federal register

Friday
December 19, 1980

Part V

Department of Health and Human Services

Office of the Secretary

Improving Government Regulations; Semiannual Agenda of Regulations

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

20 CFR Ch. 111

21 CFR Ch. 1

42 CFR Chs. I–IV

45 CFR Subtitle A Chs. II, III and XIII

Improving Government Regulations; Semiannual Agenda of Regulations

AGENCY: Department of Health and Human Services.

ACTION: Publication of the semiannual agenda of regulations (Improving Government Regulations).

SUMMARY: The President's Executive Order on Improving Government Regulations, Executive Order 12044, requires each Federal agency to publish at least twice a year a list of significant regulations under development. HHS published its last semiannual agenda on June 13, 1980 (45 FR 40356).

This semiannual agenda contains: (1) All non-FDA regulations being developed within the Department; and (2) FDA regulations classified as "policy significant". Many of the regulatory actions listed in this agenda will be reviewed by a new Secretary of Health and Human Services after January 20, 1981. Review by the new Secretary may result in modifications to the agenda.

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: Glenn Kamber, Deputy Executive Secretary (Regulations), Office of the Secretary, Department of Health and Human Services, 200 Independence Avenue, S.W., Washington, D.C. 20201, Telephone: (202) 245–3160.

Patricia Roberts Harris

Secretary of Health and Human Services.

REGULATIONS AFFECTING SERVICES AND OPPORTUNITIES TO INDIVIDUALS

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HDS–7 Child Abuse and Neglect Prevention and Treatment Program: General Rules
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SSA–44 Determination of Assistance Payment When One or More Family Members Are SSI Beneficiaries (AFDC)
SSA–50 Additional Drop Out Years for Child Care (OASDI)
SSA–51 Proration of Shelter Utilities and Similar Expenses for AFDC Children Living with Ineligible Relative (AFDC)

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HDS–22 Joint Recodification Project–Application, Eligibility Determination
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PHS–112 Redesignation of the Contract Health Service Delivery Area (CHSDA) for the Passamaquoddy Reservation
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SUNSET REVIEW REGULATIONS

The following regulations are listed for the purposes of Section 4 of Executive Order 12044, which requires a periodic review of existing regulations. They are described in more detail elsewhere in this agenda.

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FDA 23—New Drug Evaluation; Revision of IND/NDA Regulations
FDA 76—Medicated Feed Task Force Implementation
HCFA–6 Medicare/Medicaid Program: Conditions of Participation for Hospitals—Revised Conditions for Participation
HCFA–13 Medicare/Medicaid Program: Conditions of Participation for Skilled Nursing Facilities (SNFs) and Intermediate Care Facilities (ICFs)—Conditions of Participation
HCFA–21 Medicare Program: Provider Reimbursement Determinations—Criteria and Procedures for PRRB Hearings and Decisions
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PHS–33 Medical Care for Uniformed Services Personnel of the Coast Guard, Public Health Service, and National Oceanic and Atmospheric Administration, 42 CFR 31
PHS–34 Medical Care for Seafarers and Others at Public Health Service Facilities
PHS–35 Public Health Service Hospital and Clinic Managment, 42 CFR 35
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PHS–17 Medical Examinations of Aliens
PHS–31 Persons to Whom Services Will Be Provided
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SSA–27 Old Age, Survivors, Disability Insurance and Supplemental Security Income Programs—Disability, 20 CFR Part 404, Subpart P and Part 416, Subpart I
SSA–29 Old Age, Survivors, Disability Insurance and Supplemental Security Income Programs—Representative Payee, 20 CFR Part 404, Subpart Q and Part 416, Subpart F
SSA–30 Supplemental Security Income Program—Eligibility, 20 CFR Part 416, Subpart B
SSA–45 Fair Hearings, 45 CFR Part 205.10
SSA–46 Application Eligibility Determinations, and Furnishing Assistance 45 CFR Part 206
OCSE–2 Office of Child Support Enforcement—Strengthening of CSE, Audit and Penalty Regulations, 45 CFR Parts 301, 302, 304 and 305
OCSE–3 Office of Child Support Enforcement—Optional Procedures for Distribution of Child Support Collections (Immediate Distribution), 45 CFR Parts 302 and 304
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PHS–2—National Library of Medicine Programs: Revision of General Rules for the National Library of Medicine, National Library of Medicine Grants, National Institutes of Health and National Library of Medicine Traineeships, and National Institutes of Health and National Library of Medicine Training Grants.	A. *Description:* There are 4 NLM regulations undergoing revision. The regulations at 42 CFR Part 4 relate to the access of facilities and library collections. Those at 42 CFR Part 59a deal with the NLM extramural programs. These rules provide guidance for applying for grants for establishing, expanding and improving basic library resources and for establishing Regional Medical Libraries. The regulations at 42 CFR Part 63 deal with both NIH and NLM traineeships. The regulations at 42 CFR Part 64 govern the training grants of NIH and NLM. B. *Why Significant:* These proposed amendments will bring up to date the NLM regula-	

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	tions by (1) improving readability by the use of the HEW Operation Common Sense principles, and (2) allowing for inclusion of updated nondiscrimination language. In addition, the regulation at 42 CFR Part 59a will be revised to remove the requirement of providing photocopies of biomedical materials without charge to users. C. *Regulatory Analysis:* Not required. D. *Need:* These revisions are necessary to comply with the Department's programs of recodification and "Operation Common Sense." E. *Legal Basis:* 42 USC 216, 42 USC 276 and 42 USC 280b-2. F. *Chronology:* Notice of Decision to Regulate published November 21, 1979 (44 FR 66852)	Kenneth Carney, Acting Executive Officer, National Library of Medicine, Bethesda, Md. 20209, (301) 496-649.
PHS-5—Protection of Human Research Subjects—Institutional Review Boards.	A. *Description:* These revised regulations will govern the IRB mechanism. The purpose of IRBs is to assure that biomedical and behavioral research, conducted or supported by HEW, meets the requirements concerning informed consent by persons involved as subjects in research. The revision is based on recommendation of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. B. *Why Significant:* These regulations are significant in that review of proposed research by IRBs is the primary mechanism for assuring that the rights of human subjects are protected. C. *Regulatory Analysis:* Not required; however, under consideration. D. *Need:* The National Research Act created the Nat'l. Comm. One of the topics of study identified in the mendate to the Commission wes "Institutionel Review Boards". The Commission was required to make recommendations to the Secretary, regarding IRB mechanisms and appropriate enforcement mechanisms for carrying out decisions. The Commission's report was published in the FEDERAL REGISTER and public comments were received. After reviewing the recommendations end comments, the Secretary decided to issue regulations on this subject. E. *Legal Basis:* 5 U.S.C. 301. F. *Chronology:* Recommendations of the Commission regarding IRBs published Nov. 30, 1978 (43 FR 56174). Comment period ended Jan. 29, 1979. NPRM published August t4, 1979 (44 FR 47688). Comment period ended Nov. 12, 1979.	F. William Dommel, Jr., J.D., Assist. Dir. for Regs., Office for Protection from Research Risks, National Institutes of Health, Bethesda, Md. 20205, (301) 496-7163.
PHS-6—Protection of Human Subjects: Regulations on Research Involving Children.	A. *Description:* These regulations will provide additional protections for children who are research subjects of DHEW conducted or supported research. B. *Why Significant:* These regulations define the circumstances under which such research can be conducted or supported, describe procedures for the review and approval of the research, and identify the requirements for informed consent to participate in research by and for such subjects. C. *Regulatory Analysis:* Not required. D. *Need:* The National Research Act, requires the Secretary to publish all recommendations of the National Commission for the Protection of Human Subjects of Biomedical end Behavioral Research in the FEDERAL REGISTER, to solicit public comment, to consider the recommendations end relevant comments end to take appropriate administrative action with respect to the recommendations. After reviewing the recommendations and comments, the Secretary decided to issue regulations on this subject. E. *Legal Basis:* 5 U.S.C. 301. F. *Chronology:* Recommendations of the Commission regarding children published Jan. 13, 1978 (43 FR 2084). Comment period ended March 14, 1978. NPRM published July 21, 1978 (43 FR 31786). Comment period originally ended Sept. 19, 1978, but was extended by the NPRM on IRBs to Nov. 12, 1979.	F. William Dommel, Jr., J.D., Assist. Dir. for Regs., Office for Protection from Research Risks, National Institutes of Health, Bethesda, Md. 20205, (301) 496-7163.
PHS-7—Protection of Human Subjects: Regulations on Research Involving Those Institutionelized as Mentally Disabled.	A. *Description:* These regulations will provide additional protections for those institutionalized es mentally disabled persons who participate as subjects in DHEW conducted or supported research. B. *Why Significant:* These regulations would implement the recommendations of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research by defining the circumstances under which research projects involving the institutionalized mentally disabled can be conducted or supported. The implementing regulations would also spell out requirements for consent or, in the absence of competence, assent of the institutionalized mentally disabled. The regulations would also require increasing evidence of benefit to the subjects as the risks of the research escalated. C. *Regulatory Analysis:* Not required. D. *Need:* The National Research Act, requires the Secretary to publish all recommendations of the National Commission for the Protection of Human Subjects of Biomedical end Behavioral Research in the FEDERAL REGISTER, to solicit public comment, to consider the recommendations and relevent comments and to take appropriate action with respect to the recommendations end comments. The Secretary decided to issue regulations on this subject. E. *Legal Basis:* 5 U.S.C. 301. F. *Chronology:* Recommendations of the Commission regarding Those Institutionalized es Mentally Disabled published March 17, 1978 (43 FR 11328). Comment period ended May 16, 1978. Notice of decision to develop regulations published April 24, 1978 (43 FR 17375). Notice of Proposed Rulemaking published Nov. 17, 1978 (43 FR 53950). Comment period originally ended Jan. 16, 1979, but wes extended by the NPRM on IRBs to Nov. 12, 1979.	F. William Dommel, Jr., J.D., Assist. Dir. for Regs., Office for Protection from Research Risks, National Institutes of Health, Bethesda, Md. 20205, (301) 496-7163.Q04
PHS-10—Health Incentive Grants for Comprehensive Public Health Services.	A. *Description:* Establishes requirements for health incentive grents to States to assist them in providing comprehensive public health services. Will provide e method for the equitable distribution of funds among State end local public health entities within the State and define program accountability measures. B. *Why significant:* State and local health agencies have the primary responsibility for a broad area of public health: health protection end health maintenance directed et populations, and personal health services directed et disadvantaged persons and those et special nsk. This program makes grants to provide a Federal sharing in the costs of those vital services, in a manner designed to encourage State and local health entities to increase their own investments. C. *Regulatory Analaysis:* Not required. D. *Need:* To implement Section 314(d) of the Public Health Service Act, es emended by the Health Services end Centers Amendments of 1978. E. *Legal Basis:* 42 U.S.C. 246d F. *Chronology:* Notice of Decision to Develop Regulations published on May 1, 1979 (44 FR 25476). Development of NPRM in abeyence pending legislative action.	Mr. Dennis D. Tolsma, Office of the Center Director, Center for Disease Control, 1600 Clifton Road, NE, Atlanta, Georgia 30333. Phone: (404) 329-3243, FTS: 236-3243.
PHS-12—Grants for Preventive Health Services (42 CFR Part 51b): Subpart F—Grants	A. *Description:* Established requirements for research, demonstrations and public information and education grants for the prevention and control of venereal disease and	

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for Research, Demonstrations, and Public Information and Education for the Prevention and Control of Venereal Diseases.	Implements an amendment to Section 318 of the Public Health Service Act that at least 5 percent of grant funds appropriated under Section 318 for the prevention and control of venereal diseases be expended for this program. B. *Why significant:* Provides regulatory base to expand capability to refine venereal disease prevention and control technology. C. *Regulatory Analysis:* Not required. D. *Need:* To implement changes made to Section 318(b) of the Public Health Service Act by the Health Services and Centers Amendments of 1978. E. *Legal Basis:* Section 318 of the Public Health Service Act (42 U.S.C. 247c), as amended by the Health Services and Centers Amendments of 1978. F. *Chronology:* Notice of Decision to Develop Regulations published April 13, 1979 (44 FR 22133). Comment period will end 45 days after publication of NPRM. NPRM published July 17, 1980 (45 FR 47878). Comment period ended Sept. 2, 1980.	Dr. Paul J. Wiesner, Director, Venereal Disease Control Division, Bureau of State Services, Center for Disease Control, Atlanta, Georgia 30333, Phone: (404) 329-3343, FTS: 236-3343.
PHS-13—Grants for Preventive Health Services (42 CFR Part 51b): Subpart H—Grants for Detection, Treatment, and Prevention of Lead-Based Paint Poisoning.	A. *Description:* Governs the award of grants for lead-based paint poisoning prevention programs. B. *Why significant:* Reflects the transfer of statutory authority for the program and revisions in the law pertaining to advisory committees and the use of local resources. C. *Regulatory Analysis.* Not required. D. *Need:* The revised regulation is necessary to reflect both the transfer of the authority for this program from the Lead-Based Paint Poisoning Prevention Act to Section 316 of the Public Health Service Act and the amendments to the authority. E. *Legal Basis:* Section 318 of the Public Health Service Act (42 U.S.C. 247a), as amended by the Health Services and Centers Amendments of 1978. F. *Chronology:* Notice of Decision to Develop Regulations published September 27, 1979 (44 FR 55602). NPRM published July 17, 1980 (45 FR 47878). Comment period ended Sept. 2, 1980.	Dr. Vernon N. Houk, Director, Environmental Health Services Division, Bureau of State Services, Center for Disease Control, 1600 Clifton Road, NE, Atlanta, Georgia 30333, Phone: (404) 262-6645, FTS: 236-6645.
PHS-15—Foreign Quarantine Regulations: Requirements and Inspections.	A. *Description:* Provides procedures on preventing the introduction, transmission, or spread of communicable diseases from foreign countries into the United States. B. *Why significant:* The procedures affected all international traffic arriving in the U.S. by ship, aircraft, or land conveyances. C. *Regulatory Analysis:* Not required. D. *Need:* To update the regulations in accordance with current concepts of disease surveillance, investigation, and control. E. *Legal Basis:* Section 361 of the Public Health Service Act (42 U.S.C. 264) F. *Chronology:* Notice of Decision to Develop Regulations published June 29, 1979 (44 FR 37963). Comment period will end 60 days after publication of the NPRM.	Mr. Joseph F. Giordano, Director, Quarantine Division, Bureau of Epidemiology, Center for Disease Control, 1600 Clifton Road, NE, Atlanta, Georgia 30333, Phone: (404) 329-3674, FTS: 236-3674.
PHS-17—Medical Examination of Aliens.....	A. *Description:* Provides for the physical and mental examination of aliens within the United States or in other countries as required by the Immigration laws. B. *Why significant:* The regulations provide the basis for the physical and mental examination of aliens to determine whether the aliens are afflicted with any of the excludable conditions as stated in the Immigration and Nationality Act. C. *Regulatory Analysis:* Not required. D. *Need:* To implement changes in accordance with current epidemiological concepts and medical diagnostic standards. E. *Legal Basis:* Section 325 of the Public Health Service Act (42 U.S.C. 264) and Section 212(a) of the Immigration and Nationality Act (8 U.S.C. 1182). F. *Chronology:* Notice of Decision to Develop Regulations published June 29, 1979 (44 FR 37962). Comment period will end 60 days after publication of NPRM.	Mr. Joseph F. Giordano, Director, Quarantine Division, Bureau of Epidemiology, Center for Disease Control, 1600 Clifton Road, NE, Atlanta, Georgia 30333. Phone: (404) 329-3674, FTS: 236-3674.
PHS-24—Subpart F—Qualification of Health Maintenance Organizations.	A. *Description:* This regulation establishes the requirements for determining whether an entity is a qualified HMO. B. *Why Significant:* This regulation describes the procedurea and information that an HMO must provide in making application to become federally qualified. C. *Regulatory Analysis:* Not required. D. *Need:* To update program changes in the qualification process and information provided the public. E. *Legal Basis:* Sec. 215, 58 Stat. 690 (42 U.S.C. 216); Secs. 1301-1318, as amended. 92 Stat. 2131-2141 (42 U.S.C. 300e-300e-17). F. *Chronology:* —Notice of Decision to Revise Regulations. 44 FR 22133. —Interim Regulations—42 CFR Part 110, subpart F. 42 FR 29400-16. (Under revision.) —Further revisions to be made through a NPRM.	Howard R. Veit, Director, Office of Health Maintenance Organizations, Park Building, 12420 Parklawn Drive, Rockville, Maryland 20857, 301/443-4106.
PHS-26—Subpart I—Continued Regulation of HMOs and Other Entities.	A. *Description:* This regulation establishes the requirements for continued compliance of federally qualified HMOs. B. *Why Significant:* This regulation describes the enforcement and compliance procedures with respect to HMOs and other entities which fail to comply with such requirements. C. *Regulatory Analysis:* Not required. D. *Need:* To amend the enforcement and compliance procedures to reflect the operating experience of the program. E. *Legal Basis:* Sec. 215, 58 Stat. 690 (U.S.C. 216); Secs. 1301-1318, as amended, 92 Stat. 2131-2141 (42 U.S.C. 300e-300e-17). F. *Chronology:* —Notice of Decision to Revise Regulations. 44 FR 22133. —Final Regulations—42 CFR Part 110, subpart I. Comment period: none. 43 FR 32254-8. —Further revisions to be made through a NPRM.	Howard R. Veit, Director, Office of Health Maintenance Organizations, Park Building, 12420 Parklawn Drive, Rockville, Maryland 20857, 301/443-4106.
PHS-27—Subpart J—Reconsiderations and Hearings (NPRM).	A. *Description:* This regulation would have established requirements for investigating and determining whether HMOs have violated the HMO Act or the regulations. In addition, it would have established procedures for requesting reconsiderations and hearings with respect to denial of qualification applications. B. *Why Significant:* This regulation described the requirements for investigating and determining whether HMOs have violated the HMO Act or regulations and procedures to follow in requesting reconsiderations and hearings in the denial of qualification applicants. C. *Regulatory Analysis:* Not required. D. *Need:* To establish grievance and appeals procedures. E. *Legal Basis:* Sec. 215, 58 Stat. 690 (42 U.S.C. 216); Secs. 1301-1318, as amended. 92 Stat. 2131-2141 (42 U.S.C. 300e-300e-17). F. *Chronology:* —Notice of Decision to Revise Regulations. 44 FR 22133. —NPRM—Comment period: 9/17/76-11/1/76. 41 FR 40292-5.	Howard R. Veit, Director, Office of Health Maintenance Organizations, Park Building, 12420 Parklawn Drive, Rockville, Maryland 20857, 301/443-4106.

