, October 1, 1988. Minimum standards for home health

aide training and competency evaluation programs must, pursuant to P.L. 100-203, be established by October 1 1988

Abstract: These regulations specify requirements for home health agencies for: protecting and promoting patient rights; training and competency of home health aides; notifying State entities responsible for the licensing or certification of HHAs of changes in ownership, managing employees, and managing organizations; including an individual's plan of care as part of the individual's clinical records; and operating and furnishing services in compliance with accepted professional standards and principles that apply to professionals furnishing home health services.

#### Timetable:

Action	Date	FR Cite
Final With Comment Period	10/01/88	

## Small Entities Affected: None Government Levels Affected: None

Agency Contact: Thomas Hoyer, Director, Division of, Provider Services Coverage Policy, Department of Health and Human Services, Health Care Financing Administration, Room 405, EHR, 6325 Security Blvd, Baltimore, MD 21207, 301 966-4607

RiN: 0938-AD45

#### 855. SCHEDULES OF LIMITS ON HOME HEALTH AGENCY COSTS PER VISIT FOR COST REPORTING PERIODS BEGINNING ON OR AFTER JULY 1, 1988

Significance: Agency Priority

Legal Authority: 42 USC 1395hh; 42 USC 1302; 42 USC 1395x(v)(1)(A); 42 USC 1395x(v)(1)(L)

CFR Citation: 42 CFR 413.30

**Legal Deadline:** Final, Statutory, July 1, 1989.

Pub.L. 100-360 requires the development of a wage index based on wage data from HHAs by July 1, 1989.

**Abstract:** This final notice with comment period set forth an updated schedule of limits on home health agency costs that may be reimbursed

under the Medicare program. This updated schedule of limits will be applicable to cost reporting periods beginning on or after July 1, 1988.

#### Timetable:

Action	Date	FR	Cite

Final Notice With 10/00/88 Comment

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: William J. Goeller, Director, Division of Payment and Reporting, Department of Health and Human Services, Health Care Financing Administration, 1-F-5 ELR, 6325 Security Blvd., Baltimore, MD 21207, 301 966-4513

RIN: 0938-AD47

#### 856. CHANGES TO THE INPATIENT HOSPITAL PROSPECTIVE PAYMENT SYSTEM AND FISCAL YEAR 1989 RATES

Significance: Regulatory Program

Legal Authority: 42 USC 1395ww; 42 USC 1302; 42 USC 1395hh

**CFR Citation:** 42 CFR 405; 42 CFR 412; 42 CFR 413

Legal Deadline: Final, Statutory, October 1, 1988.

In accordance with 42 USC 1395ww an NPRM must be published by 06/01/88. Final rule must be published by 09/01/88.

Abstract: This final rule makes revisions to the inpatient hospital prospective payment system. It also includes changes in the methods, amounts and factors used to determine the prospective payment rates applicable to discharges occurring during FY 1989. In addition, this final rule implements relevant provisions of both PL 100-203 that are applicable to discharges occurring during FY 1988 and 1989 and Pub. L. 100-360 that are applicable to discharges occurring during FY 1989. This rule also finalizes miscellaneous changes proposed on March 22, 1988 (53 FR 9337).

#### Timetable:

Action	Date		FR	Cite
NPRM	05/27/88	53	FR	19498
NPRM Comment Period End	07/26/88	53	FR	1948
Final Action with	09/30/88	53	FR	38476

Action	Date	FR Cite
Final Action generally effective	10/01/88	
Final Action Public Comment Period End	11/29/88	

**Small Entities Affected:** Businesses

Government Levels Affected: Undetermined

Agency Contact: Linda Magno, Director, Division of Hospital Payment Policy, Department of Health and Human Services, Health Care Financing Administration, 1-H-1 ELR, 6325 Security Blvd., Baltimore, MD 21207, 301 966-4529

RIN: 0938-AD49

## 857. PROTOCOL FOR THE REUSE OF DIALYSIS BLOODLINES

Legal Authority: 42 USC 1395rr(a)(7), as amended by PL 100-203; 42 USC 1302; 42 USC 1395hh

CFR Citation: 42 CFR 405.2150(d)

Legal Deadline: None

While the Secretary is not required to publish a regulation, ESRD facilities will not otherwise be permitted to reuse bloodlines after June 30, 1988.

Abstract: This rule would establish standards for safe and effective reuse of bloodlines. The statute forbids ESRD facilities to reuse bloodlines beginning July 1, 1988, unless the Secretary has established and the facilities follow, protocols for their reuse. The protocols would be incorporated into conditions of coverage.

#### Timetable:

Action	Date		FR	Cite
NPRM	07/27/88	53	FR	26236
NPRM Comment Period End	09/26/88	53	FR	28236
Final Action	00/00/00			

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Rita McGrath, Chief, Alternate Delivery Organization Branch, Department of Health and Human Services, Health Care Financing Administration, Room 469 EHR Bldg., 6325 Security Blvd., Baltimore, MD 21207, 301 966-4635

RIN: 0938-AD52

#### 858. UNIFORM RELATIVE VALUE GUIDE FOR ANESTHESIA SERVICES FURNISHED BY PHYSICIANS

Legal Authority: PL 100-203, Sec 4048(b); 42 USC 1302; 42 USC 1395hh

CFR Citation: 42 CFR 405.553

Legal Deadline: Final, Statutory, January 1, 1989. Under section 4048(b) of PL 100-203 the relative value guide is to be used for

Under section 4048(b) of PL 100-203 the relative value guide is to be used for physician anesthesia services furnished on or after 01/01/89.

Abstract: This final rule with comment period establishes a relative value guide for use in all carrier localities in making payment for anesthesia services furnished by physicians under Medicare Part B. This rule implements section 4048(b) of PL 100-203. Payments made using the relative value guide are designed to ensure that expenditures do not exceed the amount that otherwise would have been made absent the implementation of the relative value guide.

#### Timetable:

Action			Date	FR	Cite
Final No comm	ent	with	10/00/88		

Small Entities Affected: Undetermined

## Government Levels Affected: Undetermined

Agency Contact: Bernard Patashnik, Director, Division of, Medical Services Reimbursement, Department of Health and Human Services, Health Care Financing Administration, Room 1-H-5 ELR, 6325 Security Blvd., Baltimore, MD 21207, 301 966-4497

RIN: 0938-AD63

#### 859. INPATIENT HOSPITAL DEDUCTIBLE, SNF COINSURANCE AMOUNT AND PART A PREMIUM FOR THE UNINSURED AGED FOR 1989

**Legal Authority:** 42 USC 1395e; 42 USC 1395i-2

**CFR Citation:** 42 CFR 408.22; 42 CFR 409.80; 42 CFR 409.82; 42 CFR 409.83; 42 CFR 409.85

**Legal Deadline:** Final, Statutory, September 15, 1988.

Abstract: This notice announces the inpatient hospital deductible and SNF coinsurance amounts and the monthly hospital insurance premium for calendar year 1989 under Medicare's

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hospital insurance program. The Medicare statute specifies the formulae to be used to determine these amounts.

#### Timetable:

Action	Date		FR	Cite	
Notice (Inpatient Hospital Deductible)	09/30/88	53	FR	38537	
Notice (Skilled Nursing)	10/00/88				

#### Small Entities Affected: None

#### Government Levels Affected: None

Agency Contact: Solomon Mussey, Supervisory Actuary, Department of Health and Human Services, Health Care Financing Administration, M-1 1705 Equitable Bldg., 6325 Security Blvd., Baltimore, MD 21207, 301 966-6386

RIN: 0938-AD68

## 860. ● PERIODIC PAYMENTS FOR HOSPITALS AND OTHER PROVIDERS

**Legal Authority:** 42 USC 1395g(e); 42 USC 1395h(c)(2); PL 99-509, Sec 9311; 42 USC 1302; 42 USC 1395hh

CFR Citation: 42 CFR 412.116

#### Legal Deadline: None

Abstract: In this final rule, we set forth the circumstances under which the periodic interim payment method is available for services furnished by hospitals and other providers. Generally, inpatient hospital services furnished by hospitals excluded from the prospective payment system, as well as skilled nursing facility services, home health services, and hospice care services, may be paid for on a periodic interim payment basis. With certain exceptions, inpatient hospital services furnished by prospective payment hospitals are not eligible for payment on a periodic interim payment basis.