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	—Notice to withdraw this NPRM was submitted for official clearance on 4/28/79. Since the conditions that prompted the NPRM to be issued have changed, there is no need for this rule to be published.	
PHS-28—New Subpart J—Loans and Loan Guarantees for Acquisition and Construction of Ambulatory Health Care Facilities.	A. *Description:* This regulation establishes the requirements for qualified HMOs to obtain loans and loan guarantees to acquire or construct ambulatory health care facilities and acquire equipment for those facilities. B. *Why Significant:* This regulation allows the Secretary to make and guarantee loans to qualified HMOs. C. *Regulatory Analysis:* Not required. D. *Need:* To implement the HMO Amendments of 1978 concerning the authority to provide loan assistance to eligible HMOs. E. *Legal Basis:* Sec. 215, 58 Stat. 690 (42 U.S.C. 216); Secs. 1301-1318, as amended, 92 Stat. 2131-2141 (42 U.S.C. 300e-300e-17). F. *Chronology:* Interim Final Regulations published April 9, 1980 (45 FR 24352). Comment period ended June 9, 1980.	Howard R. Veit, Director, Office of Health Maintenance Organizations, Park Building, 12420 Parklawn Drive, Rockville, Maryland 20857, 301/443-4106.
PHS-29—Subpart K—Grants and Cooperative Agreement for Training and Technical Assistance.	A. *Description:* This regulation establishes the requirements for the award of grants and cooperative agreements for management and technical assistance. B. *Why Significant:* This regulation allows the Secretary to make grant funds available to support the training of qualified management personnel. D. *Need:* To implement the HMO Amendments of 1978 to support management training activities. E. *Legal Basis:* Sec. 215, 58 Stat. 690 (42 U.S.C. 216); Secs. 1301-1318, as amended, 92 Stat. 2131-2141 (42 U.S.C. 300e-300e-17). F. *Chronology:* —Dratt NPRM under development.	Howard R. Veit, Director, Office of Health Maintenance Organizations, Park Building, 12420 Parklawn Drive, Rockville, Maryland 20857, 301/443-4106.
PHS-30—Indian Health Care Improvement Act Programs.	A. *Description:* Amends 42 CFR 36, Subpart J—Indian Health Care Improvement Act Program (Pub. L. 94-437)—to reflect conformance with the Department's new regulations on grant administration which should result in greater standardization and simplification for IHS grant administration and a greater reliance on the grantee's own management systems. B. *Why Significant:* The regulations will conform existing IHS grant administration regulations to the Department's new regulations which establishes uniform requirements for the administration of HHS grants and principles for determining costs applicable to activities assisted by HHS grants. C. *Regulatory Analysis:* Not required. D. *Need:* IHS has been directed by the Department to revise 42 CFR 36, Subpart J, as required by the Uniform Administrative Requirements for Grants-in-Aid to State and Local Governments, Circular No. A-102, Revised (published September 12, 1977, 42 FR 45828), to conform to the Department's new regulations on grant administration (45 CFR Part 74). E. *Legal Basis:* 5 U.S.C. 301; 42 FR 45828; 25 U.S.C. 1601. F. *Chronology:* Changes to subpart J are governed by Section 702(b) of Pub. L. 94-437. That section requires that any changes be published in the FEDERAL REGISTER with at least a 60 day comment period and that IHS will consult with appropriate national or regional Indian organizations to the extent practicable. G. *Citation:* 42 CFR 36, Subpart J.	Richard J. McCloskey, Indian Health Service, Room 6A-20, 5600 Fishers Lane, Rockville, Maryland 20857, (301)-443-1116).
PHS-31—Persons to whom services will be provided.	A. *Description:* The regulation will amend 42 CFR 36.12 to specify eligibility for services for dependent members of an eligible Indians' household and will correct the illegal sex-discrimination clause so that the eligibility status of non-Indian spouses will be the same regardless of sex. B. *Why significant:* The regulation will amend basic eligibility criteria and, therefore, affect delivery of IHS services to the Indian population. C. *Regulatory Analysis:* Not required. D. *Need:* To amend currrent regulation because OGC and the Justice Department have advised that the current regulation which provides eligibility only for non-Indian wives of eligible Indians is legally indefensible being an illegal discrimination based on sex and OGC has also advised that IHS policy of serving dependent members of an eligible Indians' household both Indian and non-Indian should be provided for in regulation rather than only in the IHS manual. E. *Legal Basis:* 25 U.S.C. 13 (Snyder Act) and 42 U.S.C. 2001 (Transfer Act). F. *Chronology:* Intent to issue a NPRM dealing with these issues was published in the preamble to the final regulations for Contract Health Services, 42 CFR 36, Subpart C, 43 FR 34649, August 4, 1978. Notice of decision to amend regulations was published on April 13, 1979 (44 FR 22132). G. *Citation:* 42 CFR 36.12.	Richard J. McCloskey, Room 6A-20; 5600 Fishers Lane, Rockville, Maryland 20857; (301-443-1116).
PHS-32—Grants for Development, Construction, and Operations of Facilities and Services.	A. *Description:* Amends 42 CFR 36, Subpart H—Grants for Development, Construction, and Operations of Facilities and Services (Pub. L. 93-638)—to reflect conformance with the Department's new regulations on grant administration which should result in greater standardization and simplification for IHS grant administration and a greater reliance on the grantee's own management systems. B. *Why Significant:* The regulation will conform existing IHS grant administration regulations to the Department's new regulations which establishes uniform requirements for the administration of HHS grants and principles for determining costs applicable to activities assisted by HHS grants. C. *Regulatory Analysis:* Not Required. D. *Need:* IHS has been directed by the Department to revise 42 CFR 36 Subpart H, as required by the Uniform Administrative Requirements for Grants-in-Aid to State and Local Governments, Circular No. A-102, Revised (published September 12, 1977, 42 FR 45828), to conform with the Department's new regulations on grant administration (35 CFR Part 74). E. *Legal Basis:* 5 U.S.C. 301; 42 FR 45828; 25 U.S.C. 450. F. *Chronology:* Changes to Subpart H are governed by the procedures outlined in Section 107(c) of Pub. L. 93-638 which require any changes to be submitted to the committees on Interior and Insular Affairs of the respective Houses of Congress and be published in the FEDERAL REGISTER with at least a 60 day comment period. IHS is also to consult with appropriate national or regional Indian organizations to the extent practicable. In addition to the legislative requirements, the current regulation itself requires that IHS consult with the tribes and that the final rule not go into effect until 30 days after publication in the FEDERAL REGISTER. G. *Citation:* 42 CFR 36, Subpart H.	Richard J. McCloskey, Indian Health Service, Room 6A-20, 5600 Fishers Lane, Rockville, Maryland 20857, (301-443-1116).

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PHS-33—Medical Care for Uniformed Services personnel of the Coast Guard, Public Health Service, and National Oceanic and Atmospheric Administration 42 CFR 31.	A. *Description:* Provides conditions under which beneficiaries will receive medical, dental, and surgical care at Public Health Service and Non-Public Health Service facilities. B. *Why significant:* Explains benefits available to beneficiaries and the rules they must follow to secure benefits. Rules may serve to enhance or deny care to certain beneficiaries. C. *Regulatory Analysis:* Not required. D. *Need:* Regulations are needed to implement Public Health Service Act, administrative decisions. E. *Legal Basis:* Sec. 326 of the Public Health Service Act (42 U.S.C. 253) F. *Chronology:* None.	Mr. Walter W. Ward, Procedural Implementation Section, Policy Coordination Branch, Bureau of Medical Services, 6525 Belcrest Road, West Hyattsville, Md. 20782, (301) 436-6261.
PHS-34—Medical Care for Seafarers and others at Public Health Service facilities.	A. *Description:* Provides conditions under which beneficiaries will receive medical, dental, and surgical care at Public Health Service and Non-Public Health Service facilities. B. *Why significant:* Explains benefits available to beneficiaries and the rules they must follow to secure benefits. Rules may serve to enhance or deny care to certain beneficiaries. C. *Regulatory Analysis:* Not required. D. *Need:* Regulations are needed to implement Public Health Service Act, administrative decisions. E. *Legal Basis:* Sec. 322 of the Public Health Service Act (42 U.S.C. 249). F. *Chronology:* Previous (existing) regulations published 8/17/75.	Mr. Walter W. Ward, Procedural Implementation Section, Policy Coordination Branch, Bureau of Medical Services, 6525 Belcrest Road, West Hyattsville, Md. 20782, (301) 436-6261.
PHS-35—Public Health Service Hospital and Clinic Management, 42 CFR 35.	A. *Description:* Provides how the Public Health Service will manage facilities and relate to patients and visitors; and generally describe how health care should be provided. B. *Why significant:* Established the responsibilities, standards, and authorities under which managers operate Public Health Service facilities, and rules of conduct for patients and visitors. C. *Regulatory Analysis:* Not required. D. *Need:* Regulations are needed to implement Public Health Service Act, administrative decisions. E. *Legal Basis:* Sec. 321 of the Public Health Service Act (42 U.S.C. 248).	Mr. Walter W. Ward, Procedural Implementation Section, Policy Coordination Branch, Bureau of Medical Services, 6525 Belcrest Road, West Hyattsville, Md 20782, (301) 436-6261.
PHS-38—Amendments to MCH CC Services Programs.	A. *Description:* This regulation will implement statutory amendments dealing with reasonable costs and will make clarifying administrative changes. B. *Why Significant:* These are technical amendments. C. *Regulatory Analysis:* Not Required. D. *Need:* To improve implementation of Title V, Social Security Act, based on minor statutory changes and experience in administering the program. E. *Legal Basis:* Sections 503 and 504, Social Security Act, as amended. F. *Chronology:* None.	James J. Corrigan, Director, Division of Policy Development, BCHS, Rm. 6-40, Parklawn Building, 5600 Fishers Lane, Rockville, Md. 20857, (301) 443-1034.
PHAS-39—Grants to Plan, Develop and Operate Hospital-Affiliated Primary Care Centers	A. *Description:* Regulations will implement a demonstration program for providing comprehensive primary health care services to medically underscrved communities by community hospitals through reorganized outpatient resources. B. *Why Significant:* Within the limits of a demonstration program, the impact will be on medically underserved populations. C. *Regulatory Analysis:* Not required. D. *Need:* To implement Section 328, Public Health Service Act. E. *Legal Basis:* 42 U.S.C. 254a-1. F. *Chronology:* Notice of Decision to Develop Regulations was published 4/13/79.	James J. Corrigan, Director, Division of Policy Development, BCHS, Rm. 6-40, Parklawn Building, 5600 Fishers Lane, Rockville, Md. 20857, (301) 443-1034.
PHS-40—Project Grants for Community Health and Migrant Health.	A. *Description:* Regulations will implement statutory provisions requiring that pharmaceutical services be mandatory, some supplemental services be defined as priority services, and allowing grantees to retain half of earned income. Migrant high impact area is reduced from 6,000 migrants to 4,000. B. *Why Significant:* These regulations have impact on the primary care delivery capacity in medically underserved areas. C. *Regulatory Analysis:* Not required. D. *Need:* To implement Sections 329 and 330 of the Public Health Service Act, as amended by Pub. L. 95-626. E. *Legal Basis:* 42 U.S.C. 247 and 254c. F. *Chronology:* NOI published 4/13/79.	James J. Corrigan; Director, Division of Policy Development, BCHS, Rm. 6-40, Parklawn Building, 5600 Fishers Lane, Rockville, Md. 20857, (301) 443-1034
PHS-41—Demonstration Health and Nutrition Projects.	A. *Description:* These regulations will implement a statute for multicounty health and demonstration projects in economic development regions. B. *Why Significant:* These projects will provide health and nutrition services and contribute to regional economic development. C. *Regulatory Analysis:* Not needed. D. *Need:* To implement Section 516 of the Regional Development Act of 1975. E. *Legal Basis:* Section 516, Regional Development Act of 1975. F. *Chronology:* None.	James J. Corrigan; Director, Division of Policy Development, BCHS, Rm. 6-40, Parklawn Building, 5600 Fishers Lane, Rockville, Md. 20857, (301) 443-1034.
PHS-42—Project Grants to States for Hypertension Services.	A. *Description:* Regulations will implement statutory amendments changing formula grants to project grants, requiring greater accountability and more effective service programs. B. *Why Significant:* State hypertension programs previously funded under formula grants will now be funded under project grants, requiring greater accountability for Federal funds. C. *Regulatory Analysis:* Not required. D. *Need:* To implement Section 317 of the Public Health Service Act, as amended by Pub. L. 95-626. E. *Legal Basis:* 42 U.S.C. 247b. F. *Chronology:* Notice of Intent published 4/13/79. Announcement requesting grant applications published 6/27/79.	James J. Corrigan; Director, Division of Policy Development, BCHS, Rm. 6-40, Parklawn Building, 5600 Fishers Lane, Rockville, Md. 20857, (301) 443-1034.
PHS-46—Grants for Drug Abuse Prevention, Treatment, and Rehabilitation; requirements for State participation in formula grants.	A. *Description:* These regulations establish requirements for receiving and administering formula grants to assist States in designing, establishing, conducting, coordinating, and evaluating projects for the development of more effective training, treatment, rehabilitation, and research projects to deal with drug abuse and drug dependence. B. *Why Significant:* To receive an allotment, a State must submit to and have approved by the Secretary a State plan or modification of a State plan which meets the requirements specified in the statute and these regulations. (Formula grants are currently being awarded under National Institute on Drug Abuse guidelines developed in 1973 and updated annually.) C. *Regulatory Analysis:* Not required. D. *Need:* These regulations are required to implement section 409 of the Drug Abuse Office and Treatment Act of 1972, as amended. The regulations required by section 409(c)(1)(B)(iii) were published as a Final Rule on June 24, 1976 (41 FR 26012).	Nancy Soulen, Legal Assistant, Office of Director, National Institute on Drug Abuse, Room 10-14, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, (301) 443-6482.

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	E. *Legal Basis:* Section 409 of Pub. L. 92-255, the Drug Abuse Office and Treatment Act of 1972, as amended by Pub. L. 94-237 (90 Stat. 245-247), Pub. L. 94-371 (90 Stat. 1040), Pub. L. 95-83 (91 Stat. 397), and Pub. L. 95-461 (92 Stat. 1268-1269) (21 U.S.C. 1176). F. *Chronology:* Notice of Proposed Rulemaking was published August 28, 1973 (38 FR 22968) with a 30-day comment period. A second Notice of Proposed Rulemaking was published January 14, 1977 (42 FR 2988) with a 45-day comment period.	
PHS-48—Confidentiality of Alcohol and Drug Abuse Patient Records; minimum requirements for protecting.	A. *Description:* These regulations apply to the records of the identity, diagnosis, prognosis, or treatment of alcohol and drug abuse patients. They require that records be kept confidential and be disclosed only (1) with the written consent of the patient, (2) pursuant to an authorizing court order based upon a finding of good cause, or (3) without either a written consent or an authorizing court order in the following limited circumstances: for a medical emergency, for the conduct of scientific research, an audit, or program evaluation. B. *Why significant:* This rule applies to alcohol and drug abuse patient records maintained in connection with any alcohol abuse or drug abuse program conducted, regulated, or directly or indirectly assisted by any department or agency of the United States. It implements statutory requirements which encourage alcohol and drug abusers to seek treatment by removing the fear that attempts to enroll in treatment programs would lead to disclosure to employers and other members of the public or lead to police harassment and/or arrest. C. *Regulatory Analysis.* Not required. D. *Need:* These regulations are required by section 333(g) of the Comprehensive Alcohol Abuse and alcoholism Prevention, Treatment, and Rehabilitation Act of 1970, as amended, and by section 408(g) of the Drug Abuse Office and Treatment Act of 1972, as amended. Rewrite of these regulations will fulfill the Department's commitment to make regulations clearer and more concise and will take into consideration the Departments experience with the regulation over the past four years. E. *Legal Basis:* Section 408 of Pub. L. 92-255, the Drug Abuse Office and Treatment Act of 1972 (21 U.S.C. 1175) as amended by section 303 of Pub. L. 93-282 (88 Stat. 137); and section 333 of Pub. L. 91-616, the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970, (42 U.S.C. 4582), as amended by section 122(a) of Pub. L. 93-282 (88 Stat. 131). F. *Chronology:* Final Rule, published July 1, 1975 (40 FR 27802), has been reviewed under Operation Common Sense and a decision made to recodify.	Judith T. Galloway, Legal Assistant, Alcohol, Drug Abuse, and Mental Health Administration, Room 13C-06, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone: (301) 443-3200. Notice of Decision to develop, Regulations published January 2, 1980 (45 FR 53) with a 60 day comment period.
PHS-56—Project Grants for Establishment of Departments of Family Medicine.	A. *Description:* To govern grants to schools of medicine and osteopathy to meet the projects to establish and maintain academic administrative units to provide clinical instruction in family medicine. B. *Why Significant:* Promotes the adequate supply and equitable distribution of health manpower throughout the United States. C. *Regulatory Analysis:* Not required. D. *Need:* Required by statute to implement the Public Health Service Act. E. *Legal Authority:* 42 U.S.C. 295g F. *Chronology:* None. NPRM published 10-16-80 (45 FR 68902) Comment period ends 12-15-80	Kenneth Moritsugu, Bureau of Health Professions, HRA, Center Building, 3700 East-West Highway, Hyattsville, Md. 20782, (301) 436-6418.
PHS-57—Araa Haalth Education Centers	A. *Description:* To govern programs to improve the distribution, supply, quality, utilization, and efficiency of health personnel in the health services delivery system and to encourage the regionalization of educational responsibilities of health professions schools. B. *Why Significant:* Promotes the adequate supply and equitable distribution of health manpower throughout the United States. C. *Regulatory Analysis:* Not required. D. *Need:* Required by statute to implement the Public Health Service Act. E. *Legal Authority:* 43 FR 55242. F. *Chronology:* Interim-final published November 27, 1978 (43 FR 55242). The comment period closed Jan. 26, 1979.	Kenneth Moritsugu, Bureau of Health Professions, HRA, Center Building, 3700 East-West Highway, Hyattsville, Md. 20782, (301) 436-6418.
PHS-63—Interdisciplinary Team Training and Curriculum Development for Health Manpower Training.	A. *Description:* To establish requirements for grants for interdisciplinary team training among schools in various health disciplines and for curriculum development in various areas related to health manpower. B. *Why Significant:* Promotes the adequate supply and equitable distribution of health manpower throughout the United States. C. *Regulatory Analysis:* Not required. D. *Need:* Required by statute to implement the Public Health Service Act. E. *Legal Authority:* 42 USC 295g-7. NPRM published 8-1-80 (CF42FR51241)	David B. Hoover, Bureau of Health Professions, HRA, Center Building, 3700 East-West Highway, Hyattsville, Md. 20782, (301) 436-6838.
PHS-69—Grants for Nurse Practitioner Traineeship Programs.	A. *Description:* To set forth requirements for grants to schools of nursing, medicina, and public health, public or nonprofit private hospitals, and other nonprofit entities to meet the costs of traineeships for the training of nurses who reside in health manpower shortage areas having shortages of primary medical care manpower. B. *Why Significant:* Promotes the adequate supply and equitable distribution of health manpower throughout the United States. C. *Regulatory Analysis:* Not required. D. *Need:* The Department has decided that regs are needed to implement the Public Health Service Act. E. *Legal Authority:* 2 USC 296m. F. *Chronology:* Interim final regulations published May 6, 1980 (45 FR 29803). The Comment period closed July 7, 1980.	Dr. Mary Hill, Bureau of Health Professions, HRA, Center Building, 3700 East-West Highway, Hyattsville, Md. 20782, (301) 436-6681.
PHS-72—National Guidelines for Health Planning (Goals).	A. *Description:* The guidelines consist of National Health Planning goals with respect to health status, health promotion, and disease prevention, and access to services. B. *Why Significant:* Sets goals for health planning.	James Stockdill, Office of Planning, Evaluation, and Legislation, HRA, Center Building, 3700 East-West Highway, Hyattsville, Md. 20782, (301) 436-7270.

Department of Health and Human Services Semiannual Regulations Agenda and Review List—Continued

Title	Summary	Contact
	C. *Regulatory Analysis:* Not required. D. *Need:* Required by statute to implement the Health Planning and Resources Development Act. E. *Legal Authority:* 42 USC 300k-1. F. *Chronology:* Notice of availability of Draft Regulations October 19, 1979 (44 FR 60342). NPRM Published 11-25-80. Comment period ends 2-23-81.	
PHS-73—Health Systems Agency Review of Certain Proposed Uses of Federal Health Funds.	A. *Description:* Amends regulations establishing requirements governing the review and approval or disapproval by Health Systems Agencies of certain proposed uses of Federal funds. B. *Why significant:* Implements one aspect of the Federal health planning program to promote access to health care services and control health care costs through State and local review of health services and expenditures. C. *Regulatory Analysis:* Not required. D. *Need:* Required by statute to implement the Health Planning and Resources Development Amendments of 1979. E. *Legal Authority:* The Health Planning and Resources Development Amendments of 1979. F. *Chronology:* NPRM was published Mey 9, 1978 (43 FR 19988) Final published August 10, 1979 (44 FR 47084). Regulations to be amended to implement the Health Planning and Resource Amendments of 1979.	Colin C. Rorrie, Jr., Ph. D., Director, Bureau of Health Planning, HRA, Center Building, 3700 East-West Highway, Hyattsville, Md. 20782, (301) 436-6850.
PHS-74—Health Systems Agency Reviews of Certain Proposed Uses of Federal Funds; Proposed Uses for Research and Training.	A. *Description:* Establishes requirements governing the review and approval or disapproval by health systems agencies of certain proposed uses of Federal health funds through research and training grants and contracts. B. *Why significant:* Implements one aspect of the Federal health planning program to promote access to health care services and control health care costs through State and local review of health services and expenditures C. *Regulatory Analysis:* Not required. D. *Need:* Required by statute to implement the Health Planning and Resources Development Act of 1978. E. *Legal Authority:* 42 USC 300 1-2. F. *Chronology:* None.	Colin C. Rorrie, Jr., Ph. D., Director, Bureau of Health Planning, HRA, Center Building, 3700 East-West Highway, Hyattsville, Md. 20782, (301) 436-6850.
PHS-75—Health Systems Agency and State Agency Reviews of the Appropriateness of Existing Institutional Health Services.	A. *Description:* Establishes minimum procedures and criteria for health systems agencies to review the appropriateness of all existing institutional health service in their areas. B. *Why Significant:* Implements one aspect of the Federal health planning program to promote access to health care services and control health care costs through State and local review of health services and expenditures. C. *Regulatory Analysis:* Not required. D. *Need:* Required by statute to implement Health Planning and Resources Development Act of 1978 and Amendments of 1979. E. *Legal Authority:* 43 FR 21274 and the Health Planning and Resources Development Amendments of 1979. F. *Chronology:* NPRM published May 18, 1978 (43 FR 21274) The comment period closed June 30, 1978. Final regulations published December 11, 1979 (44 FR 71754). Regulations to be amended to implement the Health Planning and Resource Amendments of 1979.	Colin C. Rorrie, Jr., Ph. D., Director, Bureau of Health Planning, HRA, Center Building, 3700 East-West Highway, Hyattsville, Md. 20782, (301) 436-6850.
PHS-76—Designation and funding of Health Systems Agencies.	A. *Description:* Amends regulations establishing criteria for the designation and funding of health systems agencies. B. *Why Significant:* Implements one aspect of the Federal health planning program to promote access to health care services and control health care costs through State and local review of health services and expenditures. C. *Regulatory Analysis:* Not required. D. *Need:* Required by statute to implement Health Planning and Resources Development Amendments of 1979. E. *Legal Authority:* The Health Planning and Resources Development Amendments of 1979. F. *Chronology:* NPRM wes published October 17, 1975 (43 FR 48802). The comment period closed November 17, 1975. The final was published March 28, 1976 (41 FR 12812). Regulations to be amended to implement the Health Planning and Resource Amendments of 1979.	Colin C. Rorrie, Jr., Ph. D., Director, Bureau of Health Planning, HRA, Center Building, 3700 East-West Highway, Hyattsville, Md. 20782, (301) 436-6850.
PHS-77—Designation of States Health Planning and Development Agencies.	A. *Description:* Amends regulations establishing criteria for the designation of State Health Planning and Development Agencies. B. *Why Significant:* Implements one aspect of the Federal health planning program to promote access to health care services and control health care costs through State and local review of health services and expenditures. C. *Regulatory Analysis:* Not required. D. *Need:* Required by statute to implement the Health Planning and Resources Development Amendments of 1979. E. *Legal Authority:* The Health Planning and Resources Development Amendments of 1979. F. *Chronology:* NPRM was published March 19, 1978 (41 FR 11688). Comment period closed May 3, 1976. Interim-final published June 3, 1978 (41 FR 22524). Final was published March 10, 1978 (43 FR 10100). Regulations to be amended to implement Health Planning and Resource Development Amendments of 1979.	Colin C. Rorrie, Jr., Ph. D., Director, Bureau of Health Planning, HRA, Center Building, 3700 East-West Highway, Hyattsville, Md. 20782, (301) 436-6850.
PHS-80—Inclusion of Computed Tomographic Scanning Services under Capital Expenditure Review.	A. *Description:* Amends regulations for the capital expenditure review program by establishing rules regarding reviews of proposed capital expenditures for computed tomographic scanner services. B. *Why Significant:* Implements one aspect of the Federal health planning program to promote access to health care services and control health care costs through State and local review of health services and expenditures. C. *Regulatory Analysis:* Not required. D. *Need:* Required by statute to implement the Health Planning and Resources Development Act of 1978. E. *Legal Authority:* 44 FR 24428. F. *Chronology:* Interim-final regulations were published April 25, 1979. The comment period closed June 25, 1979.	Colin C. Rorrie, Jr., Ph. D., Director, Bureau of Health Planning, HRA. Center Building, 3700 East-West Highway, Hyattsville, Md. 20782, (301) 436-6850.
PHS-81—Limitation on Federal Participation for Capital Expenditures.	A. *Description:* Amends regulations for the capital expenditure review program to take into account certain requirements respecting 1122 reviews imposed by Title XV of the Public Health Service Act. B. *Why Significant:* Implements one aspect of the Federal health planning program to promote access to health care services and control health care costs through State and local review of health services and expenditures. C. *Regulatory Analysis:* Not required. D. *Need:* Required by statute to implement the Health Planning and Resources Development Act of 1976.	Colin C. Rorrie, Jr., Ph. D., Director, Bureau of Health Planning, HRA, Center Building, 3700 East-West Highway, Hyattsville, Md. 20782, (301) 436-6850. E. *Legal Authority:* 41 FR 11688. F. *Chronology:* NPRM published March 19, 1976 (41 FR 11688). The comment period closed May 3, 1976.

Department of Health and Human Services Semiannual Regulations Agenda and Review List—Continued

Title	Summary	Contact
PHS–83—National Institutes of Health Center Grants.	A. *Description:* These regulations would provide for the operation of NIH Research and Demonstration Centers. They would replace similar rules that now apply to centers of the National Heart, Lung, and Blood Institute. B. *Why significant:* Legislation has authorized research and demonstration centers for other diseases such as arthritis and diabetes. C. *Regulatory Analysis:* Not required.	Lowell D. Peart, NIH Regulations Officer, Division of Management Policy, National Institutes of Health, Bethesda, MD 20205, Phone: (301) 496–4606. D. *Need:* To implement legislation that extend to other NIH programs the present regulations regarding research and demonstration centers for the National Heart, Lung, and Blood Institute. E. *Legal Authority:* Section 415(b) of the Public Health Service Act; Pub. L. 93–354; and Pub. L. 93–640. F. *Chronology:* Notice of Decision to Regulate was published July 17, 1978 (43 FR 31583).

Center for Disease Control

Title	Summary	Contact
PHS–84—Clinical Laboratories: Revision of Quality Control Regulations to include Additional Requirements for Alpha-fetoprotein Testing (42 CFR Parts 74 and 405).	A. *Description:* Current regulations include quality control and testing requirements of a general nature applicable to measurement of alpha-fetoprotein (AFP) levels. The revision of these regulations proposes to amend the quality control regulations applicable to clinical laboratones by including additional quality control and testing requirements for procedures which measure AFP levels in mid-pregnancy maternal sera, plasma, and amniotic fluids. B. *Why significant:* To assure the safe and effective use of AFP testing kits.	Dr. Joseph F. Boutwell, Deputy Director, Bureau of Laboratories, Center for Disease Control, 1600 Clifton Road, N.E., Atlanta, Georgia 30333, Phone: (404) 329–3263, FTS: 236–3263. C. *Regulatory analysis:* Not required. D. *Need:* The Food and Drug Administretion has decided to announce its intent to approve for marketing commercial test kits for use by clinical laboretories in measuring AFP levels in maternal sera, plasma, and amniotic fluid in prenatal detection of neural tube defects. Additional quality control and testing requirements are being proposed in order to assure the safe and effective use of AFP testing kits. E. *Legal Basis:* For laboratories licensed under the Clinical Laboratories Improvement Act of 1967, see Section 353 of the Public Health Service Act (42 U.S.C. 263a). For laboratories certified under the Medicare program, see Section 1961(s) (3), (10), and (11) of the Social Security Act (42 U.S.C. 1395x(s) (3), (10), and (11)), and Section 1881(e)(9) of the Social Security Act (42 U.S.C. 1395x(e)(9)). F. *Chronology:* Notice of Decision to Develop Regulations published on April 15, 1980 (45 FR 25412). NPRM published 11–7–80. Comments due by 1–6–81.
PHS–86—NIOSH Investigations of Places of Employment (42 CFR Part 85).	A. *Description:* This rule proposes to integrate existing provisions pertaining to NIOSH health hazard evaluations and research investigations (42 CFR Parts 85 and 85a) into a single regulation as part of the Department's "Operation Common Sense" program. Procedures for investigations will be revised as necessary based on past experience in conducting investigations. B. *Why significant:* To eliminate duplicate provisions and possible procedural errors, and to permit current employees greater access to the health hazard evaluation program. C. *Regulatory Analysis:* Not required.	Philip J. Bierbaum, Deputy Director, Division of Surveillance, Hazard Evaluations, and Field Studies, National Institute for Occupational Safety and Health, 4676 Columbia Parkwey, Cincinneti, Ohio 45226, Phone: (513) 684–2422, FTS: 684–2422 D. *Need:* To comply with "Operation Common Sense" and to update procedures. E. *Legal Basis:* Occupational Safety and Health Act of 1979 (29 U.S.C. 651 et seq.) and Federal Mine Safety and Health Act of 1977 (30 U.S.C. 801 et seq.). F. *Chronology:* Notice of Decision to Develop Regulations published on December 4, 1979 (44 FR 69689).
PHS–87—NIOSH Grant Regulations; Conformence with Part 74 (42 CFR Parts 55, 86, and 87).	A. *Description:* The following grant regulations are being combined into a single regulation and are being revised to conform them to 45 CFR Part 74: (1) Grants for research and demonstrations relating to occupational safety and health (42 CFR Part 87); (2)grants for advancement of health in coal mining. B. *Why Significant:* These regulations provide the regulatory base for these grants programs. C. *Regulatory Analysis:* Not required. D. *Need:* to conform the regulations to 45 CFR Part 74 and to implement changes made by the Federal Mine Safety and Health Act of 1977. E. *Legal Basis:* (1) Occupational Safety and Health Act of 1970 (29 U.S.C. 669(a)(1)); and Federal Mine Safety and Health Act of 1977 (30 U.S.C. 801 et seq.). F. *Chronology:* Notice of Proposed Rulemaking published on March 13, 1980.	Ms. Mary L. Flint, Regulations Specialist, National Institute for Occupational Safety and Health, 5600 Fishers Lane, Room 8–11, Rockville, Maryland 20857, Phone: (301) 443–4493, FTS: 443–4493.
PHS–88—Fees for Direct Training, Center for Disease Control (42 CFR Part 65).	A. *Description:* Under Section 311(b) of the Public Health Service Act, the Center for Disease Control provides technical training to help ensure that health workers throughout the country possess the necessary skills and knowledge to achieve the objectives of disease control programs. The existing regulation sets forth a fee policy for this training and provides for a fee schedule. A waiver procedure to permit States time to include training costs in their budgets was included in the final rule. Subsequent amendments to legislation eliminated the need for a waiver of fees. Therefore, the proposed revision will delete this requirement in the regulation. B. *Why significant:* The proposed revision will clarify the policy regarding tuition for training. It will specify who shall pay tuition for training, and the outdated waiver provision will be removed from the existing regulation. C. *Regulatory analysis:* Not required. D. *Need:* To update the existing regulation to delete the procedure requiring written requests for waiver of fees. Section 311(b) of Public Health Service Act was amended by Public Law 94–317 (June 1976) to eliminate the need for waivers. E. *Legal Basis:* Section 311(b) of the Public Health Service Act (42 U.S.C. 243). F. *Chronology:* The Regulations Proposal is the first step in the development of the proposed amendment.	Dr. Seth N. Leibler, Director, Bureau of Training, Center for Disease Control, 1600 Clifton Road, N.E., Atlanta, Georgia 30333, Phone: (404) 262–6671, FTS: 236–6671.
PHS–90—Possession, Use, and Transport of Smallpox and Whitepox Viruses.	A. *Description:* Establishes regulations restricting the possession, use, and transportation of smallpox (variola major and variola minor) and whitepox viruses. B. *Why significant:* Natural transmission of smallpox was last reported in October 1977 and the disease was declared eradicated by the World Health Organization on October 26, 1979. Smallpox and whitepox viruses now exist only in laboratories. The Foreign Quarantine regulations (42 CFR, Section 71.156) authorize restrictions on the importation or subsequent receipt by transfer of imported materials. Similar authority regulating the possession, use, or transportation of indigenous strains of smallpox virus does not exist. C. *Regulatory analysis:* Not required. D. *Need:* Required by statute to implement the final consolidation of all smallpox and whitepox viruses and all activities with these agents in a single national facility located at the Center for Disease Control, Atlanta, Georgia.	Dr. John H. Richardson, Director, Office of Biosafety, Center for Disease Control, 1600 Clifton Rd., N.E., Atlanta, Georgia 30333, Phone: (404) 329–3885, FTS: 236–3885.

Center for Disease Control—Continued

Title	Summary	Contact
	E. *Legal Basis:* Section 361 of the Public Health Service Act (42 U.S.C. 264). F. *Chronology:* The RP is the first step in the regulations development process.	
PHS–91–Indian Health	A. *Description:* Subpart A, Scope and Definition, and Subpart B, Availability of Services, are revised as part of the Department's "Operation Common Sense" to make them clearer. Subpart D, Contagious and Infectious Diseases, is being proposed for recision because it is no longer necessary given present day treatment modalities. B. *Why Significant:* These are technical amendments. C. *Regulatory Analysis:* Not required. D. *Need:* Required by Executive Order No. 12044. E. *Legal Basis:* 25 U.S.C. 13 (Snyder Act) and 42 U.S.C. 2001 (Transfer Act). F. *Chronology:* NOI published February 7, 1980. G. *Citation:* 42 CFR, Subparts A, B, and D. NPRM published 11–19–80 (45 FR 76497). Comment period will end 1–5–81.	Richard J. McCloskey, Indian Health Service, Room 6A–20, 5600 Fishers Lane, Rockville, Maryland 20857, (301–443–1116).

Health Resources Administration

Title	Summary	Contact
PHS–92—Redesignation of Health Service Areas.	A. *Description:* Sets down criteria for revising health service area boundaries. B. *Why Significant:* May result in changes to health service area boundaries. C. *Regulatory Analysis:* Not required. D. *Need:* Required by statute to implement the Health Planning and Resources Development Amendments of 1979. E. *Legal Authority:* The Health Planning and Resources Development Amendments of 1979. F. *Chronology:* None.	Colin C. Rorrie, Jr., Ph. D., Director, Bureau of Health Planning, Health Resources Administration, 3700 East-West Highway, Hyattsville, Maryland 20782, Phone: (301) 436–6850.
PHS–94—Discretionary Funding of Health Systems Agencies.	A. *Description:* Allows up to five percent of the total appropriation for HSAs to be used to supplement the base grant of selected HSAs to assist them in meeting extraordinary expenses, such as those resulting from interstate status or from serving a large geographic area. B. *Why significant:* Impacts funding of HSAs. C. *Regulatory Analysis:* Not required. D. *Need:* To implement the Health Planning and Resources Development Amendments of 1979. E. *Legal Authority:* The Health Planning and Resources Development Amendments of 1979. F. *Chronology:* None. Interim Final published 9–5–80 (45 FR 59132) Comment period ended 11–4–80.	Colin C. Rorrie, Jr., Ph. D., Director, Bureau of Health Planning, Health Resources Administration, 3700 East-West Highway, Hyattsville, Maryland 20782, Phone: (301) 436–6850.
PHS–95—National Guidelines for Health Planning Standards (Other than CT Scanners).	A. *Description:* The guidelines consist of national health planning standards respecting the supply, distribution and organization of health resources. B. *Why Significant:* Sets standards for health planning. C. *Regulatory Analysis:* Not required. D. *Need:* Required by the Health Planning and Resources Development Act of 1978 and Amendments of 1979 to issue resource standards by regulation and to annually review and revise these standards as necessary. E. *Legal Authority:* 42 USC 300k–1 and Health Planning and Resources Development Amendments of 1979. F. *Chronology:* None.	James Stockdill, Director, Office of Planning, Evaluation and Legislation, Health Resources Administration, 3700 East-West Highway, Hyattsville, Maryland 20782, Phone: (301) 436–7270.
PHS–96—Tax-exempt Refinancing of Health Facilities Construction Loans.	A. *Description:* Provides criteria for determining "the best financial interest of the United States" as it relates to tax-exempt refinancing of health facilities construction loans. B. *Why Significant:* Impacts tax revenues received by U.S. Treasury. C. *Regulatory Analysis:* Not required. D. *Need:* Department has decided that regulations are necessary because of continuing discussions as to the appropriateness of tax-exempt refinancing. E. *Legal Authority:* 42 U.S.C. 291j–3; 42 U.S.C. 300q–2; 42 U.S.C. 293i. F. *Chronology:* Notice of moratorium on approving "refinancing" of certain Federally guaranteed loans published in the FEDERAL REGISTER on October 15, 1979 (44 FR 59291). NPRM published 11–18–80 (45 FR 76212). Comment period ending 1–19–81.	William R. Berry, Bureau of Health Facilities, Health Resources Administration, 3700 East-West Highway, Hyattsville, Maryland 20782, Phone: (301) 436–7702.
PHS–97—Governing Body Requirements of Health Systems Agencies.	A. *Description:* Amends composition requirements and the characteristics members must have to meet these requirements, and mandates a technical assistance program for governing body members as well as selection procedures. B. *Why Significant:* Impacts the composition of governing bodies. C. *Regulatory Analysis:* Not required. D. *Need:* Required by the Health Planning and Resources Development Amendment of 1979. E. *Legal Authority:* Health Planning and Resources Development Amendment of 1979. F. *Chronology:* NPRM published May 26, 1978 (43 FR 22858). The comment period closed July 10, 1978.	Colin C. Rorrie, Jr., Ph. D., Director, Bureau of Health Planning, Health Resources Administration, 3700 East-West Highway, Hyattsville, Maryland 20782, Phone: (301) 436–6850.
PHS–98—Drug Abuse Project Grant Program	A. *Description:* These regulations would establish requirements for drug abuse treatment and prevention programs. An eligible applicant for the treatment and rehabilitation services program is the institution, organization, agency, department or other accountable entity of State government that assumes legal and financial responsibility for the administration and performance of the Statewide Services Grant Program. Applications for the State Grants Program are limited to the States and jurisdictions (the District of Columbia, the Commonwealth of Puerto Rico, and the Trust Territories of the Mariana Islands, Virgin Islands, Guam, and American Samoa) through their respective Single State Agencies for Drug Abuse Prevention or the officially designated State unit responsible for drug abuse prevention programs. B. *Why Significant:* This rule would implement Section 410 of P.L. 92–255, the Drug Abuse Office and Treatment Act of 1972, as amended, and replace the current guidelines. C. *Regulatory Analysis:* Not required. D. *Need:* These regulations would implement Section 410 of the Drug Abuse Office and Treatment Act of 1972, as amended. Further, the Public Health Service Grants Administration Manual requires PHS agencies to publish in the FEDERAL REGISTER program rules, program priorities for funding and statements regarding the availability of funds. E. *Legal Basis:* Section 410 of P.L. 92–255, the Drug Abuse Office and Treatment Act of 1972 (21 U.S.C. 1177) as amended by P.L. 94–237 (90 Stat. 247–248), P.L. 94–371 (90 Stat. 1040–1041), and P.L. 95–461 (92 Stat. 1268) (21 U.S.C. 1177). F. *Chronology:* None.	Nancy Soulen, Legal Assistant, Office of the Director, National Institute on Drug Abuse, Room 10–14, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, (301) 443–6482.
PHS–99—Employee Protection—Mental Health Systems Act.	A. *Description:* These regulations establish requirements for each State mental health authority to have in effect equitable arrangements to protect the interests of employees affected adversely by actions taken by State mental health authorities to emphasize	Dr. Alex Rodriquez, Special Assistant to the Secretary, Department of Health and Human Services, Washington, D.C. 20201, (202) 245–7593.