#### Timetable:

Action	Date	FR	Cite
Final Action	00/00/00		

Small Entities Affected: Undetermined

#### Government Levels Affected: Undetermined

Agency Contact: William Goeller, Director, Division of Payment and Reporting Policy, Department of Health and Human Services, Health Care Financing Administration, 1-F-5 East Low Rise, 6325 Security Boulevard, Baltimore, Maryland 21207, 301 966-4513 RIN: 0938-AD71

#### 861. ● HOSPICE CAP

Legal Authority: 42 USC 1395f(i) CFR Citation: 42 CFR 418.309

Legal, Deadline: None

Abstract: This notice announces an updated payment cap for hospice care under the Medicare program. The revised cap amount applies to payments made to a hospice during the period November 1, 1987 through October 31, 1988.

#### Timetable:

Action	Date	 Cite
Notice	10/00/88	

Small Entities Affected: Undetermined

#### Government Levels Affected: Undetermined

Agency Contact: Anthony Lovecchio, Director, Div of Alternative Reimbursement System, Department of Health and Human Services, Health Care Financing Administration, 1-A-3 ELR, 6325 Security Boulevard, Baltimore, Maryland 21207, 301 966-4575

RIN: 0938-AD75

## 862. ● PAYMENT FOR OUTPATIENT SURGERY AT EYE SPECIALTY HOSPITALS AND EYE AND EAR SPECIALTY HOSPITALS

Legal Authority: 42 USC 1395l(i)(3)(B)(ii); PL 100-203, Sec 4068(a)

CFR Citation: 42 CFR 413.118

**Legal Deadline:** None

Abstract: In accordance with section 4068(a) of PL 100.203, we are revising the payment provisions concerning hospital outpatient services furnished in connection with ambulatory surgical procedures for certain qualified eye hospitals and eye and ear hospitals. For cost reporting periods beginning on or after October 1, 1988 and before October 1, 1980, the blended payment amount applicable to these hospitals remains at 75 percent of the hospital-specified amount and 25 percent of the ambulatory surgical center amount.

#### Timetable:

Action	Date	FR Cite
Final with comment period	00/00/00	

#### Small Entities Affected: None

#### Government Levels Affected: None

Agency Contact: William Goeller, Director, Division of Payment and Reporting Policy, Department of Health and Human Services, Health Care Financing Administration, 1-F-5 ELR, 6325 Security Boulevard, Baltimore, Maryland 21207, 301 966-4513

RIN: 0938-AD76

## 863. ● SWING-BED PROGRAM CHANGES

**Legal Authority:** 42 USC 1302; 42 USC 1320a-1; 42 USC 1395f(b); 42 USC 1395g; 42 USC 1395l(a); 42 USC 1395x(v); 42 USC 416(j); 42 USC 1395hh

**CFR Citation:** 42 CFR 413; 42 CFR 424; 42 CFR 482; 42 CFR 489

#### Legal Deadline: None

Abstract: These regulations revise the Medicare rules relating to approved swing-bed hospitals. They implement the provisions of Pub. L. 100-203 which expand the swing-bed program to rural hospitals with less than 100 beds. Payment for extended care services furnished by hospitals with 50-99 beds are subject to additional conditions.

#### Timetable:

Action	Date	FR Cite
Final with comment period	00/00/00	

#### Small Entities Affected: None

#### Government Levels Affected: None

Agency Contact: Tom Hoyer, Director, Div. of Provider Services Coverage Policy, Department of Health and Human Services, Health Care Financing Administration, Room 405, EHR, 6325 Security Boulevard, Baltimore, Maryland 21207, 301 966-4607

RIN: 0938-AD83

## 864. ● COVERAGE OF AND PAYMENT FOR CERTIFIED NURSE-MIDWIFE SERVICES

**Legal Authority:** PL 100-203, Sec 4073; 42 USC 1395k(a)(2)(B); 42 USC

1395l(a)(1) and (m); 42 USC 1395x(s)(2); 42 USC 1395hh; 42 USC 1395ff

CFR Citation: 42 CFR 405; 42 CFR 410

Legal Deadline: None

Abstract: This final rule with comment period provides for the establishment of a fee schedule for the services of certified nurse midwives under the Medicare program. As required by section 4073 of the Omnibus Budget Reconciliation Act of 1987 (PL 100-203) the fee schedule would apply to Medicare services provided by certified nurse midwives on or after July 1, 1988.

#### Timetable:

Action	Date	FR Cite
Final with comment period	00/00/00	

Small Entitles Affected: None

**Government Levels Affected: None** 

Agency Contact: Robert E. Wren, Director, Office of Coverage Policy, Department of Health and Human Services, Health Care Financing Administration, Room 401, EHR, 6325 Security Boulevard, Baltimore, Maryland 21207, 301 966-5661

RIN: 0938-AD85

## 865. ● SECOND SURGICAL OPINION REQUIREMENTS FOR MEDICAID RECIPIENTS

Legal Authority: 42 USC 1302; 42 USC 1396a(30)(A)

CFR Citation: 42 CFR 431.400 to 431.430

Legal Deadline: None

Abstract: These regulations require each Medicaid plan to include a program requiring second surgical opinions for certain surgical procedures. This program is aimed at preventing unnecessary surgery and improving patient awareness of all treatment options, where alternatives to surgery are available.

#### Timetable:

Action	Date	FR Cite
NPRM	06/17/86	
Final Action	04/00/89	

Small Entities Affected: None

**Government Levels Affected: State** 

Agency Contact: Ernestine Jones, Program Analyst, Department of Health and Human Services, Health Care

Financing Administration, Room 463, EHR, 6325 Security Boulevard, Baltimore, Maryland 21207, **301 966-4646** 

RIN: 0938-AD86

## 866. ● CONFORMING AMENDMENTS RESULTING FROM THE OMNIBUS BUDGET RECONCILIATION ACT OF 1987

Legal Authority: 42 USC 1395x(r); 42 USC 1395l(ell); 42 USC 1395x(s); 42 USC 1395x; 42 USC 1395x; 42 USC 1395x; 42 USC 1396d; 42 USC 1396h; 42 USC 1396h; 42 USC 1396h; 42 USC 1392hh; 42 USC 1302

**CFR Citation:** 42 CFR 400.200; 42 CFR 400.203; 42 CFR 405.522; 42 CFR 405.1101; 42 CFR 405.1202; 42 CFR 405.1702; 42 CFR 405.2102; 42 CFR 408.20; 42 CFR 408.24; 42 CFR 417.104; 42 CFR 417.107; 42 CFR 417.144; 42 CFR 417.174; 42 CFR 417.242;

Legal Deadline: None

Abstract: These regulations conform HCFA rules to certain self-executing provisions of the Omnibus Budget Reconciliation Act of 1987. They are needed to made HCFA rules consistent with current provisions of law and to ensure that users of the regulations are not confused by outdated provisions or unclear language. Under the Medicare program's rules changes are made affecting: services of podiatrists; outpatient psychiatric services; physician assistant services; and comprehensive outpatient rehabilitative facility services. Under the Medicaid program changes are made affecting: services of dentists; clinic services; and waivers of certain State plan requirements. In addition, we make other conforming and transitional amendments.

#### Timetable:

Action	Date	FR	Cite
Final with comment period	00/00/00		

Small Entities Affected: Undetermined

Government Levels Affected: Undetermined

Agency Contact: Luisa V. Iglesias, Technical Assistant, Department of Health and Human Services, Health Care Financing Administration, Room 4243 Cohen Building, 300 Independence Avenue, SW, Washington, D.C. 20201, 202 245-0343

RIN: 0938-AD92

## 867. ● CATASTROPHIC COVERAGE CONFORMING AMENDMENTS

Legal Authority: 42 USC 1302; 42 USC 1395hh; 42 USC 1395e; 42 USC 1395f; 42 USC 1395i; 42 USC 1395r; 42 USC 1396a; 42 USC 1396d; 42 USC 1395v; 42 USC 1396b

**CFR Citation:** 42 CFR 406; 42 CFR 408; 42 CFR 409; 42 CFR 418; 42 CFR 435

Legal Deadline: None

Abstract: These regulations conform HCFA rules to certain self executing provisions of the Medicare Catastrophic Coverage Act of 1988 which: expand the scope of benefits under Medicare Part A; change the rules applicable to deductible and coinsurance; effect the determination and promulgation of Medicare Part A premiums; impose additional premiums for Medicare Part B; require Medicaid agencies to pay Medicare premiums deductibles and coinsurance on behalf of qualified Medicare beneficiaries and make other conforming and transitional amendments. They are needed to make HCFA rules consistent with current provisions of law and to ensure that users of the regulations are not confused by outdated provisions or unclear language.

#### Timetable:

Action	Date	FR Cite
Final Action	12/00/88	

Small Entities Affected: Undetermined Government Levels Affected:

Agency Contact: Luisa V. Iglisias, Technical Assistant, Department of Health and Human Services, Health Care Financing Administration, Room 4243, Cohen Building, 300 Independence Avenue, SW, Washington, D.C. 20201, 202 245-0383

RIN: 0938-AD93

Undetermined

## 868. © CARRIER BONUSES FOR INCREASING PHYSICIANS' PARTICIPATION OR PAYMENTS

Legal Authority: 42 USC 1395m(b)(3)(iii); 42 USC 1395h; PL 100-360, Sec 411(f)(2)(D); PL 99-509, Sec 9332(a); PL 100-203, Sec 4041(a); PL 100-203, Sec 4085(i)

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## CFR Citation: Not applicable Legal Deadline: None

Abstract: This notice describes the methodology we will use to award incentive payments to carriers that successfully increase the number of participating physicians, i.e., physicians who agree to accept Medicare's reasonable charge for Part B services that they provide to Medicare beneficiaries.It implements provisions of the Omnibus Budget Reconciliation Act of 1986, the Omnibus Budget Reconciliation Act of 1987, and the Medicare Catastrophic Coverage Act of 1988 which require us to publish our system for providing payment of a bonus to carriers based on their performance in increasing the number of participating physicians' services in their service areas.

#### Timetable:

Action	Date	FR	Cite
Notice	00/00/00		

Small Entitles Affected: None

#### **Government Levels Affected: None**

Agency Contact: Louis Palmieri, Jr., Budget Analyst, Bureau of Program Operations, Department of Health and Human Services, Health Care Financing Administration, Room 368, Meadows East Building, 6325 Security Boulevard, Baltimre, Maryland 21207, 301 966-7542

#### 869. ● NATIONAL AVERAGE ACTUARIAL VALUE OF DUPLICATIVE PART A AND PART B MEDICARE

Legal Authority: PL 100-360, Sec 421 CFR Citation: Not applicable

#### Legal Deadline: None

RIN: 0938-AD96

BENEFITS

Abstract: This final notice announces the national average actuarial value (NAAV) of duplicative Part A benefits and duplicative Part B benefits for 1988. Under sec. 421 of the Medicare Catastrophic Coverage Act of 1988 an employer that provides to current or retired employees benefits, the actuarial

value of which is at least 50 percent of the NAAV, it must provide those persons with additional benefits, a refund, or some combination. Guidelines also will be included for employers to use in computing the actuarial value of duplicative benefits, as required by sec. 421

#### Timetable:

Action	Date	FR	Cite
Final Action	12/00/88		

Small Entities Affected: Undetermined

#### Government Levels Affected: Undetermined

Agency Contact: Solomon Mussey, Director, Office of Medicare Cost Estimates, Department of Health and Human Services, Health Care Financing Administration, Room M-1, EQ-05, 1705 Whitehead Road, Baltimore, Maryland 21207, 301 966-6386

RIN: 0938-AD98

## DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) Health Care Financing Administration (HCFA)

**Completed Actions** 

#### 870. PAYMENTS TO INSTITUTIONS

Significance: Agency Priority

CFR Citation: 42 CFR 435.722; 42 CFR 435.725; 42 CFR 435.733; 42 CFR 435.832; 42 CFR 436.832

#### Completed:

 FR	3586
3/88 53 3/88	3/88 53 FR 3/88

Small Entities Affected: Businesses Government Levels Affected: State

Agency Contact: Marinos Svolos 301 966-4457

RIN: 0938-AB00

## 871. CHANGES TO THE LESSER OF COSTS OR CHARGES PROVISIONS

Significance: Regulatory Program CFR Citation: 42 CFR 413.13

#### Completed:

Reason	Date		FR	Cite
Final Action	03/29/88	53	FR	10077
Final Action	04/28/88			

Small Entities Affected: Businesses

**Government Levels Affected: None** 

Agency Contact: William Goeller 301 966-4513

RIN: 0938-AB29

## 872. REVISIONS IN REPORTING AND RECORDKEEPING REQUIREMENTS

CFR Citation: 42 CFR 405.1413(c); 42 CFR 405.1716(c); 42 CFR 405.1716(d); 42 CFR 405.1717(e); 42 CFR 405.1717(e); 42 CFR 405.1725(a); 42 CFR 405.1731(c); 42 CFR 405.1731(a); 42 CFR 405.1731(c); 42 CFR 434.36; 42 CFR 434.55; 42 CFR 405.1733(a); 42 CFR 405.1733(b); 42 CFR 434.27(a)

#### Completed:

Reason	Date		FR	Cite
Final Action	04/12/88	53	FR	12010
Final Action Effective	05/12/88	53	FR	12010

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Stanley Katz 301 966-4637

RIN: 0938-AB46

## 873. PHYSICIAN CERTIFICATION AND PLAN OF CARE REQUIREMENTS AND INSPECTION OF CARE REVIEWS

**CFR Citation:** 42 CFR 400; 42 CFR 440; 42 CFR 441; 42 CFR 456

#### Completed:

Reason	Date	FR	Cite
Withdrawn Will be developed into three separate regulations.	03/11/88		

Small Entities Affected: Businesses
Government Levels Affected: None

Agency Contact: Thomas E. Hoyer 301 966-4607

RIN: 0938-AB55

874. TREATMENT OF SOCIAL SECURITY COST OF LIVING INCREASES FOR INDIVIDUALS WHO LOSE SSI ELIGIBILITY

Significance: Agency Priority

CFR Citation: 42 CFR 435.135; 42 CFR 435.136

Completed:

 Reason
 Date
 FR Cite

 Final Action
 05/10/88
 53 FR 16550

Small Entities Affected: None

**Government Levels Affected: State** 

Agency Contact: Roy Trudel 301 966-4457

RIN: 0938-AB62

875. OMB REVIEW OF INFORMATION COLLECTION AND RECORDKEEPING REQUIREMENTS FOR HOME HEALTH AGENCIES, AND PROVIDERS OF OUTPATIENT, PHYSICAL THERAPY AND/OR (CONT)