Health Resources Administration—Continued

Title	Summary	Contact
	outpatient mental health services. These arrangements include those designed to preserve employee rights and benefits and to provide training and retraining of employees, where necessary, for work in mental health or other fields and arrangements under which maximum effort will be made to place employees in employment. B. *Why Significant:* These regulations are necessary to ensure that efforts planned and undertaken by state mental health authorities to emphasize out patient treatment do not cause significant adverse effects amoong employees currently working in other settings.	
PHS-100—Mental Health Service Programs...	A. *Description:* These regulations would set out the form and manner in which each State's Mental Health Service Program is to be submitted and establish other responsibilities of State mental health authorities. B. *Why Significant:* Neither State mental health authority nor other entities within a State is eligible to receive a grant under Title II of the Mental Health Systems Act unless the State has in effect a State Mental Health Service Program. C. *Regulatory analysis:* Not required. D. *Need:* These regulations are needed to implement provisions of the Mental Health Systems Act regarding State Mental Health Service Programs. E. *Legal Basis:* Mental Health Systems Act (P.L. 96-398) F. *Chronology:* None.	Dr. Alex Rodriquez, Special Assistant to the Secretary, Department of Health and Human Service, Washington, D.C. 20201, (202) 245-7593.
PHS-101—Grants for Mental Health Service Programs.	A. *Description:* These regulations would govern the awarding of grants for mental health services under the State mental health service programs. B. *Why Significant:* These regulations would set forth the requirements for the awarding of grants for mental health services. C. *Regulatory analysis:* Not required. D. These regulations are needed to implement provisions of the Mental Health Systems Act regarding grants for state mental health services. E. *Legal Basis:* Mental Health Systems Act. (P.L. 96-398). F. *Chronology:* None.	Dr. Alex Rodriquez, Special Assistant to the Secretary, Department of Health and Human Services, Washington, D.C. 20201, (202) 245-7593.
PHS-102—Mental Health Rights and Advocacy	A. *Description:* These regualtions would govern the award of grants to public or nonprofit private entities for projects to protect and advocate the rights of mentally ill individuals. B. *Why Significant:* These regulations would establish a system to assure that mental health patients receive the protection and services they require. C. *Regulatory analysis:* Not required. D. *Need:* These regulations are needed to implement provisions in Title V of the Mental Health Systems Act regarding grants to protect and advocate the rights of mentally ill individuals. E. *Legal Basis:* Mental Health Systems Act (P.L. 96-398). F. *Chronology:* None.	Dr. Alex Rodriquez, Special Assistant to the Secretary, Department of Health and Human Services, Washington, D.C. 20201, (202) 245-7593.
PHS-103 Rape Prevention and Control.....	A. *Description:* These regulations would govern grants to public and private nonprofit entities to provide services to rape victims. B. *Why significant:* Grants would be awarded to provide counseling for rape victims and the immediate family; assistance to victims in securing mental health; social, medical, and legal services, and prevention of rape. C. *Regulatory Analysis.* Not required. D. *Need:* To implament the provisions of Title VI of the Mental Health System Act regarding grants to provide services to rape victims. E. *Legal Basis:* Mental Health Systems Act (P.L. 96-398) F. *Chronology:* None.	Dr. Alex Rodriquez, Special Assistant to the Secretary, Department of Health and Human Services, Washington, D.C. 20201, (202) 245-7593.
PHS-104-Project Grants for Preventive Health Services—Subpart I—Grants for Other Preventive Health Programs (42 CFR Part 51b).	A. *Description:* Amends 42 CFR Part 51b by adding a new subpart which would be applicable to any grant program implemented under Section 317(a)(2) of the Public Health Service Act not governed by any other subpart in Part 51 except Subpart A—General Provisions. B. *Why significant:* Provides a regulatory base for other preventive health programs which may be implemented under Section 317(a)(2) and covered by appropriations authorized under Section 317(j)(5). C. *Regulatory Analysis.* Not required. D. *Need:* The general grant authority in Setion 317(j)(5) was provided primarily to address health problems which could not be anticipated when the legislation was being developed. Since such problems generally will require a quick response, prior establishment of a regulatory base will be helpful. E. *Legal Basis:* Section 317(a)(2) 42 U.S.C. 247b) of the Public Health Service Act, as amended by the Health Services and Centers Amendments of 1978. F. *Chronology:* Regulations Proposal currently being developed.	Windell R. Bradtor, Associate Director, Bureau of State Services, Centers for Disease Control, 1600 Clifton Road, N.E., Atlanta, Georgia 30333, Phone: (404) 329-3773, FTS 236-3773.
PHS-105-Cooperative Agreements for Nutrition Surveillance Systems.	A. *Description:* Establishes requirements for cooperative agreements to States to assist them in developing, implementing, and managing nutrituion surveillance as an integral part of their service delivery programs. B. *Why significant:* Provides regulatory base for cooperative agreements to enable States to provide data which will result in minimization of nutrition-related health problems, a possibly "early warning" of broader community problems, improvement in the delivery of health-related nutritional services, the evaluation and improvement of various food delivery and supplementation programs, and other nutrition intervention activities. C. *Regulatory Analysis.* Not required. D. *Need:* The regulation is necessary to establish requirements to implement these programs in response to the Congressional mandate contained in the Food and Agriculture Act of 1977 (Public Law 95-113) which directed the Secretaries of Agriculture and Health and Human Services to establish a comprehensive nutritional status monitoring system throughout the United States. E. *Legal Basis:* Section 301(b)(3) of the Public Health Service Act (42 U.S.C. 241(b)(3)) as amended. F. *Chronology:* The Regulations Proposal is the first step in the regulations development process.	Gordon E. Robbins, Center for Health Promotion and Education, Centers for Disease Control, 1600 Clifton Road, N.E., Atlanta, Georgia 30333, Phone: (404) 329-2564, FTS: 236-2564.
PHS-106—Administrative and Managerial Arrangements.	A. *Description:* This rule proposes to amend the requiements for the organization and operation of federally qualified HMOs by adding a provision concerning the amount of time the executive director devotes to the managing of the HMO. B. *Why significant:* The rule would require the executive to devote at least 80 percent of his or her professional activity to the management of the HMO, unless a waiver was requested by the HMO and granted by the Secretary. C. *Regulatory Analysis.* Not required. D. *Need:* (P) To provide more specificity to the requirements for the executive director based on the HMO program's experience in administering the Federal Program. E. *Legal Basis:* Sec. 215, 88 Stat. 690 (42 U.S.C. 216); Secs. 1301-1318, as amended, 92 Stat. 2131-2141 (42 U.S.C. 300e-300e-17). F. *Chronology:* None.	Howard R. Veit, Director, Office of Health Maintenance Organizations, Park Building, 12420 Parklawn Drive, Rockville, Maryland 20857, (301) 443-4106.

Health Resources Administration—Continued

Title	Summary	Contact
PHS-107—"ERISA" Rule	A. *Description:* This rule amends the requirements for the operation of federally qualified HMOs regarding the disclosure of information by HMOs to members, potential members, and employers. Publication of this PHS regulation is being coordinated with the Department of Labor which administers the Employee Retirement Income Security Act of 1974 (ERISA). B. *Why Significant:* This rule requires federally qualified HMOs to disclose clearly (1) certain information similar to that required by the Department of Labor's Employee Refirement Income Security Act of 1974 (ERISA) regulations, 29 CFR Part 2520, and (2) information about the financial conditions of the HMO. C. *Regulatory Analysis:* Not required. D. *Need:* (L) To avoid any duplicative or unnecessary requirements that might rasult with respect to ERISA and Title XIII of the PHS Act. E. *Legal Basis:* Section 215, 88 Stat. 690 (42 U.S.C. 216); Secs. 1301-1318, as amended, 92 Stat. 2131-2141 (42 U.S.C. 300e-300e17). F. *Chronology:*—Notice of Decision to Revise Regulations. 44 FR 22133. —NPRM-42 CFR § 110.108(c)(1) Full and Fair Disclosure; § 110.108(c)(2) Broadly representative enrollment; § 110.108(s) Reporting and Disclosure under the Employee Retirement Income Security Act of 1974 ("ERISA"). Comment period: 6/22/79-8/21/79. 44 FR 36862-5.	Howerd R. Veit, Director, Office of Health Maintenance Organizations, Park Building, 12420 Perklewn Drive, Rockville Maryland 20857, (301) 443-4106.
PHS-108—National Guidelines for Health Planning (CT Scanner Standards).	A. *Description:* The guidelines consist of national health planning standards respecting the supply, distribution and organization of health resources. B. *Why Significant:* Sets standards for health planning. C. *Regulatory Analysis:* Not required. D. *Need:* Required by the Health Planning and Resources Development Act of 1976 and Amendments of 1979 to issue resource standards by regulation and to annually review and revise these standards as necessary. E. *Legal Basis:* 42 U.S.C. 300k-1 and Health Planning and Resources Development Amendments of 1979. F. *Chronology:* None.	James Stockdill, Director, Office of Planning, Evaluation, and Legislation, HRA, 3700 East-West Highway, Hyattsville, Maryland 20782, (301) 436-7270.
PHS-109—Health Education Assistance Loans (HEAL).	A. Description: These amendments raise the maximum amount a student may borrow under the HEAL program and make other technical changes. B. Why Significant: Students will be able to borrow higher amounts of money necessary for their education. C. Regulatory Analysis: Not required D. Need: These amendments are necessary to implement statutory changes to the HEAL legislation and to meet needs program as identified. E. Legal Basis: 42 U.S.C. 216 and 42 U.S.C. 294c. F. Chronology: Interim Final regulations were published on August 3, 1978 (43 FR 34320).	Alice Swift, Bureau of Health Professions, HRA, Room G-66, Center Building, 3700 East-West Highway, Hyattsville, Maryland 20782, (301) 436-6788.
PHS-110—Amendments to 42 CFR Part 124, Subpart F—Reasonable Volume of Uncompensated Services to Persons Unable to Pay	A. Description: These amendments will revise the existing regulations to better reflect the characteristics of long-term care facilities and public health laboratories and hospitals. B. Why Significant: Long-term facilities and public health hospitals and laboratories will be better able to respond to regulatory requirements. C. Regulatory Analysis: Not required. D. Need: The program has identified a need for these amendments. E. Legal Basis: 42 U.S.C. 3000-1(6). F. Chronology: NPRM was published on 10/25/78 (43 FR 49954). The comment period closed 12/26/78. Final Rules were published on 5/18/79 (44 FR 29371).	Martin J. Frankel, Bureau of Health Facilities, HRA, Center Building, 3700 East-West Highway, Hyattsville, Maryland 20782, (301) 436-7795
PHS-111—Redesignation of the Contract Health Services Delivery Area (CHSDA) for the Penobscot Reservation.	A. *Description:* Amends 42 CFR 36.22(a)(6) to change the counties included in the CHSDA for the Penobscot Reservation. B. *Why significant:* This is a technical amendment affecting only the Penobscot Nation. C. *Regulatory Analysis:* None required. D. Need: The Penobscot Nation has requested a change in their reservation's CHSDA. E. *Legal Basis:* 25 U.S.C. 13 (Snyder Act) and 42 U.S.C. 2001 (Transfer Act). F. *Chronology:* None. Since it is a technical amendment, a Notice of Intent is not required.	Richard J. McCloskay, Indian Health Service, Room 5A-39, 5600 Fishers Lane, Rockville, Maryland 20857, (301-443-1116).
PHS-112—Redesignation of the Contract Health Services Delivery Area (CHSDA) for the Passamaquoddy Reservation.	A. *Description:* Amends 42 CFR 36.22(a)(6) to change the counties included in the CHSDA for the Penobscot Reservation. B. *Why significant:* This is a technical amendment affecting only the Penobscot Nation. C *Regulatory Analysis:* Not required. D. *Need:* The Penbscot Nation has raquested a change in their reservation's CHSDA. E. *Legal Basis:* 25 U.S.C. 13 (Snyder Act) and 42 U.S.C. 2001 (Transfer Act). F. *Chronology:* None. Since it is a technical amendment, a Notice of Intent is not required.	Richerd J. McCloskey, Indian Health Service, Room 5A-39, 5600 Fishers Lane, Rockville, Maryland 20857, (301-443-1116).
PHS-113—Redesignation of the Contract Health Services Delivery Area (CHSDA) for the Reservation of the Mississippi Band of Choctaw Indians	A. *Description:* Amends 42 CFR 36.22(a)(6) to change the CHSDA for the Mississippi Band of Choctaw Indians. B. *Why significant:* This is a technical amendment affecting only the Mississippi Band of Choctaw Indians. C. *Regulatory Analysis:* None required. D. *Need:* The CHSDA for the Mississippi Choctaw Reservation needs to be amended to add two counties which were inadvertently omitted when the regulation was initially published. E. *Legal Basis:* 25 U.S.C. 13 (Snyder Act) and 42 U.S.C. 2001 (Transfer Act). F. *Chronology:* None. Since it is a technical amendment, a Notice of Intent is not required.	Richard J. McCloskay, Indian Health Service, Room 5A-39, 5600 Fishers Lane, Rockville, Maryland 20857, (301-443-1116).
PHS-114—National Center for Health Care Technology Research Grant Program.	A. *Description:* Governs the awards of grants to support research on health care technologies. B. *Why significant:* Those regulations would provide a basis for awarding grants to conduct systematic assessments of new, emerging, and established health care technologies in response to national needs and priorities. C. *Regulatory Analysis:* None required. D. *Need:* These regulations are needed to implement grants to support research on health care technologies under Section 309(b) of the Public Health Service Act. E. *Legal Basis:* Section 309(b) of the Public Health Service Act (42 U.S.C. 242n) as amended by the Health Services Research, Health Statistics, and Health Care Technology Act of 1978, P.L. 95-623. F. *Chronology:* None.	Norman Weisman, Ph. D., Associate Director of Extramurel Research NCHCT, Room 17A-32, Perklawn Bldg., 5600 Fishers Lane, Rockville, Maryland 20857, (301) 443-1820.

Health Care Financing Administration—Significant Regulations

Title	Summary	Contact
HCFA-2—Medicare-Medicaid Programs: Payment for Services Which Are Not Medically Necessary and/or Not Rendered in the Appropriate Setting.	A. *Description:* This regulation would propose criteria for determining when a patient or provider would not be held liable for knowing that the services were medically unnecessary or otherwise inappropriate, before the services have been disapproved by PSROs for Medicare and Medicaid payments. B. *Why Significant:* The regulation would reduce waste by eliminating Federal payments for unnecessary care. In addition, there is strong public interest in completing regulations for PSROs. C. *Regulatory Analysis:* Not required. D. *Need:* To implement the 1972 and 1977 amendments to the Social Security Act. E. *Legal Basis:* Secs. 1158(a) and 1158(d) of the Social Security Act; Pub. L. 92-603; Sec. 22 of Pub. L. 95-142. F. *Chronology:* The proposal is currently under review. When the review is completed it will be submitted to the Department for approval.	Marion Lebron, Senior Analyst, IRB, DPR; HSQB, 1st Flr., Dogwood East Bldg., 1849 Gwynn Oak Ave., Baltimore, MD 21207, 301-594-3980.
HCFA-3—Medicare/Medicaid Program: Professional Standards Review Organizations (PSROs) Reconsideration and Appeals—Procedures for Reconsiderations.	A. *Description:* This regulation contains procedures for the reconsideration of the medical necessity determinations of PSROs and the review of such reconsiderations by Statewide Professional Standards Review Councils. B. *Why Significant:* This regulation would clarify the process for appealing PSRO determinations. In addition, there is strong public interest in completing regulations for PSROs. C. *Regulatory Analysis:* Not required. D. *Need:* To implement 1972 amendments to the Social Security Act. E. *Legal Basis:* Sec. 1159(a) of the Social Security Act (42 U.S.C. 1320c-8); Sec. 249F of Pub. L. 92-603. F. *Chronology:* NPRM was published on March 5, 1979 (44 FR 12067). The comment period closed on May 4, 1979. The final is currently under review in the Department.	Paul Machove, Program Analyst, IRB, DPR, HSQB, 1st Flr., Dogwood East Bldg., 1849 Gwynn Oak Ave., Baltimore, MD 21207 301-594-3980.
HCFA-4—Medicare/Medicaid Program: Hospital Utilization Review—Revised Requirements and Procedures for Utilization Review	A. *Description:* The regulations will revise requirements and procedures for utilization review in health care institutions participating in Medicare and Medicaid programs. These regulations will provide for review of the medical necessity of admissions and continued stays, the appropriateness and quality of patient care, and the effectiveness of utilization of facility and health professional services. B. *Why Significant:* This regulation would assure quality care by establishing requirements for conducting concurrent and retrospective review of the health care provided to Medicare beneficiaries and Medicaid recipients. C. *Regulatory Analysis:* Not required. D. *Need:* To implement the 1976 amendments to the Social Security Act regarding utilization review requirements in hospitals not covered by PSROs. E. *Legal Basis:* Sec. 1903(g)(1)(C) of the Social Security Act; Sec. 110 of Pub. L. 94-182 F. *Chronology:* NPRM was published on March 3, 1980. Correction Notice was published on May 2, 1980. Comment period closed July 1, 1980.	Beverly Christian, Program Analyst, IRB, DPR, HSQB, 1st Flr., Dogwood East Bldg., 1849 Gwynn Oak Ave., Baltimore, MD 21207 301-594-3980.
HCFA-6—Medicare/Medicaid Program: Conditions of Participation for Hospitals—Revised Conditions for Participation.	A. *Description:* This regulation will revise conditions of participation for hospitals in Medicare and Medicaid. It would simplify the language and update the requirements to reflect changes in legislation and advances in technology B. *Why Significant:* This regulation would simplify the regulatory requirements hospitals must meet to be certified for participation in Medicare and Medicaid. The amendments are intended to hold down costs while maintaining an acceptable level of patient care. C. *Regulatory Analysis:* Not required. D. *Need:* To add greater requirements for accountability while allowing flexibility for hospitals in performing administrative and managenal functions; and to implement the 1975 amendments to the Social Security Act. E. *Legal Basis:* Secs. 1102, 1861(e), 1861(f), 1861(g), 1864, and 1891 of the Social Security Act (42 U.S.C. 1302, 1395 et seq.); Sec. 102 of Pub. L. 94-182. F. *Chronology:* General Notice published on November 2, 1977 (42 FR 57351). NPRM was published on June 20, 1980 (45 FR 41794). The comment period closed on August 19, 1980.	Susan Anderson, Standards and Certification Analyst, HSQB, 2nd Floor, Dogwood East Bldg., 1849 Gwynn Oak Ave., Baltimore, MD. 21207 301-594-9714
HCFA-8—Medicare/Medicaid Program: Confidentiality and Disclosure of Information of Professional Standards Review Organizations (PSROs)—Criteria Governing Confidentiality and Disclosure of Information.	A. *Description:* These regulations set forth criteria governing the acquisition, protection, and disclosure of information obtained or generated by PSROs. B. *Why Significant:* These regulations place limits on the disclosure of PSRO information and establish penalties for unauthorized disclosure. These regulations are intended to assure that PSROs have access to necessary information, that confidental information is adequately safeguarded and that the information may be used as effectively as possible. C. *Regulatory Analysis:* Not required. D. *Need:* To implement the 1977 amendments to the Social Security Act. E. *Legal Basis:* Secs. 1166(a) of the Social Security Act; Sec. 5(h) of Pub. L. 95-142 F. *Chronology:* Interim regulation was published on January 16, 1978 (43 FR 2282). NPRM was published on January 15, 1979 (44 FR 3058). The comment period closed on March 16, 1979.	Tony Tirone, Legal Analysts, OPDC, HSOB 2nd Floor, Dogwood East Bldg., 1849 Gwynn Oak Ave., Baltimore, MD 21207, 301-597-2753
HCFA-11—Medicare/Medicaid Program: Protection of Patients for Patient Funds—Procedures for Protection of Funds	A. *Description:* This regulation expands standards for protection of personal funds of Medicare and Medicaid patients in skilled nursing facilities and intermediate care facilities. B. *Why Significant:* The regulation will curtail the reported misuse of patient funds and assure that personal funds are fully accounted for and made not commingled with facility funds. In addition, there is strong public interest in adequately safeguarding patient funds. C. *Regulatory Analysis:* Not required. D. *Need:* To implement the 1977 and 1978 amendments to the Social Security Act. E. *Legal Basis:* Sec. 1861(j)(14) and 1905(c) of the Social Security Act, Sec. 21(a) of Pub. L. 95-142; Sec. 8(a) of Pub. L. 95-292. F. *Chronology:* NPRM was published on September 1, 1978 (43 FR 39154). The comment period closed on October 31, 1978. The final was published on July 24, 1980 (45 FR 49440). A notice was published on October 1, 1980, announcing a stay of effective date pending approval of recordkeeping requirements from the Office of Management and Budget (45 FR 64913). A notice will be published in December 1980.	Janet Packer, Reg. Analyst, ORM, 785 East High Rise Bldg 6401 Security Boulevard Baltimore, MD 21235. DLTC, HSQB, 2nd Floor Dogwood East Bldg., 1849 Gwynn Oak Ave., Baltimore, MD 21207 301-594-5014.
HDFA-13—Medicare/Medicaid Program: Conditions of Participation for Skilled Nursing Facilities (SNFs) and Intermediate Care Facilities (ICFs)—Conditions of Participation.	A. *Description:* The regulations will recodify, revise and consolidate present regulations governing conditions of participation for skilled nursing and intermediate care facilities under the Medicaid and Medicare programs. B. *Why Significant:* This regulation, will focus on patient care, promote cost containment while improving quality care, and achieve more effective compliance. C. *Regulatory Analysis.* Yes, being conducted. D. *Need:* Change in methods of delivering health care and the need to control the most of long term care while improving quality patient care. E. *Legal Basis.* Secs. 1102, 1814, 1832, 1833, 1861, 1863, 1865, 1866, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395, 1395t, 1395k, 1395x, 1395z, 1395bb, 1395cc, 1395hh, 1396(d)(8), and 1905(c)). F. *Chronology:* Notice was published on June 8, 1978 (43 FR 24873). NPRM was published on July 14, 1980 (45 FR 47368). Notice of public meetings was published on July 29, 1980 (45 FR 50373). A notice was published on September 15, 1980, which extended the comment period to October 15, 1980 (45) FR 60945).	J. Richard Lenehan, Jr., Program Analyst, HSQB, 2nd Flr., Dogwood East Bldg., 1849 Gwynn Oak Ave., Baltimore, MD 21207, 301-594-7651.