CFR Citation: 42 CFR 405.1221(e); 42 CFR 405.1221(f); 42 CFR 405.1221(g); 42 CFR 405.1221(i); 42 CFR 405.1223(b); 42 CFR 405.1229(a); 42 CFR 405.1720(b); 42 CFR 405.1721; 42 CFR 405.1224; 42 CFR 405.1228; 42 CFR 405.1225(a); 42 CFR 405.1226

#### Completed:

Reason	Date	FR Cite
Withdrawn To be included in various other HCFA regulations.	08/03/88	

Small Entities Affected: None

**Government Levels Affected: None** 

Agency Contact: Stefan Miller 301 966-4633

RIN: 0938-AB68

876. CONDITIONS FOR INTERMEDIATE CARE FACILITIES FOR THE MENTALLY RETARDED

Significance: Agency Priority

**CFR Citation:** 42 CFR 435; 42 CFR 442; 42 CFR 431.610(f)(1); 42 CFR 440.150(c)(3); 42 CFR 483

#### Completed:

Reason	ason Date I		FR	Cite
Final Action Final Action Effective	06/03/88 10/03/88			20448 20448

Small Entities Affected: None

Government Levels Affected: Local, State

Agency Contact: Samuel Kidder 301 966-4620

RIN: 0938-AB76

## 877. REASONABLE CHARGE LIMITATIONS

Significance: Regulatory Program
CFR Citation: 42 CFR 405.502

Completed:

Reason	Date		FR	Cite	
Final Action	07/11/88	53	FR	26067	-
Final Action Effective	09/09/88	53	FR	26067	

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Bernard Patashnik 301 966-4495

RIN: 0938-AC08

878. ASSIGNMENT AND
REASSIGNMENT OF PROVIDERBASED HOME HEALTH AGENCIES
AND HOSPICES TO DESIGNATED
REGIONAL INTERMEDIARIES

Significance: Regulatory Program CFR Citation: 42 CFR 421.3; 42 CFR 421.117; 42 CFR 421.128

#### Completed:

Reason	Date		FR	Cite
Final Action	05/19/88	53	FR	17936
Final Action Effective	06/20/88	53	FR	17936

Small Entities Affected: Undetermined

Government Levels Affected: Undetermined

Agency Contact: Irvin Robinson 301 966-7422

RIN: 0938-AC20

879. FIRE SAFETY STANDARDS FOR HOSPITALS, SKILLED NURSING FACILITIES, HOSPICES, INTERMEDIATE CARE FACILITIES AND AMBULATORY SURGICAL CENTERS

Significance: Agency Priority

CFR Citation: 42 CFR 405.1022(b)(1); 42 CFR 405.1134(a); 42 CFR 416.44(b); 42 CFR 442.321(a); 42 CFR 442.321(c); 42 CFR 442.322; 42 CFR 442.323; 42 CFR 418.100(d); 42 CFR 482.41(b)

#### Completed:

Reason	Date	FR	Cite
Final Action Final Action Effective	04/07/88 05/09/88	 	11504 11504

Small Entities Affected: None

**Government Levels Affected:** Local, State

Agency Contact: Samuel Kidder 301 966-4620

RIN: 0938-AC28

## 880. ALTERNATE SANCTIONS FOR ESRD FACILITIES

CFR Citation: 42 CFR 405

#### Completed:

Reason	Date		FR	Cite
Final Action	09/19/88 10/19/88	53	FR	36274
Effective				

Small Entities Affected: Businesses Government Levels Affected: None

Agency Contact: Spencer B. Colburn 301 966-6823

RIN: 0938-AC68

#### 881. LONG TERM CARE SURVEY

**CFR Citation:** 42 CFR 405.1901 to 1913; 42 CFR 442.30; 42 CFR 488.1 to 488.115

#### Completed:

State

Date		FR	Cite	
	06/17/88	06/17/88 53	06/17/88 53 FR	Date         FR Cite           06/17/88         53 FR 22850           07/18/88         53 FR 22850

Small Entitles Affected: Organizations Government Levels Affected: Local,

Agency Contact: Wayne Smith 301 966-6763

RIN: 0938-AD41

**Completed Actions** 

#### 882. MISCELLANEOUS CHANGES AFFECTING PAYMENT FOR INPATIENT HOSPITAL SERVICES

Significance: Agency Priority

CFR Citation: 42 CFR 405.310; 42 CFR 412.2; 42 CFR 412.50; 42 CFR 412.63; 42 CFR 412.92; 42 CFR 412.106; 42 CFR 412.210; 42 CFR 413.30; 42 CFR 413.40; 42 CFR 489.23

#### Completed:

Reason	Date	FR Cite
Withdrawn Will be incorporated into another regulation	05/03/88	

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Linda Magno 301 966-4529

RIN: 0938-AD46

#### 883. FEES FOR APPEALS

CFR Citation: 42 CFR 405.701 to 42

#### Completed:

Date	FR	Cite
06/23/88	Mirangijara svedilo	

analyze issues.

Small Entities Affected: Undetermined

#### **Government Levels Affected:**

Undetermined

Agency Contact: James Conrad 301 966-6477

RIN: 0938-AD54

#### 884. REVISIONS TO MEDICAID **ELIGIBILITY QUALITY CONTROL** PROGRAM REQUIREMENTS BASED ON FINDINGS OF COBRA STUDIES

CFR Citation: 42 CFR 431

#### Completed:

Reason	Date	FR Cite
Withdrawn Analyzing findings of the NAS and Department studies.	03/30/88	

Small Entities Affected: Undetermined

**Government Levels Affected: State** 

Agency Contact: Larry Reed 301 966-

RIN: 0938-AD56

#### 885. PROCEDURES FOR **TERMINATING PROGRAM** PARTICIPATION OF PROVIDERS AND SUPPLIERS

CFR Citation: 42 CFR 405; 42 CFR 416.35; 42 CFR 431.154; 42 CFR 442; 42 CFR 488; 42 CFR 489.53; 42 CFR 498.53; 42 CFR 498.5; 42 CFR 498.20; 42 CFR 498,56

#### Completed:

Reason	Date	FR Cite
Withdrawn To be incorp. into other regs implementing 'OBRA 89.	05/31/88	

Small Entities Affected: Businesses. Organizations

**Government Levels Affected:** Undetermined

Agency Contact: Alfreda Staton 301 966-6670

RIN: 0938-AD57

#### 886. MONTHLY ACTUARIAL RATES AND PART B PREMIUM RATES **BEGINNING JANUARY 1, 1989**

CFR Citation: 42 CFR 408.20

#### Completed:

Reason	Date		FR	Cite
Notice	09/30/88	53	FR	38348

Small Entities Affected: Undetermined

#### **Government Levels Affected:**

Undetermined

Agency Contact: Solomon Mussey 301 966-6386

RIN: 0938-AD58

#### 887. MISCELLANEOUS AMENDMENTS TO THE HMO AND CMP REQUIREMENTS

CFR Citation: 42 CFR 417

#### Completed:

Reason	Date	FR Cite
Withdrawn To be incorporated into another regulation	05/27/88	

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Larry Sobel 202 245-0197

RIN: 0938-AD61

## DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Family Support Administration (FSA)

888. AID TO FAMILIES WITH DEPENDENT CHILDREN PROGRAM: **ADMINISTRATIVE IMPROVEMENT IN** THE AFDC PROGRAM

Significance: Regulatory Program

Legal Authority: 42 USC 303; 42 USC 602; 42 USC 606; 42 USC 1403; 42 USC 1383 Note; 42 USC 1302

CFR Citation: 45 CFR 205; 45 CFR 224; 45 CFR 232; 45 CFR 233; 45 CFR 238

Legal Deadline: None

Abstract: The proposed rule will organize and codify those administrative changes which will better target program resources, reduce administrative cost, or increase State flexibility.