Health Care Financing Administration—Significant Regulations—Continued

Title	Summary	Contact
HCFA-15—Medicare/Medicaid Programs: Automatic Extinguishment Sprinkler Systems for New Long Term Care Facilities—Requirements for Fire Extinguishment Systems	A. *Description:* The regulation will expend requirements for fire extinguishment systems in skilled nursing end intermediate care facilities. B. *Why Significant:* Automatic extinguishment systems ere an important espect to patient safety in long term cere facilities, but are also costly to install; especially in existing facilities. C. *Regulatory Analysis:* Not required. D. *Need:* Concern by the public to extent requirements for automatic extinguishment systems to ell facilities. E. *Legal Basis:* Secs. 1102, and 1861(j) (13) of the Social Security Act (42 U.S.C. 1302.) F. *Chronology:* Notice of Intent was published on December 6, 1978 (43 FR 57168. The comment period closed on January 30, 1979. NPRM was published 7-28-80 (45 FR 50373). The comment period closed on 10-26-80.	Robert Jevec. Program Analyst, HSQB, 2nd Flr., Dogwood Eest Bldg., 1849 Gwynn Oek Ave., Baltimore, MD 21207, 301-594-3314
HCFA-16—Medicare/Medicaid Program: Termination of Federat Financial Participation (FFP) in Long Term Care Facilities—Change of FFP Requirements.	A. *Description:* The regulation would amend the Medicaid regulations concerning Federal finencial participation (FFP) in cases where e Medicaid nursing home's provider agreement is not renewed or is terminated because the home is out of compliance with Federal requirements. B. *Why Significant:* Guidelines for the termination of FFP in long term care facilities. C. *Regulatory Analysis:* Not required. D. *Need:* This regulation is needed to establish a uniform nationwide Medicaid policy. E. *Legal Basis:* Sec. 1102 of the Social Security Act (42 U.S.C.1302). F. *Chronology:* The proposal is currently under review in the Dept.	Stanley Ketz, Director, BPP, 2nd Flr., Dogwood West Bldg. 6401 Security Blvd., Baltimore, MD 21235, 301-594-9595.
HCFA-18—Medicare Program: Reimbursement Prepaid Health Plans—Conditions and Principles of Reimbursement.	A. *Description:* This regulation will esteblish qualifying conditions and principles of reimbursement for Health care prepayment plans (HCPPs), other than health maintenance organizetions, (HMOs), which elect to receive reimbursement under the Medicere Supplementary Medical Insurance Program. B. *Why Significant:* The requirements on this regulation for HCPPs are similar to the extent possible, to those provided by the Medicare payment for HMOs reimbursed on a reasonable cost basis. C. *Regulatory Analysis:* Not required. D. *Need:* The consistency in qualifying conditions end reimbursement principles will assure uniform treatment of both these types of prepeyment organizations under Medicare. E. *Legal Basis:* Secs. 1802 and 1833(a)(1)(A) of the Social Security Act. F. *Chronology:* NPRM was published on 10-31-80 (45 FR 72538) The comment period closes 12-30-80.	Marimos Svolos Dep'y Director, DMSCP, Rm. 469 EHR, ELR, 6401 Security Blvd., Baltimore, MD 21235, 301-597-2968.
HCFA-21—Medicare Program: Provider Reimbursement Determinations—Criteria and Procedures for PRRB Hearings and Decisions	A. *Description:* This regulation criteria for reopening certain provider cost reimbursement determinations. It would also contain procedures for final review of Provider Reimbursement Review Board (PRRB) decisions. B. *Why Significant:* Include more detailed guidelines for PRRB decisions end hearings. C. *Regulatory Analysis:* Not required. D. *Need:* To streamline procedures and to resolve a number of problems which have been identified through experience under current regulations. E. *Legal Basis:* Secs. 1102, 1861(v)(1)(A)(ii), and 1878(f)(1) of the Social Security Act (42 U.S.C. 139500.) F. *Chronology:* NPRM was published on Februery 14, 1980 (45 FR 9953). The comment period closed on April 14, 1980.	Stanley Katz, Director, DTPL, BPP, 2nd Flr., Dogwood West Bldg. 6401 Security Blvd., Baltimore, MD 21235, 301-594-9595.
HCFA-25—Medicare Program: Part A Entitlement and Copayments—Clarification of Eligibility Requirements.	A. *Description:* This regulation will clarify, simplify end update existing regulations pertaining to (1) entitlement to Medicare hospitel insurance for certain groups and (2) the Medicare inpatient hospital coinsurance, the post-hospital extended cere coinsurance, and the blood deductible. B. *Why Significant:* Beneficiaries and potential beneficiaries can more easily understand the conditions that will make them eligible for Medicare and how much money they will have to contribute toward the cost of their hospital care.	Lulsa Iglesias, Regulation Analyst BPP, 357G Humphrey Bldg., Washington, D.C. 20201, 202-755-1290. C. *Regulatory Analysis:* Not required. D. *Need:* To clarify certain portions of the Medicare, Part A regulations so that beneficiaries and potential beneficiaries cen more easily understand the conditions thet would make them eligible for Medicare and how much money they would have to contribute toward the cost of their hospital care. E. *Legal Basis:* Secs. 226, 1102, 1813 and 1871 of the Social Security Act (42 U.S.C. 426, 426a, 1302, 1395e, and 1395hh). F. *Chronology:* NPRM was published on May 30, 1980 (45 FR). The Comment period closed on 7-29-80.
HCFA-26—Medicare/Medicaid Program: Reimbursement: Internship and Residency Program—Change in Reimbursement Requirements	A. *Description:* This regulation will eliminate the requirement that a provider's costs be reduced by the amounts of certain grents and donations when calculating the reimbursement allowed under Medicare, Medicaid, or the Maternal and Child Health Program. These grents end donations are those which support approved internship end residency programs in family practice, general medicine, and general pediatrics. The regulation will also require providers to report primary care progrem costs and revenues. B. *Why Significant:* The regulation will allow providers to realize the full benelit of grants for primary care residency programs by not deducting these grants from incurred provider cost before determining Medicare and Medicaid reimbursement.	William J. Goeller, Chief, PRB, BPP, Rm. 1-D-1 ELR, 6401 Security Blvd., Baltimore, MD 21235, 301-597-1802. C. *Regulatory Analysis:* Not required. D. *Need:* To evoid nullifying the purpose of specific grants for primary care internship and residency programs. E. *Legal Basis:* Secs. 1102, 1814(b) end 1833(a)(2) of the Social Security Act. F. *Chronology:* NPRM was published on August 10, 1979 (44 FR 47117). The comment period closed on October 9, 1979. The final was published on August 5, 1980 (45 FR 51783). A correction notice was published on September 8, 1980 (45 FR 59158). The reporting requirements will not be effective until they are approved by the Office of Management and Budget (OMB). A notice will be published to announce the outcome of the OMB review.
HCFA-27—Medicere Program: Teaching Hospitals' Physicians Costs—Criteria for Peyments to Teaching Hospitals.	A. *Description:* This regulation proposes criteria under which Medicare would pay reasonable charges for physician services in teaching hospitals or would reimburse teeching hospitals for the reasonable costs of physician services. It would also specify the manner and extent to which payments would be mede for certain medical school costs end for services of volunteer physicians. B. *Why Significant:* The regulation provides that the reasonable cost of physician services would be besed on that portion of each physician's total compensation which is properly attributable to furnishing services to Medicare beneficiaries; end specifies the conditions under which physician services in a teaching hospital may be reimbursed on a reasonable charge basis under the "grendfather clause" or "private patient" exceptions	Bill Birney, Chief, PPR Section, BPP, Rm. 1-E-5, ELR, 6401 Security Blvd., Baltimore, MD 21235, 301-594-5431.

Health Care Financing Administration—Significant Regulations—Continued

Title	Summary	Contact
HCFA-30—Medicare Program: End-stage Renal Disease (ESRD) Networks—Requirements for ESRD Networks.	A. *Description.* The proposed regulation requires that networks establish goals to maximize use of self-dialysis and kidney transplantation and that there be at least one patient representative on each network coordinating council and executive committee. It will also require networks to submit annual reports, ESRD facilities to make individual patient information available to their network medical review boards upon request; and that network meetings be advertised and open to the public.	Tony Culotta, Program Analyst, Office of End Stage Renal Disease, OSP, Rm. 1-D-3, Dogwood West Bldg., 1848 Gwynn Oak Ave., Baltimore, MD 21235, 301-594-6530. B. *Why Significant:* This regulation is intended to: 1) given ESRD patients and the general public a more active role in network decision making processes; 2) encourage maximum use of the lower cost forms of treatment, self-dialysis and kidney transplantation; and 3) encourage greater objectivity in network decision-making. C. *Regulatory Analysis:* Not required. D. *Need:* To implement the 1978 amendments to the Social Security Act. E. *Legal Basis:* Sec. 1881(c) of the Social Security Act; Pub. L. 95-292. F. *Chronology:* NPRM was published on July 18, 1979 (44 FR 41841). The comment period closed on September 17, 1979. The final notice is currently under review in the Department.
HCFA-31—Medicare Program: Incentive Reimbursement for End-Stage Renal Disease (ESRD) Services—Methods and Procedures for Reimbursement.	A. *Description:* The regulation sets forth methods and procedures for reimbursing providers and facilities for outpatient renal dialysis services provided to ESRD patients. B. *Why Significant.* The regulation will provide for prospective payment on various types of dialysis treatment through national rates, periodically adjusted. The rates will be paid subject to an exception process.	Bernadette Schumaker, Chief, Alter. Reim. Systems Branch, Rm. 1-A-1 ELR, 6401 Security Blvd., Balto., MD 21235, 301-597-1048. C. *Regulatory Analysis:* Not required. D. *Need:* The regulation provides for an incentive reimbursement method to encourage economies in the delivery of ESRD services. E. *Legal Basis:* Secs. 1102, 1814(b), 1833, 1861(v)(1), 1871, and 1881 of the Social Security Act (42 U.S.C. 1302, 1395(f), 1395e, 1395(b)(1), 1395hh and 1395rr). F. *Chronology.* NPRM was published on 9-26-80 (45 FR 64008). The comment period closed on 11-25-80.
HCFA-33—Medicare Program: Educational Programs Reimbursement..	A. *Description:* This proposal would revise the regulation governing the amount of reasonable cost reimbursement due health care providers under Medicare. B. *Why Significant:* The regulation would more clearly identify the provider costs for approved medical, nursing, and paramedical education programs that are allowable and to specify procedures for calculating a provider's net costs of these programs.	William Goeller, Chief, Provider Reimbursement Br., BPP, Rm. 1-D-1 ELR, 6401 Security Blvd., Baltimore, MD 21235, 301-597-1802. C. *Regulatory Analysis.* Not required. D. *Need:* Changes which have occurred in the way health care education programs are operated and financed necessitate the revision. Providers and the public generally need to be informed of clarifications of Medicare reimbursement policy. E. *Legal Basis:* Secs. 1102, 1814(b) and 1833(a)(2) of the Social Security Act (42 U.S.C. 1302, 1395f(b), and 1395d(a)(2)). F. *Chronology:* The proposal is currently under review. When the review is completed it will be submitted to the Department for approval.
HCFA-34—Medicare/Medicaid Program: Proposed List of Additional Items and Services Subject to the Lowest Charge Level—List of Items and Services Subject to Lowest Level Charge Criteria. 93A. *Description:* This regulation will add to the list of items and services subject to the lowest charge criteria, 15 of the frequently performed laboratory services for Medicare-Medicaid beneficiaries and 5 items of durable medical equipment most frequently rented or purchased. A laboratory test or service on this list could be subject to the lowest charge provision regardless of whether it was performed on an individual basis (manually or on an automated equipment) or as part of an automated battery.. B. *Why Significant:* The lowest charge level regulation implements certain cost containment provisions as set forth by law.. C. *Regulatory Analysis:* Not required. .... D. *Need:* To implement the 1974 and 1975 amendments to the Social Security Act.. E. *Legal Basis:* Secs. 1102, 1842(b), 1971, and 1903(i)(1) of the Social Security Act (42 U.S.C. 1302, 1395(b), 1395hh, and 1396(b)(i)(1)). F. *Chronology:* Notice was published on March 26, 1979 (44 FR 18116). The comment period closed on May 10, 1979..		Paul Riesel, Branch Chief, PPRB, BPP, Rm. 1-A-3 6401 Security Blvd., Baltimore, MD 21235, 8-594-1843
HCFA-35—Medicare/Medicaid Program: Prospective Reimbursement of Rural Health Clinic Services—Principles of Reimbursement93A. *Description:* This regulation provides for a prospective payment method for reimbursement of rural health clinic services under Medicaid and Medicare. B. *Why Significant.* The regulation will increase efficiency and increase beneficiary access to rural health services.. C. *Regulatory Analysis:* Not required. ... . D. *Need:* To implement the 1977 and 1978 amendments to the Social Security Act.. E. *Legal Basis:* Secs. 1833(a)(3), 1861(v)(1)(A) and 1902(a)(13) of the Social Security Act, Pub. L. 95-210 and Pub. L. 95-292.		

Health Care Financing Administration—Significant Regulations—Continued

Title	Summary	Contact
F. *Chronology:* NPRM was published on September 10, 1980 (45 FR 59734). A notice was published on November 7, 1980, which extended the comment period to December 10, 1980 (45 FR 73978). A correction notice was published on November 13, 1980.		
		Bernie Truffer, Acting Section Chief Health Organization, BPP, Rm. 181, EHR, 6401 Security Blvd., Baltimore, MD 21235, 301-597-2584. Francina Spencer, Health Insurance Policy Specialist, BPP, Rm. 431 EHR, 6401 Security Blvd., Baltimore, MD 21235, 301-594-9825.
HCFA-36—Medicaid Program: Family Planning—Requirements for Family Planning Services93A. *Description:* This regulation will specify Federal requirements for provision of family planning services under Medicaid. It also will specify types and ranges that may be included by States.. B. *Why Significant:* Regulations will assure that States will provide a uniform minimum set of family planning services to carry out the statutory requirement.. C. *Regulatory Analysis:* Not required. ..... D. *Need:* To implement the 1972 amendments to the Social Security Act.. E. *Legal Basis:* Secs. 1102, 1905(a)(4)(C) of the Social Security Act (42 U.S.C. 1302, 1396d(a)(4)(C)).. F. *Chronology:* NPRM was published on August 9, 1979 (44 FR 46899). The comment period closed on October 9, 1979..		
HCFA-37—Medicaid Program: Reasonable Cost-Related Reimbursement for Skilled Nursing and Intermediate Care Facility Services—Requirements for State Methods of Payment93A. *Description:* This regulation will clarify and expand requirements for State methods of payment for skilled nursing and intermediate care facility services under State Medicaid programs.. B. *Why Significant:* The regulation will make cost-related reimbursement for long-term care facilities a more effective, more accurate form of payment.. C. *Regulatory Analysis:* Not required. ..... D. *Need:* The regulations are needed to clarify inconsistancies in the cost-related reimbursement rules published in the FEDERAL REGISTER July 1, 1976. (41 FR 27300). E. *Legal Basis:* Secs. 1102, and 1902(a)(13)(E) of the Social Security Act.. F. *Chronology:* NPRM was published on April 18, 1979 (44 FR 23095). The comment period closed on June 18, 1979..		Milton Dezube, Section Chief, Issues Section, BPP, Rm. 1-A-1 ELR, 6401 Security Blvd., Baltimore, MD 21235 301-597-1804.
HCFA-38—Medicaid Program: State Medicaid Contracts—Procedures for Contract Practices93A. *Description:* This regulation proposes requirements to strengthen protections against questions on contract practices and possible program abuse and to remedy ambiguities and omissions in existing regulations.. B. *Why Significant:* The regulation would improve Medicaid program administration by ensuring proper contracting procedures and maximum appropriate competition.. C. *Regulatory Analysis:* Not required. ..... D. *Need:* The regulation is needed to implement Federal prior approval authority under 45 CFR Part 74, Administration of Grants.. E. *Legal Basis:* Sec. 1102 of the Social Security Act (42 U.S.C. 1302).. F. *Chronology:* The proposal is currently under review in the Department..		Leonard Monfred, Branch Chief, Div. of Procurement, BPO, Rm. 264 EHR, 6401 Security Blvd., Baltimore, MD 21235, 301-594-8004.
HCFA-39—Medicaid Program: Hearing Aid and Eyeglass Reimbursement—Procedures for Purchasing Hearing Aids and Eyeglasses93A. *Description:* The regulations will require Medicaid agencies to establish an acquisition cost (AC) program, volume purchase plan (VPP), or some combination of both as a method of purchasing eyeglasses and hearing aids for Medicaid recipients.. B. *Why Significant:* The regulation will limit payment to providers to the lower of the actual acquisition cost plus a reasonable dispensing fee, or the provider's usual and customary charge to the general public.. C. *Regulatory Analysis:* Not required. ..... D. *Need:* The regulations are needed to lower the cost and improve the quality of hearing aids and eyeglasses paid for under the State Medicaid program..		Pete Rodler, Acting Chief, Pharmaceutical & Medical Services Reimbursement Branch, BPP, Rm. 1-A-3, ELR, 6401 Security Blvd., Baltimore, MD 21235, 301-597-1845.

Health Care Financing Administration—Significant Regulations—Continued

Title	Summary	Contact
E. *Legal Basis:* Sec. 1102 of the Social Security Act.. F. *Chronology:* NPRM was published on May 25, 1979 (44 FR 30382). The comment period closed on July 24, 1979. The final is currently under review in the Dept..		
HCFA-41—Medicaid Program Medicaid Quality Control (MQC) Time Requirements for Review; Technical Amendments93A. *Description:* The regulations will amend the current Medicaid Quality Control (MQC) regulations by requiring States, within specific time frames to: (1) complete a set percentage of eligibility reviews (active cases and negative case actions); and (2) submit individual case review findings.. B. *Why Significant:* The regulations will make it easier for States to understand and operate the Medicaid Quality Control program, and improve Federal and State program management by ensuring timely completion of reviews and reports.. C. *Regulatory Analysis:* Not required. ..... D. *Need:* The regulations are needed to amend Medicaid Quality Control regulations by specifying time periods for completion of reviews of the cases in the monthly MQC samples.. E. *Legal Basis:* Sec. 1102 of the Social Security Act (42 U.S.C. 1302).. F. *Chronology:* NPRM was published on October 24, 1980 (45 FR 64912). The comment period closed December 23, 1980..		Carlton Stockton, Director, DQCR, BQC, 2-E-5 ELR, 6401 Security Blvd., Baltimore, MD 21235, 301-597-1350 .
HCFA-44—Medicare/Medicaid Program: Psychosurgery—Requirements for Psychosurgery Procedures93A. *Description:* This regulation would mandate specific requirements for the performance of psychosurgical procedures. The regulation would establish a mechanism for assuring that any psychosurgical procedures would be performed with appropriate safeguards and offer a model for State and local governments as well as for other concerned organizations.. B. *Why Significant:* The regulation would provide specific procedures and constraints in regard to psychosurgical procedures. It should adequately protect human subjects by requiring approval by a panel before procedure takes place.. C. *Regulatory Analysis:* Not required. ..... D. *Need:* The regulation addresses the concern of the public and Congress which generated the report by the National Commission for the Protection of Human Subjects of Biomedical and Behavorial Research in psychosurgery.. E. *Legal Basis:* Sec. 1102 of the Social Security Act; (42 U.S.C. 1302).. F. *Chronology:* The proposal is currently under review in the Department..		Mendel J. Kaufman, Chief, Special Cov. Issues Br., BPP, Rm. 463 EHR, 6401 Security Blvd., Balto., MD 21235, 301-594-8569.
HCFA-46—Medicare Program: Withholding Payments to Practitioners Providers, and Suppliers of Services 93A. *Description:* This regulation will clarify due process procedures that must be followed when payments to providers, practitioners and suppliers of services under the Medicare program are withheld because of suspected fraud or willfull misrepresentation.. B. *Why Significant:* The regulation will clarify existing procedures providing timely notice and administrative review.. C. *Regulatory Analysis:* Not required. ..... D. *Need:* Current regulations do not provide clear notification and review procedures. The regulation will establish procedures to safeguard Federal financial interest as well as the interests of the affected party.. E. *Legal Basis:* Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395).. F. *Chronology:* NPRM was published on December 1, 1980. The comment period closes January 30, 1981..		James F. Patton, Director, DVPS, OPV, BQC, Rm. 2-E-5, ELR, 6401 Security Blvd., Baltimore, MD 21235, 301-594-8000.
HCFA-47—Medicaid Program: Title XIX Administrative Sanctions93A. *Description:* This regulation would establish State plan requirements and procedures which require State Medicaid agencies to exclude from Medicaid program reimbursement providers who defraud or abuse the Medicaid program..		

Health Care Financing Administration—Significant Regulations—Continued

Title	Summary	Contact
B *Why Significant:* This regulation will give States a clear regulatory authority to pursue appropriate administrative sanctions in the cases of fraud or abuse.. C. *Regulatory Analysis:* No1 required. ..... D. *Need:* To strengthen and clarify State Medicaid agency responsibilites for the control of Medicaid fraud or abuse.. E. *Legal Basis:* Secs. 1102, 1902(a)(4)(A), and 1902(a)(30) of the Social Secunty Act, Pub L. 95-142.. F. *Chronology.* The proposal is currently under review in the Department.79James F. Patton, Director, DVPS, OFV, BQC, Rm. 2-E-5 ELR, 6401 Security Blvd., Baltimore, MD 21235, 301-594-8000..		
HCFA-49—Medicare/Medicaid Program: Annual Hospital Report Requirements for Hospital Cost Reporting93A. *Description.* The regulations require all hospitals that receive payments under the Medicare and Medicaid programs to report cost-related information, such as cost of operation, volume of services, and capital assets, in a prescribed uniform manner.. B *Why Significant:* The purpose is to obtain comparable cost and related data on all participating hospitals for reimbursement, effective cost, and policy analysis, assessment of alternative reimbursemont mechanisms and health planning.. C. *Regulatory Analysis:* Yes. ..... D. *Need:* To implement the 1977 amendments to the Social Security Act.. E *Legal Basis:* Secs. 1121, 1861(v)(1)(F) and 1902(a)(40) of the Social Security Act (42 U.S.C. 1320(a)); Sec. 19 of Pub. L. 95-142 93. F *Chronology:* NPRM was published on January 23, 1979 (44 FR 4741). The comment period closed on April 23, 1979. A new NPRM was published on March 19, 1980 (45 FR 17894) because of the large number of comments received in response to the original notice published and because of the extensive changes made in the system. The comment period closed on May 28, 1980. Comments are currently under review. When the review is completed, a final rule will be submitted to the Department for approval.		Bill Cresswell, ORDS, Rm. 1-E-6, Oak Meadows Bldg., 6340 Security Blvd., Balto., MD 21207, 301-597-2380
HCFA-50—Medicare/Medicaid Program: Skilled Nursing Facility/Intermediate Care Facility (SNF/ICF) Uniform Cost Reporting—Requirements for Cost Reporting 93A. *Description.* This regulation would propose uniform systems that SNFs and ICFs participating in the Medicaid or Medicare program must use to report cost of operation, volume of services, and capital assets.. B *Why Significant:* This regulation would enable the Department to obtain comparable cost and related data on all participating SNFs and ICFs for effectivo cost and policy analysis, assessment of alternative reimbursement mechanisms and health planning C. *Regulatory Analysis.* Decision pending on completion of preliminary study . D *Need:* To implement the 1977 amendments to the Social Security Act.. E *Legal Basis:* Secs. 1121, 1861(v)(1)(F) and 1902 (a)(40) of the Social Security Act (42 U.S.C. 1320a); Sec. 19 of Pub. L. 95-142.. F *Chronology:* The proposal is currently under review. When the review is completed, it will be submitted to the Department for approval..		Bill Cresswell, ORDS, Rm. 1-E-6, Oak Meadows Bldg., 6340 Security Blvd., Balto, MD 21207, 301-597-2380
HCFA-51—Medicare/Medicaid Program. Hospital Discharge and Data Reports—Requirements for Discharge and Bill Data Reports	A. *Description:* This regulation would require all hospitals to report discharge and billing data in a uniform manner. B. *Why Significant:* This regulation would enable the Department to obtain uniform discharge and bill data on all hospital patients in order to conduct retrospective profile analysis, and to support cost containment legislation and future cost control efforts. C. *Regulatory Analysis:* Decision pending on completion of preliminary study. D. *Need:* To implement the 1977 amendments to the Social Security Act. E. *Legal Basis:* Secs. 1121, 1861(v)(1)(F), and 1902 (a)(40) of the Social Security Act (42 U.S.C. 1320a); Sec. 19 of Pub. L. 95-142. F. *Chronology:* The proposal is currently under review. When the review is completed, it will be submitted to the Department for approval.	Bill Cresswell, ORDS, Rm. 1-E-6, Oak Meadows Bldg., 6340 Security Blvd., Balto, MD 21207, 301-597-2380
HCFA-52—Medicare/Medicaid Program: Skilled Nursing Facility/Intermediate Care	A. *Description:* This regulation would require all SNFs/ICFs to report discharge and billing data in a uniform manner.	Bill Cresswell, ORDS, Rm. 1-E-6, Oak Meadows Bldg., 6340 Security Blvd., Balto., MD 21207, 301-597-2380.

Health Care Financing Administration—Significant Regulations—Continued

Title	Summary	Contact
Facility (SNF/ICF) Discharge end Bill Data—Requirements for Discharge and Bill Data Reports.	B. *Why Significant:* This regulation will enable the Department to obtain uniform discharge and bill data on all SNF/ICF patients in order to conduct retrospective profile analysis and to support cost containment legislation and future cost control efforts. C. *Regulatory Analysis:* Decision pending on completion of preliminary study. D. *Need:* To implement the 1977 amendments to the Social Security Act. E. *Legal Basis:* Secs. 1121, 1801(v)(1)(F) and 1902(a)(40) of the Social Security Act (42 U.S.C. 1320e) end Sec. 19 of Pub. L. 95-142. F. *Chronology:* The proposal is currently under review. When the review is completed, it will be submitted to the Department for epproval.	
HCFA-53—Medicare/Medicaid Program: Home Heelth Agency (HHA) Cost end Utilizetion Requirements for Cost Reporting.	A. *Description:* This regulation would propose uniform systems that HHA's perticipating in the Medicaid or Medicare program must use to report cost of operation, volume of services and capital assets. B. *Why Significant:* This regulation would enable the Department to obtain comparable cost and related data on all participeting HHAs for effective cost and policy analysis, assessment of alternative reimbursement mechanisms and health planning. C. *Regulatory Analysis:* Yes, being conducted. D. *Need:* To implement the 1977 emendments to the Social Security Act. E. *Legal Basis:* Secs. 1121, 1861(v)(1)(F), and 1902(a)(40) of the Social Security Act (42 U.S.C. 1320a) Sec. 19 of Pub. L. 95-142. F. *Chronology:* The proposal is currently under developmenl. When it is completed, it will be submitted to the Department tor approval.	Bernard Patashnik, Director, DISR, BPP, Rm. 1-G-1, ELR, 6401 Security Blvd., Baltimore, MD 21235, 301-597-1335.
HCFA-54—Medicere/Medicaid Program: Home Health Agency (HHA) Discharge end Bill Data—Requirement for Discharge and Bill data.	A. *Description:* This regulation would require all HHAs to report discharge and billing data in a uniform manner. B. *Why Significant:* The regulations would enable the Department to obtain uniform discharge and bill deta on ell HHA patients in order to conduct retrospective profile analysis, end to support cost containment legislation and future cost control efforts. C. *Regulatory Analysis:* Decision pending on completion of preliminary study. D. *Need:* To implement the 1977 amendments to the Social Security Act. E. *Legal Basis:* Secs. 1121, 1861(v)(1)(F), end 1902(a) (40) ot the Social Security Act (42 U.S.C. 1302a); and sec. 19 of Pub. L. 95-142. F. *Chronology:* The proposal is currently under development. When it is completed, it will be submitted to the Department for approval.	Bill Cresswell, ORDS, Rm. 1-E-6, Oak Meadows Bldg., 6340 Security Blvd., Balto., MD 21207, 301-597-2367
HCFA-55—Medicare/Medicaid Program: Prohibition Against Payment for Less Than Effective Drugs.	A. *Description:* The regulations will prohibit use of Federal funds under Medicare and Medicaid for certain drugs that have been classified es less than effective by the Food end Drug Administration and drugs that are illegal in interstate commerce. B. *Why Significant:* This regulation will respond to concerns of public interest groups by ensuring that services provided under the Medicare and Medicaid programs are of high quality end that Federel funds are expended in an effective and responsible manner. C. *Regulatory Analysis:* Not required. D. *Need:* To prohibit Medicare end Medicaid payments tor drugs which are illegal in interstate commerce or ineffective. E. *Legal Basis:* Secs. 1102 and 1862(a) of the Social Security Act (42 U.S.C. 1302). F. *Chronology:* MPRM was published on June 5, 1980 (45 FR 37858). The comment period closed on August 4, 1980. Comments are currently under review. When the review is completed, a final rule will be submitted to the Department for approval.	Mendell J. Kautman, Chief, SCIB, BPP, Rm. 463 EHR, 6401 Security Blvd., Balto., MD 21235, 301-594-8569
HCFA-56—Medicare Program. Common Audit Requirements.	A. *Description:* This regulation will prohibit Federal Matching of State Medicaid costs for hospital audits if they duplicate Medicare audits, and will define audit activities for purposes ot determining duplication. It will elso provide that, if a State requests Medicare to include additional items in the audit at the appropriate cost, or if a State performs these additional activities, Federal financial perticipation will be available in those costs. B. *Why Significant:* This regulation would eliminate unnecessary or duplicative audits completed for the same provider by Medicare or Medicaid and encourage sharing of audit information. C. *Regulatory Analysis:* Not required. D. *Need:* To simplify the administrative process by making Medicare and Medicaid more consistent end reducing duplicative audits. E. *Legal Basis:* Secs. 1102 and 1903(a)(7) of the Social Security Act (42 U.S.C. 1302 and 1396b). F. *Chronology:* NRPM was published on June 3, 1980 (45 FR 37466). The comment period closed on August 4, 1980.	Don Novinski, Chief, PAB, OSPE, BPO, Rm. 255 EHR, 6401 Security Blvd., Baltimore, MD 21235, 301-594-9063.
HCFA-57—Medicaid Program: Medicaid Overpayment Reporting Requirements.	A. *Description:* This regulation would require States to establish procedures to identify provider overpayments and report them to HCFA on a timely basis. B. *Why Significant:* This regulation would essure that Medicaid overpayments are properly and promptly identified and allow comparison ot provider overpayments in the Medicare and Medicaid programs. C. *Regulatory Analysis:* Not required. D. *Need:* To recover inappropriate payments made to providers under the Medicaid program E. *Legal Basis:* Secs. 1102 and 1903(d) of the Social Security Act (42 U.S.C. 1396b(d)). F. *Chronology:* The proposal is currently under review. When the review is completed, it will be submitted to the Department for approval.	Guy L. Hamman, Jr., Chief, REB, DRRE, BPO, Rm. 1-B-2 ME Bldg., 6300 Security Blvd., Baltimore, MD 21235, 301-594-8193.
HCFA-59—Medicare Program: Limits on Costs and Charges tor New Technology.	A. *Description:* This reguletion would set forth HCFA's authority to establish reasonable charge limitations for certain items end services under the Medicare program if the standard reasonable charges approach (i.e., the use ot customary end prevailing charge screens) is ineffective. B. *Why Significant:* This regulation would reduce excess program payment by setting limits on certain items and services which exceed standard reasonable charges. C. *Regulatory Analysis:* Not required. D. *Need:* To establish e clear basis for setting reimbursement limits on certain items and services under Medicare. E. *Legal Basis:* Sec. 1102, 1942(b)(3), and 1871 of the Social Security Act (42 U.S.C. 1302, 1395u(b)(3) and 1395hh). F. *Chronology:* The proposal is currently under review in the Department.	Paul Riesel, Chief, PPRB, DMSR, ORP, BPP, Rm. 1-A-3 ELR, 6401 Security Blvd., Baltimore, MD 21235, 301-597-1843.
HCFA-60—Medicare Program: Limitations on Reasonable Charges tor Computenzed Tomography Scan Services.	A. *Description:* This notice would establish limits on the amounts on which Medicare reasonable cherge reimbursement for computerized tomography scans is based. B. *Why Significant.* This regulation would reduce inappropriate program payment by setting limits on reimbursement ot computerized tomography scan services. C. *Regulatory Analysis:* Not required. D. *Need:* To ensure that payments for computerized tomography scans ere made at an appropriate level. E. *Legal Basis:* Sec. 1102, 1942(b)(3), and 1871 of the Social Security Act (42 U.S.C. 1302, 1395u(b)(3) end 1395hh). F. *Chronology:* The proposal is currently being developed. When the review is completed, it will be submitted to the Department tor epproval.	Paul Riesel, Chief, PPRB, DMSR, ORP, BPP, Rm. 1-A-3 ELR, 6401 Security Blvd., Baltimore, MD 21235, 301-597-1843.

Health Care Financing Administration—Significant Regulations—Continued

Title	Summary	Contact
HCFA-61—Medicere Program: Reconsiderations and Hearings for Providers and Suppliers.	A. *Description:* This regulation would clarify and redesignate the procedures for making and reviewing determinations that affect the status of entities that participate in the Medicare program. It will also incorporate substantive changes relating to informal reconsideration procedures. B. *Why Significant:* This regulation would be easier to understand and eliminate inconsistencies between Medicare and Medicaid in provider appeals processes. C. *Regulatory Analysis:* Not required. D. *Need:* To simplify administration and essure due process by providing uniform appeal rights within Medicare. E. *Legal Basis:* Secs. 1124, 1128, 1102, 1814(d), 1835(b), 1861(e), 1861(j), 1861(o), 1861(p), 1861(r), 1861(aa), 1862(d) and (e), 1866, 1889, 1871, 1872, 1876, and 1881 of the Social Security Act (42 U.S.C. 1302, 1320(e)-3, 1320(a)-5, 1345x(j), 1395ii, 1395mm, 1395y(d) and (e), 1395cc, 1395ff, 1395(h), 1395x(e), 1395x(o), 1395x(p), 1395x(r), 1395x(ee), 1395hh, end 1395rr). F. The proposal is currently under review. When it is completed, it will be submitted to the Department for approval. Clinical Lab. Improvement Act of 1957 (42 USC 263a).	Luisa Iglesias, Regulation Analyst, BPP, Rm. 357G, Hubert H. Humphrey Bldg., 200 Independence Ave., SW., Weshington, D.C. 20201, 202-755-1290.
HCFA-62—Medicare Program: Recodification: Medicare Entitlement and Benefits, Limitations, and Exclusions: Supplementary Medical Insurance.	A. *Description:* This recodification would revise certain regulations dealing with supplementary medicel insurance. It will clarify, reorganize, and renumber the eligibility requirements, enrollment procedures end the coverage period, the types of benefits provided and the limitetions on these benefits. B. *Why Significant:* Periodic review of existing regulations is being conducted to make sure they are up to date, easy to locate, and clear. C. *Regulatory Analysis:* Not required. D. *Need:* To make reguletions more understandable to the public. E. *Legal Basis:* Sec. 1102, 1831-1840, 1843, 1861, and 1882 of the Social Security Act (42 U.S.C. 1302; 1395j-1395p, 1395v, 1395x and 1395y). F. *Chronology:* The proposal is currently under review. When review is completed, it will be submitted to the Department for approval.	Mery E. Robinson, Program Analyst, BPP, Rm. 357G, Hubert H. Humphrey Bldg., 200 Independence Ave., SW., Washington, D.C. 20201, 202-755-1290
HCFA-63—Medicare Program: Recodilication: Medicare Limitations on Exclusions of Benefits.	A. *Description:* This recodification would rewrite and renumber the provisions that identify the types and items of services that are not paid for by Medicare; end that specify the circumstances under which expenses for items end services usually peid for by Medicare may not be reimbursed. B. Why Signilicent. Periodic review of existing regulations is being conducted to make sure they are up to date, easy to locate, and clear. C. *Regulatory Analysis:* Not required. D. *Need:* To make reguletions more understandable to the public E. *Legal Basis:* Sec. 1102 of the Social Security Act (42 U.S.C. 1302). F. *Chronology:* The proposel is currently under review. When the review is completed, it will be submitted to the Department for approval.	Luisa Iglesias, Regulation Analyst, BPP, Rm. 357G, Hubert H. Humphrey Bldg., 200 Independence Ave., SW., Weshington, D.C. 20201, 202-755-1290.
HCFA-64—Medicare Program; Recodification: Medicare Overpayments, Recoveries, end Withholding.	A. *Description:* This recodification would rewrite and renumber procedures for determining end adjusting incorrect payments and the circumstances under which edjustment will be waived and if not recovery of overpeyments. B. *Why Significant:* Periodic review of existing regulations is being conducted to make sure they ere up to date, eesy to locete, end clear. C. *Regulatory Analysis:* Not required. D. *Need:* To make the regulation more understandable to the public and streamline procedures. E. *Legal Basis:* Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh). F. *Chronology:* The proposal is currently under review. When the review is completed, it will be submitted to the Department for approval.	Luisa Iglesias, Regulation Analyst, BPP, Rm. 357G, Hubert H. Humphrey Bldg., 200 Independence Ave., SW., Washington, D.C. 20201, 202-755-1290.
HCFA-65—Medicare Program; Recodification: Medicare Provider Reimbursement Determinations and Appeals.	A. *Description:* This recodification will renumber and clarily the procedures for providers or their legal representatives to appeal reimbursement determinations or decisions under Medicare. It covers time constraints for filing appeals, perties authorized to participate et each hearing level, composition ol each review body and legal aspects of hearing and appeals system, and procedures for reopening determinations and decisions. B. *Why Significant:* This recodification will revise, simplify, clarily, end reorganize existing regulations. C. *Regulatory Analysis:* Not required. D. *Need:* To make the regulation more understandable to the public and streamline procedures. E. *Legal Basis:* Secs. 1102, 1861(v)(1)(A)(ii), and 1878(f)(1) of the Social Security Act (42 U.S.C. 1302 and 1395oo). F. *Chronology:* NPRM is being waived. NPRM with proposed policy changes (HCFA-21) affecting these regulations was published on February 14, 1980 (45 FR 9953). The comment period closed on April 14, 1980.	Luisa Iglesias, Reguletion Analyst, BPP, Rm. 357G, Hubert H. Humphrey Bldg., 200 Independence Ave., SW., Washington, D.C. 20201, 202-755-1290.
HCFA-66—Medicare Program; Recodification: Medicare Conditions for Peyment.	A. *Description:* This recodification will renumber end clarify the provisions relating to the conditions under which hospital insurence and supplementary medical insurance peyments will be made. B. *Why Significant:* This recodification would revise, simplify, clarify end reorganize existing regulations. C. *Regulatory Analysis:* Not required. D. *Need:* To make the regulation understandable to the public end streamline procedures. E. *Legal Basis:* Secs. 1102, 1114(c), 1835, 1842(b), and 1871 ol the Social Security Act (42 U.S.C. 1302 and 1395hh). F. *Chronology:* The final with comment period is currently under review. When the review is completed, it will be submitted to the Depertment for approvel. The NPRM has been waived.	Luisa Iglesias, Regulation Analyst, BPP, Rm. 357G, Hubert H. Humphrey Bldg., 200 Independence Ave., SW., Washington, D.C. 20201, 202-755-1290.
HCFA-67—Medicald Program: Requirements Applicable to Sterilizations (Hysterectomies).	A. *Description:* This regulation will waive the requirement that in order to obtain a Federelly funded hysterectomy, e woman must acknowledge receipt of information about the effects of e sterilization even if she is already sterile or requires emergency treatment. B. *Why Significant:* Existing regulations have resulted in unnecessary administrative burden on States. C. *Regulatory Analysis:* Not required D. *Need:* To eliminate administratively burdensome procedures not needed to protect patients. E. *Legal Basis:* Secs. 1102, 1902(a)(13), 1905(a)(4)(C) of the Social Security Act (42 U.S.C. 1302, 1396(a)(13) and 1396(d)(4)(C)). F. *Chronology:* NPRM is being waived. The final is currently under review in the Department. When the review is completed, it will be submitted to the Department for approval.	Raymond T. Johnson, Chief, OCP, Rm. 455 EHR, 6401 Security Blvd., Baltimore, MD 21235, 301-594-9370.