#### Timetable:

Action	Date	FR Cite
NPRM	02/00/89	
NPRM Comment Period End	04/00/89	
Final Action	12/00/89	

Small Entities Affected: None

Government Levels Affected: State

Agency Contact: Diann Dawson, Director, Division of Policy, Office of **Proposed Rule Stage** 

Family Assistance, Department of Health and Human Services, Family Support Administration, 370 L'Enfant Promenade, SW 20447, Washington, DC. 202 252-5116

RIN: 0970-AA09

#### 889. STANDARDS FOR CHILD SUPPORT ENFORCEMENT PROGRAM **OPERATIONS**

Significance: Regulatory Program

Legal Authority: 42 USC 1302

CFR Citation: 45 CFR 302; 45 CFR 303; 45 CFR 304; 45 CFR 305; 45 CFR 306

#### Legai Deadline: None

Abstract: These proposed regulations will revise requirements and program standards to streamline and improve case processing within the IV-D agency. Specific standards and timeframes will be proposed for certain actions required to be taken in processing an IV-D case.

#### Timetable:

Action	Date	FR	Cite
NPRM	12/00/88		
Final Action	07/00/89		

#### Small Entities Affected: None

Government Levels Affected: Local, State. Federal

Agency Contact: Joyce Linder, Program Specialist, Office of Child Support Enforcement, FSA, Department of Health and Human Services, Family Support Administration, 370 L'Enfant Promenade, SW, Washington, DC 20447, 202 252-5369

RIN: 0970-AA16

## 890. CHILD SUPPORT ENFORCEMENT AUDIT REGULATIONS

Significance: Regulatory Program

**Legal Authority:** 42 USC 603(h); 42 USC 604(d); 42 USC 652(a)(1); 42 USC 652(a)(4); 42 USC 1302

CFR Citation: 45 CFR 305

Legal Deadiine: None

Abstract: OCSE is proposing to amend the current program regulations governing child support program audits. These proposed rules would streamline the current audit process and requirements and make corrections to certain inaccuracies in the audit regulations. In addition, we propose to add new performance indicators and update the scoring system.

#### Timetable:

Action	Date	FR Cite
NPRM	01/00/89	
Final Action	07/30/89	
O	A ## NT	

#### Small Entities Affected: None

Government Levels Affected: Local, State. Federal

Agency Contact: Elizabeth Matheson, Chief, Policy Branch, Office of Child Support Enforcement, FSA, Department of Health and Human Services, Family Support Administration, 370 L'Enfant Promenade, SW, Washington, DC 20447, 202 252-5364

RIN: 0970-AA17

## 891. DISTRIBUTION OF CHILD SUPPORT COLLECTIONS

Legai Authority: 42 USC 657; 42 USC 1302

**CFR Citation:** 45 CFR 302.51; 45 CFR 302.32; 45 CFR 303.101

Legai Deadline: None

Abstract: OCSE is proposing to revise the child support enforcement program regulations governing the distribution of child support collections. These proposed rules would clarify the requirements that State child support enforcement agencies must adhere to when distributing payments made to AFDC families distributing collections in all IV-D cases and distributing payments made to AFDC families.

#### Timetable:

Action	Date	FR	Cite
NPRM	03/00/89		
Final Action	09/00/89		

#### Small Entities Affected: None

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

Agency Contact: Michael Fitzgerald, Program Specialist, Office of Child Support Enforcement, FSA, Department of Health and Human Services, Family Support Administration, 370 L'Enfant Promenade, SW, Washington, DC 20447, 202 252-5364

RIN: 0970-AA18

# 892. ALIEN VERIFICATION PROCEDURES FOR AFDC; STATE ADMINISTERED ADULT ASSISTANCE AND MEDICAID PROGRAMS; NOTICE OF PROPOSED RULEMAKING

Significance: Agency Priority

Legal Authority: PL 99-603, Sec 121; Immigration Reform and Control Act of 1986

**CFR Citation:** 45 CFR 233; 42 CFR 435; 45 CFR 205; 45 CFR 433; 42 CFR 436

**Legai Deadline:** NPRM, Statutory, October 1, 1987.

Abstract: IRCA imposes new procedures on the AFDC, Adult Assistance Programs and Medicaid to verify immigration status of aliens applying for benefits under these

programs with the Immigration and Naturalization Service. Under the law, States must be reimbursed at 100% for costs of their implementation and operation to access the alien status verification system. This regulation will specify what costs incurred by states will be subject to 100% reimbursement.

#### Timetable:

Action	Date	FR Cite
NPRM	11/30/88	
NPRM Comment Period End	12/30/88	
Final Action	08/30/89	
Final Action Effective	08/30/89	,

#### Small Entitles Affected: None

#### **Government Leveis Affected: State**

Additional Information: INS must establish an alien verification system that can be accessed by States by October 1, 1987. States may claim 100% reimbursement for implementing and operating SAVE on October 1, 1987.

Agency Contact: Diann Dawson, Director, Division of Policy, Office of Family Assistance, Department of Health and Human Services, Family Support Administration, 370 L'Enfant Plaza Promenade, SW, Washington, DC 20447, 202 252-5116

RIN: 0970-AA41

#### 893. EXCLUSION OF INDIAN TRUST FUNDS AND ALASKA NATIVE CLAIMS SETTLEMENT ACT DISTRIBUTIONS (ANCSA)

Significance: Regulatory Program

**Legai Authority:** PL 97-458, Sec 4; PL 98-64, Sec 2; PL 100-241, Sec 15

**CFR Citation:** 45 CFR 233.20(a)(4)(ii)(n); 45 CFR 233.20(a)(4)(ii)(o); 45 CFR 233.20(a)(4)(ii)(e); 45 CFR 233.20(a)(4)(ii)(k)

#### Legal Deadline: None

Abstract: Would update current regulations by adding statutory exclusions for certain per capita distributions of Indian judgment funds and other funds held in trust by the Department of Interior, and initial purchases made with such funds. Additionally, would exclude the following types of distributions received from a Native Corporation pursuant to the Alaska Native Claims Settlement Act. (1) Cash to the extent that it does not in the aggregate, exceed \$2,000 per

HHS-FSA

**Proposed Rule Stage** 

individual per annum; (2) Stocks; (3) A partnership interest; (4) Land or an interest in land; and (5) An interest in a settlement trust. Regulations would reflect the statutes, therefore, no alternatives are being considered. We estimate that the Federal share of the cost of the trust funds exclusions required under PL 97-458 and PL 98-64 would be \$696,960 per year, the Federal share of the cost of the Alaska Native Claims Settlement Act exclusions required under PL 100-241 would be \$1,878,108 per year. Therefore, the annual result would be a cost of \$3,575,068.

#### Timetable:

Action	Date	FR Cite
NPRM	02/00/89	
NPRM Comment Period End	04/00/89	
Final Action	11/00/89	

#### Small Entities Affected: None

#### **Government Levels Affected: None**

Agency Contact: Diann Dawson, Director, Division of Policy, Office of Family Assistance, Department of Health and Human Services, Family Support Administration, 370 L'Enfant Plaza Promenade, SW, Washington, DC 20447. 202 252-5116

RIN: 0970-AA47

## 894. COOPERATION IN THIRD PARTY HEALTH COVERAGE

Significance: Regulatory Program

Legal Authority: Sec 402(a)(26) of the Scl Scrty Act as amended by Sec 12304; The Consolidated Omnibus Budget Reconciliation Act of 1985

**CFR Citation:** 45 CFR 232.13; 45 CFR 232.40; 45 CFR 232.41; 45 CFR 232.42; 45 CFR 232.43; 45 CFR 232.45; 45 CFR 232.45; 45 CFR 232.47; 45 CFR 232.48; 45 CFR 232.49; 45 CFR 232.49; 45 CFR 234.60; 45 CFR 235.70

#### Legal Deadline: None

Abstract: The proposed rules specify that as a condition of eligibility for AFDC, each applicant or recipient must cooperate with the State by identifying and providing information to assist the State in pursuing any third party who may be liable to pay for care and services available under the State's plan for medical assistance under title XIX, unless such individual has good cause for refusing to cooperate as determined by the State agency in

accordance with standards prescribed by the Secretary.

#### Timetable:

Action	Date	FR Cite
NPRM	01/00/89	
NPRM Comment Period End	02/00/89	
Final Action	11/00/89	

#### Small Entities Affected: None

#### **Government Levels Affected: None**

Agency Contact: Diann Dawson, Director, Division of Policy, Office of Family Assistance, Department of Health and Human Services, Family Support Administration, 370 L'Enfant Plaza Promenade, SW, Washington, DC 20447, 202 252-5116

RIN: 0970-AA49

#### 895. COOPERATIVE AGREEMENTS

Significance: Agency Priority

**Legal Authority:** 42 USC 1302; 42 USC 654(7); 42 USC 652

CFR Citation: 45 CFR 302.34; 45 CFR 303.107; 45 CFR 304.22; 45 CFR 305.34

#### Legal Deadline: None

Abstract: The regulation specifies provisions that must be contained in all cooperative agreements between IV-D agencies and courts and law enforcement agencies.

#### Timetable:

Action	Date		FR	Cite
NPRM	10/05/88	53	FR	39110
NPRM Comment Period End	12/05/88			
Final Action	06/00/89			

#### Small Entities Affected: None

Government Levels Affected: Local, State, Federal

Agency Contact: Norma Staley, Program Analyst, Office of Child Support Enforcement, Department of Health and Human Services, Family Support Administration, 370 L'Enfant Promenade, SW 20447, Washington, D.C. 202 252-5374

RIN: 0970-AA50

#### 896. OMNIBUS BUDGET RECONCILIATION ACT OF 1987

Significance: Agency Priority

Legal Authority: PL 100-203, Sec 9133; The Omnibus Budget Reconciliation Act of 1987 **CFR Citation:** 45 CFR 233.53; 45 CFR 235.111; 45 CFR 233.20(a)(3)(x)

#### Legal Deadline: None

Abstract: These proposed rules implement sections of OBRA regarding the support and maintenance disregard, the optional fraud control program, and treatment of foster care payments.

#### Timetable:

Action	Date	FR Cite
NPRM	03/00/89	
NPRM Comment Period End	04/00/89	
Final Action Effective	12/00/89	

#### Small Entitles Affected: None

#### **Government Levels Affected: State**

Agency Contact: Diann Dawson, Director, Division of Policy, Office of Family Assistance, Department of Health and Human Services, Family Support Administration, 370 L'Enfant Plaza Promenade, SW, Washington, DC 20447, 202 252-5116

RIN: 0970-AA56

### 897. ● SERVICES TO POST-AFDC AND MEDICAID ONLY FAMILIES

Significance: Agency Priority

**Legal Authority:** 42 USC 654(4); 42 USC 654(5); 42 USC 657(c)

**CFR Citation:** 45 CFR 301.1; 45 CFR 302.31; 45 CFR 302.33; 45 CFR 302.70; 45 CFR 302.51; 45 CFR 303.72; 45 CFR 303.102; 45 CFR 304.20; 45 CFR 306.50; 45 CFR 306.51

#### Legal Deadline: None

Abstract: This regulation would implement sections 9141 of P.L. 100-203. the Omnibus Budget Reconciliation Act of 1987 under which child support agencies are required to continue to provide IV-D services to persons no longer eligible for AFDC without requiring an application or payment of an application fee. It also implements section 9142 of P.L. 100-203 which requires child support agencies to provide IV-D services to all families with an absent parent who receive Medicaid and have assigned their rights to medical support to the State.

#### Timetable:

Action	Date	FR	Cite
NPRM	12/00/88		
Final Action	06/00/89		

HHS-FSA

**Proposed Rule Stage** 

Small Entities Affected: None Government Levels Affected: Local, State, Federal Agency Contact: Andrew Hagan, Program Specialist, Department of Health and Human Services, Family Support Administration, 370 L'Enfant Promenade, SW, Washington, DC 20447. 202 252-5374
RIN: 0970–AA61

## DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) Family Support Administration (FSA)

Final Rule Stage

#### 898. SCOPE OF PAYMENTS

Significance: Regulatory Program

Legal Authority: 42 USC 1102; 42 USC 602

**CFR Citation:** 45 CFR 233.20(a)(2)(i); 45 CFR 233.20(a)(2)(V); 45 CFR 233.120

Legal Deadline: None

Abstract: These proposed regulations would clarify that States may not provide simultaneous multiple shelter allowances or special need allowances to recipients under Titles I, IV-A, X, XIV, and XVI of the Social Security Act based on the type of housing in which they reside. Also, these regulations would limit Federal matching under the Emergency Assistance program to one 30-day period in twelve consecutive months and would require States to specify the maximum amount of assistance to be provided for each type of emergency.

#### Timetable:

Action	Date		FR	Cite
NPRM NPRM Comment	12/14/87	52	FR	47420
Period End				
Final Action	11/00/88			

Small Entities Affected: None

Government Levels Affected: Local, State, Federal

Public Compliance Cost: Initial Cost: \$0; Yearly Recurring Cost: \$0

Additional Information: Split off from Regulation on Administrative Improvement in the AFDC Program (RIN 0960-AB72).

Agency Contact: Diann Dawson, Director, Division of Policy, Office of Family Assistance, Department of Health and Human Services, Family Support Administration, 370 L'Enfant Plaza Promenade, SW, Washington, DC 20447, 202 252-5116

RIN: 0970-AA00

### 899. RETROACTIVE MODIFICATION OF CHILD SUPPORT ARREARAGES

Legal Authority: PL 99-509, Sec 9103

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

Legal Deadline: None

Abstract: This regulation requires, as a result of the Omnibus Budget Reconciliation Act of 1986, that child support payments be judgments on and after the day they fall due as well as requires that States have procedures to prohibit the retroactive modification of child support arrearages.

#### Timetable:

Action	Date		FR	Cite
NPRM	09/14/87	52	FR	34689
Final Action	12/00/88			

Small Entities Affected: None

Government Levels Affected: Local, State, Federal

Agency Contact: Michael Fitzgerald, Program Specialist, Office of Child Support Enforcement, Department of Health and Human Services, Family Support Administration, 370 L'Enfant Promenade, SW20447, Washington, DC, 202 252-5366

RIN: 0970-AA03

#### 900. AID TO FAMILIES WITH DEPENDENT CHILDREN; DEFINITION OF PERMISSIBLE STATE PRACTICE-QUALITY CONTROL

Significance: Agency Priority

Legal Authority: 42 USC 1302; 42 USC

CFR Citation: 45 CFR 205.40(a)(8)

Legal Deadline: None

Abstract: This rule will amend the definition of "Permissible State Practice." The rule will enable quality control to review against Federal statutes and regulations when a state plan is not amended to reflect new federal rules.

#### Timetable:

Action	Date		FR	Cite
NPRM NPRM Comment	06/18/85 08/19/85	50	FR	25269
Period End				

**Next Action Undetermined** 

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Diann Dawson, Director, Division of Policy, Office of Family Assistance, Department of Health and Human Services, Family Support Administration, 370 L'Enfant Plaza Promenade, SW, Washington, DC, 202 252-5116

RIN: 0970-AA04

#### 901. AID TO FAMILIES WITH DEPENDENT CHILDREN PROGRAM; IMPLEMENTATION OF THE DEFICIT REDUCTION ACT OF 1984

Significance: Agency Priority

Legal Authority: 42 USC 1302; PL 98-369 The Deficit Reduction Act of 1984; PL 99-514 The Tax Reform Act of 1986

CFR Citation: 45 CFR 233.36; 45 CFR 237.50; 45 CFR 238.18; 45 CFR 238.20; 45 CFR 239.14; 45 CFR 239.14; 45 CFR 239.16; 45 CFR 239.24; 45 CFR 239.58; 45 CFR 239.82; 45 CFR 233.10; 45 CFR 233.35; ...