Health Care Financing Administration—Significant Regulations—Continued

Title	Summary	Contact
HCFA-68—Medicare/Medicaid Program: Permissible Charges to Patient Funds in Nursing Homes.	A. *Description:* This regulation would define those costs that may be charged to the personal funds of Medicare and Medicaid patients in skilled nursing or intermediate care facilities. B. *Why Significant:* This regulation would safeguard personal funds of Medicare/Medicaid patients in nursing homes. C. Regulatory Analysis: Not required. D. *Need:* To implement Sec. 21(b) of P.L. 95-142 (Medicare and Medicaid Amendments of 1977) and 8(c) of Pub. L. 95-292. E. *Legal Basis:* Sec. 1102 of the Social Security Act (42 U.S.C. 1302); Secs. 21(b) of P.L. 95-142 and 8(c) of P.L. 95-292. F. *Chronology:* The proposal is currently under review. When the review is completed, it will be submitted to the Department for approval.	David Chambers, Program Analyst, HSQB, 2nd Floor, Dogwood East Bldg., 1849 Gwynn Oak Ave., Baltimore, MD 21207, 301-594-7651.
HCFA-69—Medicare/Medicaid Program: Professional Standards Review Organization (PSRO) Designations.	A. *Description:* The proposed change in the PSRO area designation regulations will permit area redesignation for the purpose of increased administrative efficiency end remove the State and County specific PSRO area descriptions from the regulations and publish these in the future by notice. B. *Why Significant:* This regulation will reduce program costs for PSRO management and promote consolidation of PSRO areas where appropriate. C. *Regulatory Analysis:* Not required. D. *Need:* To reduce overall cost of PSRO review. E. *Legal Basis:* Secs. 1102 end 1152 of the Social Security Act (42 U.S.C. 1302 and 1320c(1). F. *Chronology:* NPRM was published on 8-11-80 (45 FR 53189). The comment period closed on 10-10-80.	Christine Donahue, Public Health Analyst, HSQB, First Floor, Dogwood East Bldg., 1849 Gwynn Oak Ave., Baltimore, MD 21207, 301-594-5033.
HCFA-71—Medicare/Medicaid Program: Survey and Certification.	A. *Description:* This regulation would streamline, simplify, and integrate, to the extent possible, survey and certification procedures for providers and suppliers under Medicare end Medicaid. B. *Why Significant:* This regulation would eliminate inconsistencies between Medicare end Medicaid requirements; eliminate unnecessary burden by focusing survey resources on problem providers. C. *Regulatory Analysis:* Under consideration. D. *Need:* To revise and consolidate existing survey and certification regulations. E. *Legal Basis:* 42 CFR, Part 405, Subpart S; 42 CFR, Part 402, Subpart A-E. F. *Chronology:* Notice of public hearing was published on March 7, 1980 (45 FR 14900). The proposal is currently under review. When the review is completed, it will be submitted to the Department for approval.	Terrence Skelly, Standards and Certification Analyst, DFO, HSQB, Room 2-E-2, Dogwood East Bldg., 1849 Gwynn Oak Ave., Baltimore, MD 21207, 301-594-7942.
HCFA-72—Medicare/Medicaid Program: Financial Assistance Agreement for End Stage Renal Disease (ESRD) Networks.	A. *Description:* This regulation would establish a formal mechanism (cooperative agreements) for funding ESRD Network Coordinating Councils. B. *Why Significant:* This regulation would streamline and standardize the funding process to make it more accountable. C. Regulatory Analysis: Not required. D. *Need:* To improve the financial management, efficiency, and accountability of ESRD Networks. E. *Legal Basis:* 45 CFR, Part 74. F. *Chronology:* The proposal is currently under review in the Department.	Spencer Schron, Acting Deputy Director, OSP, Rm. 2-B-2, Dogwood West Bldg., 1848 Gwynn Oak Ave., Baltimore, MD 21207, 301-594-0918.

New Initiatives

Title	Summary	Contact
HCFA-73—Medicare Program: Notice of Performance Standards for Fiscal Intermediaries.	A. *Description:* This notice establishes statistical standards for FY 81 to measure the efficiency of Part A intermediary operations. B. *Why Significant:* Current Medicare regulations require publication of statistical standards as part of a two-phase evaluation system of fiscal intermediary performance. C. *Regulatory Analysis:* Not required. D. *Need:* Establish clear standards for evaluating intermediary performance to improve Medicare contracting. E. *Legal Basis:* P.L. 95-142, Sec. 1816(f) of the Social Security Act. F. *Chronology:* The notice is currently under review. When the review is completed, it will be submitted to the Department for approval.	Lester Belsky, Chief, OSB, DS, OSPE, BPO, Rm. 1445, Meadows East Bldg., 6300 Security Blvd., Baltimore, MD 21235, 301-594-8503.
HCFA-74—Medicare Program: Medigap—Certification of Medicare Supplemental Health Insurance Policies.	A. *Description:* These regulations would establish a program of certification by the Secretary of Medicare supplemental health insurance policies (so-called Medigap policies) voluntarily submitted by insurers for review. B. *Why Significant:* These regulations would: (1) set standards for policies voluntarily submitted to HCFA for certification, (2) establish procedures for certification program, and (3) promulgate the statutory requirements that the Supplemental Health Insurance Panel, consisting of the Secretary or a designee and four State Commissioners or Superintendents of Insurance appointed by the President, would use to approve State regulatory programs for Medigap policies. C. *Regulatory Analysis:* Not required. D. *Need:* To implement, in part, section 507 of the Social Security Disability Amendments of 1980. E. *Legal Basis:* Sec. 1882 of the Social Security Act, Sec. 507 of P.L. 96-265. F. *Chronology:* The proposal is currently under review in the Department.	Thomas Hoyer, Staff Asst., OCP, BPP, Rm. 401, EHR, 6401 Security Blvd., Baltimore, MD 21235, 301-594-9690.
HCFA-75—Medicaid Program: Proposed Medicaid Management Information System (MMIS) Performance Standards and Systems Requirements.	A. *Description:* This notice would set forth performance standards and add three new systems requirements for approved State MMIS. B. *Why Significant:* The application of these performance standards is intended to improve the overall efficiency and effectiveness of the Medicaid program. C. *Regulatory Analysis:* Not required. D. *Need:* To ensure that MMIS are being used effectively to manage the Medicaid program. E. *Legal Basis:* Secs. 1102, 1902(a)(4), 1903(a)(3) and 1903(r) of the Social Security Act (42 U.S.C. 1302, 1396(a)(4) and 1936(b)(3). F. *Chronology:* The notice is currently under review. When the review is completed, it will be submitted to the Department for approval.	Robert Ouloosian, Chief, PSB, DS, OSPE, BPO, Rm. 1445, Meadows East Bldg., 6300 Security Blvd., Baltimore, MD 21235, 301-594-8040.
HCFA-76—Medicaid Program: Conditions of Approval and Reapproval for Mechanized Claims Processing and Information Retrieval Systems with Procedures for Reduction of Federal Financial Participation (FFP).	A. *Description:* This regulation would establish procedures for the reduction of FFP in State expenditures for operating MMIS if those systems fail to meet the conditions of approval that are established. B. *Why Significant:* Federal dollars would be saved by reducing the amount paid to operate MMIS which does not meet Federal requirements.	Robert Ouloosian, Chief, PSB, DS, OSPE, BPO, RM. 1445, Meadows East Bldg., 6300 Security Blvd., Baltimore, MD 21235, 301-594-8040.

New Initiatives—Continued

Title	Summary	Contact
	C *Regulatory Analysis*: Not required. D *Need*: To ensure that MMIS are bring used effectively to manage the Medicaid program. E *Legal Basis*: Secs. 1102, 1903(a)(3) and 1903(r) of the Social Security Act, (42 U.S.C. 1302, 1396(a)(3) and 1396b(r) F *Chronology*: The proposal is currently under review. When the review is completed, it will be submitted to the Department for approval.	
HCFA-77—Medicaid Program: Deeming of Income Between Spouses—Financial Eligibility Requirements	A. *Description*: This regulation will revise current rules determining Medicaid financial eligibility for the aged, blind or disabled in States and Territories using more restrictive eligibility requirements than Supplemental Security Income (SSI) requirements. B *Why Significant*: The regulation will require these States and Territories to alter their methods of deeming of income and resources between aged, blind, or disabled applicants or recipients and their spouses, when either the applicant or recipient or his or her spouse is institutionalized. C *Regulatory Analysis*: Not required D *Need*: To implement a court order by the Court of Appeals of the District of Columbia Circuit E *Legal Basis*: Gray Panthers vs. Administrator No. 79-1334, Sec. 1102 of the Social Security Act (42 U.S.C. 1203) F *Chronology*: NPRM was published October 30, 1980 (45 FR 71821). The comment period closed December 1, 1980.	Michael Fiore, Program Analyst, DMEP, BPP, Rm. 4f6 EHR, 6401 Security Blvd., Baltimore, MD 21235, 301-594-9127
HCFA-78—Medicare/Medicaid Program: Reimbursement on the Basis of the Prudent Buyer Concept	A *Description*: This regulation would clarify the rules governing Medicare reimbursement of reasonable cost by explicitly stating that providers are expected to apply sound management principles to their day-to-day business transactions. B *Why Significant*: The regulation would assure that providers actual operating costs do not exceed what a prudent and cost-conscious business manager would have incurred for similar transactions. C *Regulatory Analysis*: Not required. D. *Need*: To restate and clarify HCFA's authority to disallow for reimbursement those costs that are excessive and unreasonable. E *Legal Basis*: Secs. 1102, 1801, 1814(b), 1861(v)(1)(A) and 1871 of the Social Security Act. F *Chronology*: The notice to develop regulations was published on August 18, 1980 (42 FR 54774).	William Goeller, Chief, Provider Reimbursement Branch, BPP, Rm. 1-D-1 ELR, 6401 Security Blvd., Baltimore, MD 21235, 301-597-1802
HCFA-79—Medicare Program: Collection of Unpaid Medicare Premiums.	A *Description*: The regulation specifies the conditions under which HCFA will cease collection efforts on unpaid Medicare premiums. B *Why significant*: The regulation allows HCFA to cease collection efforts in circumstances in which it is not cost effective to continue collection efforts. C *Regulatory Analysis*: Not required. D *Need*: The regulation provides HCFA with the administrative authority required by the Federal Claims Collection Act of 1966 (31 U.S.C. 951-953). E *Legal Basis*: Secs. 1102, 1818, 1832, 1838, 1840, 1870 of the Social Security Act (42 U.S.C. 1302, 1395i-2, 1395k, 1395q, 1395s, 1395gg and 1395hh); and 31 U.S.C. 951-953. F *Chronology*: The notice of decision to develop regulations was published on July 31, 1980. The final rule with comment period is currently under review in the Department.	David Higbee, Reg. Analyst, RS, BPP, 150 EHR, 6401 Security Blvd., Baltimore, MD 21235, 301-594-9638

Food and Drug Administration—Significant Regulations

Title	Summary	Contact
FDA 1—Antigen E Assay—Potency Standards	A *Description*: This document establishes potency standards for short ragweed pollen extracts. Each final container of a lot of extract will be required to contain a minimum quantity of Antigen E relative to a reference preparation with a known quantity of Antigen E. B. *Why Significant*: The regulation establishes potency requirements for allergenic extracts. This will require manufacturers to conform to specific standards and assure the public of a uniform product. C *Regulatory Analysis*: Not required. D *Need*: To improve potency testing. E *Legal Basis*: Section 351, 58 Stat. 702, 42 U.S.C. 262. F *Chronology*: Notice of proposed rulemaking was published August 3, 1979 (44 FR 45642). Comment period extended from October 2, 1979 to November 10, 1979. The final rule is currently under review by the Agency.	Michael Hooten, Regulations Branch (HFB-620), Bureau of Biologics, Food and Drug Administration, 8800 Rockville Pike, Bethesda, MD 20205, 301-443-1306
FDA 3—Allergenic Source Material—Standards	A *Description*: This document prescribes additional criteria for source materials used in the manufacture of a final allergenic product. Specific requirements will be required for the propagation and maintenance of molds and certain animals. Inspection and record-keeping requirements will apply to all manufacturers of allergenic products. B *Why Significant*: The regulation establishes specific standards for certain source materials used to prepare allergenic extracts. This will assure product uniformity. C *Regulatory Analysis*: Not required. D. *Need*: To assure safety and identity of source material. E *Legal Basis*: Section 351, 58 Stat. 702, 42 U.S.C. 262. F *Chronology*: Notice of proposed rulemaking was published September 26, 1978 (43 FR 43472). The comment period closed on November 26, 1978. A revised proposal is currently under review by the Agency.	Michael Hooten, Regulations Branch (HFB-620), Bureau of Biologics, Food and Drug Administration, 8800 Rockville Pike, Bethesda, MD 20205, 301-443-1306
FDA 4—Radioallergosobent Test (RAST) Potency Test.	A *Description*: This document proposes to amend the regulations to require that the RAST be used as a potency test for certain allergenic extracts. Presently, no reliable test is available for most extracts. Manufacturers were invited to attend a workshop at the Bureau on September 10, 1979. A collaborative study will be initiated. The results of the study will be used to develop the proposed rule. B *Why Significant*: This regulation establishes a specific test to measure potency in a broad variety of allergenic extracts. The use of this test will result in a better measurement of potency. C *Regulatory Analysis*: Not required. D *Need*: To improve potency test. E *Legal Basis*: Section 351, 58 Stat. 702, 42 U.S.C. 262. F *Chronology*: The proposal is currently being drafted for review by the agency.	Michael Hooten, Regulations Branch (HFB-620), Bureau of Biologics, Food and Drug Administration, 8800 Rockville Pike, Bethesda, MD 20205, 301-443-1306
FDA 5—Error and Accident Reports—Amend Blood GMPs.	A *Description*: This document proposes that licensed and unlicensed blood establishments submit reports to Bureau of Biologics of errors and accidents that are imminent health hazards. The document also proposes that records of all errors and accidents, including those that are not imminent health hazards, be maintained.	Albert Rothschild, Regulations Branch (HFB-620), Bureau of Biologics, Food and Drug Administration, 8800 Rockville Pike, Bethesda, MD 20205, 301-443-1306