#### Legal Deadline: None

Abstract: The final regulations will clarify provisions first published in the Interim Final Rules implementing the Deficit Reduction Act of 1984 and as clarified by the Tax Reform Act of 1986.

#### Timetable:

Action	Date		FR	Cite
Interim Final Rule	09/10/84	49	FR	35586
Final Action	02/00/89			

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Diann Dawson, Director, Division of Policy, Office of Family Assistance, Department of Health and Human Services, Family Support Administration, 370 L'Enfant Plaza Promenade, SW20447, 202 252-5116. 202 252-5116

RIN: 0970-AA06

902. CONSISTENCY FOR THE FOOD STAMP PROGRAM, AFDC PROGRAM, AND THE ADULT ASSISTANCE PROGRAMS

Significance: Regulatory Program

**Legal Authority:** 42 USC 1302; Sec. 1102, 49 Stat. 647

CFR Citation: 45 CFR 205.10(a)(4)(ii); 45 CFR 233.31(b); 45 CFR 233.20(a)(6)(v)(B); 45 CFR 205.10(a)(7); 45 CFR 205.10(a)(13); 45 CFR 205.52; 45 CFR 233.20(a)(3)(ii)(D); 45 CFR 233.20(a)(3)(iii)

Legal Deadline: None

Abstract: Proposed rule will provide increased consistency in eligibility policies and procedures between the AFDC and Food Stamp programs, within existing statutory requirements. The aim is to improve and simplify program administration and ease the burden placed upon the State agencies and individuals applying for assistance.

#### Timetable:

Action	Date		FR	Cite
ANPRM	02/19/85	50	FR	6970
ANPRM Comment Period End	04/22/85	50	FR	6970
NPRM	09/29/87	52	FR	36546
NPRM Comment Period End	11/30/87			
Final Action	11/00/88			

Small Entities Affected: None

**Government Levels Affected: State** 

Agency Contact: Diann Dawson, Director, Division of Policy, Office of Family Assistance, Department of Health and Human Services, Family Support Administration, 370 L'Enfant Plaza Promenade, SW 20447. Washington, DC, 202 252-5116

RIN: 0970-AA08

903. REFUGEE RESETTLEMENT PROGRAM; REFUGEE CASH AND ASSISTANCE; REQUIREMENTS FOR JOB SEARCH, EMPLOYMENT SERVICES, AND EMPLOYMENT; REFUGEE MEDICAL ASSISTANCE; AND REFUGEE SOCIAL SERVICES

Significance: Regulatory Program

Legal Authority: 8 USC 1522(a)(9)

CFR Citation: 45 CFR 400 Legal Deadline: None

services, and employment.

Abstract: This regulation will establish requirements governing refugee cash assistance; refugee medical assistance; and refugee support (social) services, including job search employability

#### Timetable:

Action	Date		FR	Cite
NPRM	01/30/86	51	FR	03918
NPRM Comment Period End	04/30/86			
Final Action	00/00/00			

Small Entitles Affected: None

Government Levels Affected: State

Agency Contact: Philip A. Holman, Director, Div. of Policy & Analysis, Department of Health and Human Services, Family Support Administration, 370 L'Enfant Promenade, S.W., Washington, DC 20447. 202 252-4566

RIN: 0970-AA10

904. AID TO FAMILIES WITH DEPENDENT CHILDREN PROGRAM; GENERAL ADMINISTRATION — PUBLIC ASSISTANCE PROGRAM — QUALITY CONTROL SYSTEM

Significance: Agency Priority

Legal Authority: 42 USC 1302; PL 97-248

CFR Citation: 45 CFR 205.44

Legal Deadline: None

Abstract: These proposed rules amend the QC regulations under the AFDC program by establishing more definitive criteria to be used in determining whether waivers will be granted to states that fail to meet the statutory error standard.

#### Timetable:

I IIII G COLDIO				
Action	Date	FR	Cite	
NPRM	02/02/87	52 FR	21	
NPRM Comment	04/03/87			

Next Action Undetermined

Small Entitles Affected: None

Government Levels Affected: Local, State, Federal

Public Compilance Cost: Initial Cost: \$0; Yearly Recurring Cost: \$0; Base Year for Dollar Estimates: 86

Agency Contact: Sean Hurley, Director, Division of Quality Control, Office of Family Assistance, Department of Health and Human Services, Family Support Administration, 370 L'Enfant Plaza Promenade, SW, Washington, DC 20447, 202 252-5075

RIN: 0970-AA11

#### 905. ESSENTIAL PERSONS

Significance: Regulatory Program
Legal Authority: 42 USC 602; 42 USC 1302

CFR Citation: 45 CFR 233.20

Legal Deadline: None

Abstract: The proposed regulation would preclude States from considering individuals to be essential persons for purposes of the AFDC program if they do not provide an essential benefit or service to the family.

#### Timetable:

Action	Date		FR	Cite
NPRM	10/05/87	52	FR	37183
NPRM Comment Period End	11/19/87			
Final Action	10/00/88			

Small Entities Affected: None

Government Levels Affected: Local, State, Federal

**Public Compliance Cost:** Initial Cost: \$0; Yearly Recurring Cost: \$0

Additional Information: Split off from Regulation 00 Administrative Improvement in the AFDC Program (RIN 0970-aa09)

Agency Contact: Diann Dawson, Director, Division of Policy, Office of Family Assistance, Department of Health and Human Services, Family Support Administration, 370 L'Enfant Plaza Promenade, SW, Washington, DC 20447, 202 252-5116

RIN: 0970-AA44

906. FEDERAL TAX REFUND OFFSET PROCESS - PRE-OFFSET NOTICE FEE

Significance: Agency Priority

HHS-FSA

**Final Rule Stage** 

**Legal Authority:** 42 USC 664; 42 USC 1302; 42 USC 654(13); 42 USC 6505

CFR Citation: 45 CFR 303.72

Legal Deadline: None

Abstract: These regulations would permit OCSE to charge a fee for services provided in the Federal tax refund offset process. They would require State IV-D agencies to send preoffset notices to absent parents unless the State requests and OCSE agrees to send the notices. In addition IRS fees would be deducted from offset amounts rather than billed and collected by HHS.

#### Timetable:

Action	Date		FR	Cite
NPRM	04/12/88	53	FR	12041
Final Action	11/00/88			

Small Entitles Affected: None

Government Levels Affected: Local, State. Federal

Agency Contact: Carol Jordan, Program Specialist, Office of Child Support Enforcement, Department of Health and Human Services, Family Support Administration, 370 L'Enfant Promenade, SW 20447, Washington, D.C. 202 252-5365

RIN: 0970-AA52

907. ● EMERGENCY COMMUNITY SERVICES HOMELESS GRANT PROGRAM; INTERIM FINAL RULE WITH REQUEST FOR COMMENTS

**Legal Authority:** 42 USC 11302; 42 USC 11461 to 11464; 42 USC 11472

**CFR Citation:** 45 CFR 1080; 45 CFR 96.12; 45 CFR 96.14; 45 CFR 96C; 45 CFR 96E; 45 CFR 96F

Legal Deadline: None

Abstract: The regulations establish procedures that States, territories, Indian tribes, and other organizations must follow to apply for and use funds appropriated for the Emergency Community Services Homeless Grant Program (EHP) established by the Stewart B. McKinney Homeless Assistance Act (Published Law 100-77). The Act requires the funds to be distributed to States and territories that receive funds under the Community Services Block Grant (CSBG) program, using the CSBG allocation formula, and sets aside funds to be awarded directly to certain Indian tribes. The regulations require an annual application from the

57 States and territories, and an annual report from all grantees, including an estimated 75 Indian tribes. Annual paperwork burden estimates are: (a) 80 hours per State application, for a total of 4560 hours, (b) 30 hours per grantee to complete the report, for a total of 3960 hours, and (c) 2 hours per grantee for recordkeeping, for a total of 264 hours,

#### Timetable:

Action	Date		FR	Cite
Interim Final Rule	06/22/88	53	FR	23568
Final Action	02/00/89			

Small Entitles Affected: None
Government Levels Affected: State

Public Compliance Cost: Initial Cost: \$0; Yearly Recurring Cost: \$105,408; Base Year for Dollar Estimates: 1988

Sectors Affected: None

Agency Contact: Janet Fox, Chief, Homeless Grant Program, Department of Health and Human Services, Family Support Administration, Room 2038 Switzer Building, 330 C Street, S.W., Washington, D.C. 20201, 202 475-0418

RIN: 0970-AA57

## 908. ● TARGETING OF, AND TOLERANCES FOR, INCOME AND ELIGIBILITY VERIFICATION SYSTEM DATA

Significance: Regulatory Program

Legal Authority: PL 99-509, Sec 9101 Omnibus Budget Reconciliation Act of 1986

CFR Citation: 45 CFR 205.56

Legal Deadline: None

Abstract: These rules make revisions to the regulations designed to incorporate changes made by Section 9101 of PL 99-509, which amended Section 1137 of the Social Security Act to allow States flexibility in targeting uses of data through the Income and Eligibility Verification System. States will not be required to verify and act on all data. This changes earlier regulations which required 100% verification and allows the States the option to target their uses to those identified in the State Plan as most likely to be productive. ADDITIONAL INFORMATION: These

ADDITIONAL INFORMATION: These regulations are planned to be issued at the same time regulations being issued by the Department of Agriculture to provide consistency of implementation

with the Federally assisted benefit program at that department.

#### Timetable:

Action	Date	FR Cite
Interim Final Rule	12/00/88	

Small Entitles Affected: None

Government Levels Affected: None

Agency Contact: Sheldon Shalit, Management Analyst, Department of Health and Human Services, Family Support Administration, 370 L'Enfant Promenade, S.W., Washington, D.C. 20447, 202 252-4803

RIN: 0970-AA58

# 909. ● AUTOMATED DATA PROCESSING EQUIPMENT AND SERVICES; CONDITIONS FOR FEDERAL FINANCIAL PARTICIPATION

Significance: Regulatory Program

Legal Authority: 5 USC 301

**CFR Citation:** 45 CFR 95.601; 45 CFR 95.605; 45 CFR 95.611; 45 CFR 95.612; 45 CFR 95.613; 45 CFR 95.615; 45 CFR 95.617; 45 CFR 95.621; 45 CFR 95.623; 45 CFR 95.624; 45 CFR 95.625; 45 CFR 95.623; 45 CFR 95.6264; 45 CFR 95.626464

Legal Deadline: None

Abstract: This final rule changes regulations of 45 CFR 95.600, et seq., to reduce the amount of time necessary to review and respond to State and local agency requests for FFP. The reduction in process time will be accomplished by streamlining the review process and requiring fewer points of prior approval for smaller expenditures by the Department.

#### Timetable:

Action	Date	FR Cite
NPRM	09/21/87	52 FR 182
NPRM Comment Period End	11/30/87	
Final Action	02/00/89	

Small Entities Affected: None

**Government Levels Affected:** None

Agency Contact: Ron Lentz, Management Analyst, Department of Health and Human Services, Family Support Administration, 370 L'Enfant Promenade, S.W., Washington, D.C. 20447, 202 252-4795

RIN: 0970-AA59

#### DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) Family Support Administration (FSA)

**Completed Actions** 

#### 910. REFUGEE CASH AND MEDICAL **ASSISTANCE**

Significance: Regulatory Program CFR Citation: 45 CFR 400

Completed:

Reason	Date		FR	Cite
Final Action	08/24/88	53	FR	32222
Final Action Effective	08/24/88	53	FR	32222

Smail Entitles Affected: None

Government Levels Affected: Local, State

Agency Contact: Philip A. Holman 202 252-4566

RIN: 0970-AA01

911. AID TO FAMILIES WITH **DEPENDENT CHILDREN; TREATMENT** OF UTILITY PAYMENTS BY APPLICANT OR RECIPIENTS LIVING IN CERTAIN FEDERALLY **ASSISTANCE HOUSING** 

CFR Citation: 45 CFR 233.20

Completed:

Reason	Date		FR	Cite
Final Action	09/12/88	53	FR	35198
Final Action Effective	09/12/88			

Smail Entities Affected: None

Government Levels Affected: None

Agency Contact: Diann Dawson 202 252-5166

RIN: 0970-AA05

912. AID TO FAMILIES WITH **DEPENDENT CHILDREN PROGRAM; EXTENSION OF MEDICAID ELIGIBILITY WHEN SUPPORT COLLECTIONS RESULT IN TERMINATION OF AFDC ELIGIBILITY** 

CFR Citation: 45 CFR 233; 42 CFR 435; 42 CFR 436

Completed:

expired

Reason	Date	FR Cite
No regulation will be issued because	10/01/88	

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

**Agency Contact: Diann Dawson 202** 252-5116

RIN: 0970-AA07

913. MEDICAL SUPPORT **ENFORCEMENT #2** 

Significance: Regulatory Program CFR Citation: 45 CFR 305; 45 CFR 306

Completed:

Reason	Date		FR	Cite
Final Action	09/16/88	53	FR	36014
Final Action Effective	09/16/88			

Small Entities Affected: None

Government Levels Affected: Local, State. Federal

**Agency Contact: Andrew Hagan 202** 252-5368

RIN: 0970-AA13

914. DISREGARD OF CHILD SUPPORT **PAYMENTS: REGULATIONS** IMPLEMENTING THE DEFICIT **REDUCTION ACT OF 1984** 

CFR Citation: 45 CFR 302.51

Completed:

Reason	Date		FR	Cite
Final Action	06/09/88	53	FR	21642

Small Entities Affected: None

Government Levels Affected: Local, State, Federal

Agency Contact: Carol Jordan 202 252-5366

RIN: 0970-AA15

915. GRANTS TO STATES FOR **PUBLIC ASSISTANCE PROGRAMS.** TREATMENT OF REPLACEMENT CHECKS

CFR Citation: 45 CFR 201.5

Completed:

Reason	Date		FR	Cite
Final Action	06/28/88	53	FR	24267
Final Action	06/28/88	53	FR	24267

Smail Entitles Affected: None

Government Levels Affected: None

Agency Contact: John B. McDonald 202 252-4586

RIN: 0970-AA19

916. ALIEN LEGALIZATION

Significance: Regulatory Program

CFR Citation: 45 CFR 206.10(a)(1)(vii)(B); 45 CFR 233.20(a)(3)(vi)(B); 45 CFR 233.50(c)

Completed:

Reason	Date		FR	Cite
Final Action	08/12/88	53	FR	30432
Final Action Effective	09/30/88	53	FR	30432

Smail Entities Affected: None

**Government Levels Affected: State** Agency Contact: Diann Dawson 202 252-5116

RIN: 0970-AA48

917. FY 1988 SCORING SYSTEM FOR PERFORMANCE INDICATORS

Significance: Agency Priority CFR Citation: 45 CFR 305.98

Completed:

Reason	Date	FR Cite
Decision made to terminate	10/01/88	

rulemaking

Small Entities Affected: None Government Leveis Affected: Local, State. Federal

Agency Contact: John Treacy 202 252-5363

RIN: 0970-AA51

[FR Doc. 88-20997 Filed 10-21-88; 8:45 am] **BILLING CODE 4110-60-T**