Food and Drug Administration—Significant Regulations—Continued

Title	Summary	Contact
	B. *Why Significant:* This regulation specifies certain reports required to be submitted by licensed and unlicensed blood establishments. It will provide information to determine the need for revising existing regulations, or developing new regulations. C. *Regulatory Analysis:* Not required. D. *Need:* The data will be used to judge adequacy of existing regulations. E. *Legal Basis:* Section 351, 58 Stat. 702 (42 U.S.C. 262). F. *Chronology:* The Notice of Proposed Rulemaking was published August 8, 1980 (45 FR 52821). The comment period closed November 6, 1980	
FDA 6—Reorganize Whole Blood Regulations.	A. *Description:* This document proposes to revise and reorganize Subpart A in Part 640 which prescribes additional standards for Whole Blood (Human). The regulations are being reorganized to reflect, insofar as possible, a logical sequence beginning with the collection of blood and progressing through storage, testing, labeling and issue. This document will also propose substantive amendments of the present requirements. B. *Why Significant:* This regulation will present an orderly arrangement of requirements for blood establishments to follow. It will assure the production of a safe and effective product and protect the health and safety of donors. C. *Regulatory Analysis:* Not required. D. *Need:* To increase donor and product safety and clarity of the regulations. E. *Legal Basis:* Section 351, 58 Stat. 702, 42 U.S.C. 262. F. *Chronology:* The Notice of Proposed Rulemaking was published October 31, 1980 (45 FR 92422). The comment period closes December 6, 1980	Richard Fisher, Regulations Branch (HFB-620), Bureau of Biologics, Food and Drug Administration, 8800 Rockville Pike, Bethesda, MD 20205, 301-443-1306.
FDA 7—Uniform Blood Labeling	A. *Description:* This document proposes to amend the blood regulations as recommended by the American Blood Commission, Committee for Commonality in Blood Banking Automation. B. *Why Significant:* This regulation proposes uniform labeling requirements for blood and blood products. It will promote uniformity throughout the industry and provide increased safety to the public in blood transfusion. C. *Regulatory Analysis:* Not required. D. *Need:* To facilitate uniformity in blood labeling. E. *Legal Basis:* Section 351, 58 Stat. 702, 42 U.S.C. 262. F. *Chronology:* The Notice of Proposed Rulemaking was published October 31, 1980 (45 FR 72416). The comment period closed December 30, 1980	Steve Falter, Regulations Branch (HFB-620), Bureau of Biologics, Food and Drug Administration, 8800 Rockville Pike, Bethesda, MD 20205, 301-443-1306.
FDA 8—Notification of FDA Regarding Adverse Reactions—Recordkeeping and Reporting Requirements.	A. *Description:* This document proposes to require that manufacturers notify FDA of adverse reactions from use of their products. B. *Why Significant:* This regulation will require industry to keep records and make reports on specific adverse reactions within specified time limits to the Agency. This information will assist the Agency in evaluating the continued safety, purity, potency and effectiveness of marketed products. C. *Regulatory Analysis:* Not required. D. *Need:* To increase FDA's effectiveness in regulating biological products. E. *Legal Basis:* Section 351, 58 Stat. 702, 42 U.S.C. 262. F. *Chronology:* Notice of Availability of draft proposal was published April 24, 1979. The proposal is currently under review by the Agency.	Richard Fisher, Regulations Branch (HFB-620), Bureau of Biologics, Food and Drug Administration, 8800 Rockville Pike, Bethesda, MD 20205, 301-443-1306
FDA 9—Panel on Review of Allergenic Extracts-Product Effectiveness.	A. *Description:* This document proposes to place the subject material in categories designated as (1) safe and effective and not misbranded, (2) unsafe or ineffective and misbranded, and (3) not within category (1) or (2) above, on the basis that available data are insufficient to classify such products. B. *Why Significant:* This regulation will establish the safety and effectiveness of currently marketed products. It will assure the public of receiving only those products found to be truly safe and effective. C. *Regulatory Analysis:* Not required. D. *Need:* To bring products into conformance with current standards of safety and effectiveness. E. *Legal Authority:* Section 351, 58 Stat. 702, 42 U.S.C. 262. F. *Chronology:* The proposal is currently being drafted for review by the Agency.	Michael Hooten, Regulations Branch (HFB-620), Bureau of Biologics, Food and Drug Administration, 8800 Rockville Pike, Bethesda, MD 20205, 301-443-1306
FDA 10—Panel on Review of Viral Vaccines and Rickettsial Vaccines Product Effectiveness.	A. *Description:* This document proposes to place the subject products in categories designated as (1) safe and effective and not misbranded, (2) unsafe or ineffective and misbranded, and (3) not within category (1) or (2) above, on the basis that available data are insufficient to classify such products. B. *Why Significant:* This regulation will establish the safety and effectiveness of currently marketed products. It will assure the public of receiving only those products found to be truly safe and effective. C. *Regulatory Analysis:* Not required. D. *Need:* To bring products into conformance with current standards of safety and effectiveness. E. *Legal Basis:* Section 351, 58 Stat. 702, 42 U.S.C. 262. F. *Chronology:* The notice of proposed rulemaking was published April 15, 1980 (45 FR 25652). The comment period closes on July 14, 1980.	Steve Falter, Regulations Branch (HFB-620), Bureau of Biologics, Food and Drug Administration, 8800 Rockville Pike, Bethesda, MD 20205, 301-443-1306
FDA 11—Panel on Review of Blood and Blood Products—Product Effectiveness.	A. *Description:* This document proposes to place the subject products in categories designated as (1) safe and effective and not misbranded, and (2) unsafe or ineffective and misbranded, and (3) not within category (1) or (2) above, on the basis that available data are insufficient to classify such products. B. *Why Significant:* This regulation will establish the safety and effectiveness of currently marketed products. It will assure the public of receiving only those products found to be truly safe and effective. C. *Regulatory Analysis:* Not required. D. *Need:* To bring products into conformance with current standards of safety and effectiveness. E. *Legal Basis:* Section 351, 58 Stat. 702, 42 U.S.C. 262. F. *Chronology:* The proposal is currently being drafted for review by the Agency.	Steve Falter, Regulations Branch (HFB-620), Bureau of Biologics, Food and Drug Administration, 8800 Rockville Pike, Bethesda, MD 20205, 301-443-1306
FDA 12—Panel on Review of Bacterial Toxoids and Bacterial Vaccines With U.S. Standards of Potency—Product effectiveness.	A. *Description:* This document proposes to place the subject products in categories designated as (1) safe and effective and not misbranded, and (2) unsafe or ineffective and misbranded, and (3) not within category (1) or (2) above, on the basis that available data are insufficient to classify such products. B. *Why Significant:* This regulation will establish the safety and effectiveness of currently marketed proudcts. It will assure the public of receiving only those products found to be truly safe and effective.	Steve Falter, Regulations Branch (HFB-620), Bureau of Biologics, Food and Drug Administration, 8800 Rockville Pike, Bethesda, MD 20205, 301-443-1306

Food and Drug Administration—Significant Regulations—Continued

Title	Summary	Contact
	C. *Regulatory Analysis:* Not required. D. *Need:* To bring products into conformance with current standards of safety and effectiveness. E. *Legal Basis:* Section 351, 58 Stat. 702, 42 U.S.C. 262. F. *Chronology:* The proposal is currently being drafted for review by the Agency.	
FDA 13—Bioresearch Monitoring; Standards for Institutional Review Boards for Clinical Investigations	A. *Description:* This regulation will establish standards for the composition, operation, and responsibility of any institutional review board that reviews clinical investigations involving the use of products regulated by the Food and Drug Administration. B. *Why Significant:* The regulations will provide greater protection of the rights and safety of subjects in clinical investigations and help assure the quality and integrity of the research data used to support the marketing of products regulated by FDA by specifically defining the responsibilities of institutional review boards in clinical investigations. C. *Regulatory Analysis:* Not required. D. *Need:* To clarify existing regulations concerning institutional review boards that review clinical investigations involving new drug products and to extend those regulations to include boards that review investigations on other FDA-regulated products. The regulation will establish specific standards for the composition, operation, and responsibilities of a board in assuring protection of the rights and safety of subjects involved in clinical investigations and assuring the quality and integrity of the research data used to support the marketing of products regulated by FDA. E. *Legal Basis:* 21 U.S.C. 346, 346a, 348, 352, 353, 355, 356, 357, 380, 360c, 360f, 360h–360j, 361, 371(a), 378, 381; 42 U.S.C. 218, 262, 263b–263n. F. *Chronology:* A proposed rule was published on August 8, 1978 (43 FR 35186). On August 14, 1979, the proposal was withdrawn and reproposed (44 FR 47699). Public hearings were held in Bethesda, Maryland, on September 18, 1979, in San Francisco on October 3, 1979, and in Houston on October 16, 1979. The comment period closed on November 12, 1979.	John C. Petricciani, Associate Director for Clinical Research (HFB–4), Bureau of Biologics, Food and Drug Administration, 8800 Rockville Pike, Rockville, MD 20205, 301–496–9320
FDA 14—Bioresearch Monitoring; Informed Consent	A. *Description:* This regulation would establish a single set of informed consent requirements applicable to all investigators involved in investigational studies that either require prior FDA review or are later submitted to FDA in support of an application for a research or marketing permit. B. *Why Significant:* This regulation would clarify existing agency regulations governing informed consent and provide greater protection of the rights of human subjects involved in research activities that fall within the jurisdiction of FDA. C. *Regulatory Analysis:* Not required. D. *Need:* There has been an identifiable need to strengthen and clarify informed consent requirements as they apply to research that involves human subjects and is intended for submission to FDA. This regulation is designed to provide greater protection of the rights and safety of human subjects involved in research activities that fall within the jurisdiction of FDA. E. *Legal Basis:* 21 U.S.C. 346, 346a, 348, 352, 353, 355, 356, 357, 360, 360c, 360f, 360h–360j, 361, 371(a), 376, 381; 42 U.S.C. 216, 262, 263b–263n. F. *Chronology:* The proposed rule was published on August 14, 1979 (44 FR 47713). Public hearings were held in Bethesda, Maryland, on September 18, 1979, in San Francisco on October 3, 1979, and in Houston on October 16, 1979. The comment period closed on November 12, 1979.	John C. Petricciani, Associate Director for Clinical Research (HFB–4), Bureau of Biologics, Food and Drug Administration, 8800 Rockville Pike, Rockville, MD 20205, 301–496–9320
FDA 17—Bioresearch Monitoring; Obligations of Sponsors and Monitors of Clinical Investigations	A. *Description:* These regulations would establish procedures to be followed by a sponsor and a monitor before initiating, and during the course of, a clinical investigation involving the use of a drug, medical device, food or color additive, or electronic product. B. *Why Significant:* The regulations will provide greater protection of the rights and safety of subjects in clinical investigations and help assure the quality and integrity of the research data used to support the marketing of products regulated by FDA by specifically defining the responsibilities of sponsors and monitors in clinical investigations. C. *Regulatory Analysis:* Not required. D. *Need:* There has been an identifiable need to set forth procedures that would raise the level of the quality of clinical research by more thorough and supervisional contact between the sponsor and investigators. These regulations will define specifically the responsibilities of sponsors and monitors in assuring protection of the rights and safety of subjects involved in clinical investigations and assuring the quality and integrity of the research data used to support the marketing of products regulated by FDA. E. *Legal Basis:* 21 U.S.C. 346, 348, 352, 353, 355, 358, 357, 360, 360b–360f, 360h–360j, 361, 371(a), 376, 381, 42 U.S.C. 216, 262, 263b–263n. F. *Chronology:* The proposed rule was published on September 27, 1977 (42 FR 29412). The comment period closed on December 27, 1977.	Marilyn L. Watson, (HFD–30), Bureau of Drugs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–3640
FDA 18—Bioresearch Monitoring; Obligations of Clinical Investigators.	A. *Description:* These regulations would clarify existing regulations governing the conduct of persons who conduct clinical investigations on new drug products, and extend the regulations to include persons who conduct clinical investigations on medical devices, food or color additives, and electronic products. B. *Why Significant:* The regulations will provide greater protection of the rights and safety of subjects in clinical investigations and help assure the quality and integrity of the research data used to support the marketing of products regulated by FDA by specifically defining the responsibilities of clinical investigators. C. *Regulatory Analysis:* Not required. D. *Need:* There has been an identifiable need to clarify existing regulations concerning persons who conduct clinical investigations on new drugs and to extend those regulations to include persons who conduct clinical investigations on other FDA-regulated products. These regulations are designed to assure the validity and reliability of clinical data submitted to FDA, provide greater protection of the rights and safety of subjects involved in the investigations, and provide agency-wide regulatory standards for conducting clinical investigations more efficiently and effectively. E. *Legal Basis:* 21 U.S.C. 346, 348, 352, 353, 355, 356, 357, 360, 360b–360f, 360h–360j, 361, 371(a), 376, 381, 42 U.S.C. 216, 263b–263n. F. *Chronology:* The proposed rule was published on August 8, 1978 (43 FR 35223). The comment period closed on November 6, 1978, and on November 14, 1978 was extended to December 6, 1978.	Marilyn L. Watson, (HFD–30), Bureau of Drugs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–3640.
FDA 19—Drug Efficacy Study Implementation; Abbreviated New Drug Applications for Post-1962 Drugs.	A *Description:* This proposal would permit applicants to file abbreviated new drug applications (ANDA's) for products identical to approved post-1962 drugs and to omit certain reports that are required in a full NDA to show safety and effectiveness of the product. It would apply only to certain drug products specified by FDA. At present, ANDA's are permitted only for pre-1962 drugs that FDA has found are suitable for that kind of submission.	Jean Mansur, Deputy Assistant Director for Regulatory Affairs, (HFD–30), Bureau of Drugs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–3640.

Food and Drug Administration—Significant Regulations—Continued

Title	Summary	Contact
	B. *Why Significant:* This will reduce duplicative human testing of drugs and also reduce the cost to the manufacturer of getting the affected drugs on the market. By increasing competition among drug manufacturers, it may reduce drug costs to the consumer. C. *Regulatory Analysis:* Yes, being conducted. D. *Need:* This action has the potential to increase competition among drug sources when patents have expired and lower costs ot drug products. E. *Legal Basis:* 21 U.S.C. 355, 371(a). F. *Chronology:* The proposed rule is being prepared.	
FDA 22—New Drug Evaluation; Disclosure of Specifications.	A. *Description:* This regulation would provide for the disclosure of specifications submitted to the agency by the manufacturer of a drug product, unless the specifications serve no regulatory or compliance purpose, are exempt as trade secrets, and have not previously been publicly disclosed. B. *Why Significant:* The public availability of drug specifications will help to assure that all manufacturers of the same drug product meet the same standards of identity, strength, quality, and purity. Consumers and physicians will be able to select a brand of drug product knowing that the standards if is required to meet are comparable to those of other versions of the same drug product. Disclosure will permit the official compendia to maintain current standards applicable to the products of all manufacturers. Consistent compendial specifications and methods will contribute to improving the enforcement programs of Federal, State, and local regulatory agencies who must assure full compliance with legal requirements for drug products. C. *Regulatory Analysis:* Not required. D. *Need:* There are drugs for which specifications are not publicly available. The regulation would resolve this problem. E. *Legal Basis:* 21 U.S.C. 321 et seq., 42 U.S.C. 201 et seq., 5 U.S.C. 552. F. *Chronology:* The proposed rule was published on July 15, 1977 (42 FR 36485). The comment period closed on September 13, 1977.	Edwin V. Dutra, Jr., Precedent Regulations and Legislative Activities Branch, (HFD-30), Bureau of Drugs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-6490.
FDA 23—New Drug Evaluation; Revision of IND/NDA Regulations.	A. *Description:* This proposal would revise the regulations on investigational new drugs (IND's) and new drug applications (NDA's) to improve the efficiency of FDA's operation and to update and refine its internal policies in reviewing, processing, and communicating with sponsors and applicants on IND's and NDA's. The revision would more formally structure the IND phase so that if a drug reaches the NDA stage it would be essentially approvable. B. *Why Significant:* These revisions can be expected to aid IND sponsors and NDA applicants by expediting the review process, reducing paperwork, and redefining the IND and NDA requirements in line with FDA's experiences in current practices. They should also result in simpler and more useful reporting requirements. C. *Regulatory Analysis:* Not required. D. *Need:* Experience with these regulations after a number of years has identified areas where the IND/NDA procedure and requirements need updating and improving. E. *Legal Basis:* 21 U.S.C. 355, 357, 371(a). F. *Chronology:* A Notice of Public meeting was published on October 12, 1979 (44 FR 58919).	Michael C. McGrane, General Regulations Development Branch (HFD-30), Bureau of Drugs, Food and Drugs Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-6062.
FDA 28—Cholesterol-Free Egg Substitute.....	A. *Description:* This proposed rule will address the issue of the use of the term cholesterol-free in the name of food products. B. *Why Significant:* This issue concerns a matter on which there is substantial public interest. C. *Regulatory Analysis:* Not required. D. *Need:* To establish consistency in labeling of cholesterol content of foods. E. *Legal Basis:* Sections 201(n), 403(a), 701(a), 52 Stat. 1041, as amended; 1047-1048, as amended; 1055 (21 U.S.C. 321(n), 343(a), and 371(a)) of the Federal Food, Drug, and Cosmetic Act. F. *Chronology:* This proposed rule is currently under review.	Elizabeth Campbell, Guidelines and Compliance Research Branch (HFF-312), Bureau of Foods, Food and Drug Administration, 200 C Street, S.W., Washington, D.C. 20204, (202) 245-3092.
FDA 29—Plant Protein—Common or Usual Names for Foods, Vegetable Protein Products Which Resemble and Substitute for Meats, Seafood, Poultry, Eggs, or Cheese.	A. *Description:* This regulation will establish common or usual names for vegetable protein products and names and definitions of nutritional equivalence for substitutes for the five major protein foods. B. *Why Significant:* There is substantial public interest in having consistent labeling requirements regarding the nutrient content of vegetable protein substitutes. C. *Regulatory Analysis:* Not required. D. *Need:* To provide consistency in the labeling and in the nutrient content of vegetable protein substitutes for the five major protein foods. E. *Legal Basis:* Sections 201(n), 403, 701, 52 Stat. 1041, as amended; 1047-1048, as amended; 1055-1056, as amended (21 U.S.C. 321(n) 343, 371) of the Federal Food, Drug, and Cosmetic Act. F. *Chronology:* Tentative final rule was published on July 14, 1978 (43 FR 30472). The comment period closed on November 13, 1978.	Elizabeth Campbell, Guidelines and Compliance Research Branch (HFF-312), Bureau of Foods, Food and Drug Administration, 200 C Street, S.W., Washington, D.C. 20204, (202) 245-3092.
FDA 30—Sugar Labeling of Foods	A. *Description:* This proposed rule would amend the nutritional labeling format so that the carbohydrate declaration will have subsets for simple sugars, as well as complex sugar. B. *Why Significant:* There is substantial public interest in having a declaration of sugar content. C. *Regulatory Analysis.* Not required. D. *Need:* To notify the public of the type and amount of carbohydrate being taken in. E. *Legal Basis:* Sections 201(n), 403, 701, 52 Stat. 1041, as amended; 1047-1048, as amended; 1055-1056, as amended (21 U.S.C. 321(n), 343, 371) of the Federal Food, Drug, and Cosmetic Act. F. *Chronology:* This proposed rule is currently being drafted in the Bureau of Foods.	Elizabeth Campbell, Guidelines and Compliance Research Branch (HFF-312), Bureau of Foods, Food and Drug Administration, 200 C Street, S.W., Washington, D.C. 20204, (202) 245-3092.
FDA 33—Aflatoxin in Peanuts	A. *Description:* This final rule will set tolerances for aflatoxin in peanuts. B. *Why Significant:* There is a public health concern regarding the amount of aflatoxin found in peanuts. C. *Regulatory Analysis:* Not required. D. *Need:* To prevent avoidable residues of aflatoxins in peanuts and peanut products. E. *Legal Basis:* Sections 306, 402, 406, 701, 52 Stat. 1045-1046, 1049, 1055-1056, as amended; and 72 Stat. 948 (21 U.S.C. 336, 342, 346, 371) of the Federal Food, Drug, and Cosmetic Act. F. *Chronology:* The proposed rule published on December 6, 1974 (39 FR 42748). Notice of availability of the assessment of estimated risk resulting from aflatoxins in consumer peanut products and notice of reopening of the comment period published on March 3, 1978 (43 FR 8808). Extension of comment period was published on April 18, 1978 (43 FR 16349). The comment period closed May 17, 1978. This final rule is currently under review.	Elizabeth Campbell, Guidelines and Compliance Research Branch (HFF-312), Bureau of Foods, Food and Drug Administration, 200 C Street, S.W., Washington, D.C. 20204, (202) 245-3092.

Food and Drug Administration—Significant Regulations—Continued

Title	Summary	Contact
FDA 34—Color Certification—Procedures for Non-Conforming Batches.	A. *Description:* This notice would establish guidelines for the certification of color additives to prescribe procedures for the rejection of samples submitted for certification on the basis of analytical response, when the substance causing the response is unidentified. B. *Why Significant:* Procedures for the certification of colors should be uniform and industry should be fully advised of them. C. *Regulatory Analysis:* Not required. D. *Need:* To establish guidelines which formalize the procedures used in certification of colors. E. *Legal Basis:* Section 706 (21 U.S.C. 376) of the Federal Food, Drug, and Cosmetic Act. F. *Chronology:* This notice is currently being drafted in the Bureau of Foods.	Gerald McCowin, Director, Division of Food and Color Additions (HFF-300) Bureau of Foods, Food and Drug Administration, 330 Independence Avenue, S.W., Washington, D.C. 20201, (202) 472-5676
FDA 35—Use of Food Preservatives BHT.....	A. *Description:* This final rule will establish an interim food additive for BHT. B. *Why Significant:* BHT is a widely used preservative heretofore considered GRAS and about which substantial safety questions have been raised, rendering it subject to the food additive law. Recent re-evaluation of available data indicates that additional information is required to substantiate that its use in food can continue to be deemed safe. C. *Regulatory Analysis:* Not required D. *Need:* To determine if food preservative BHT can continue to be deemed safe for use in foods. E. *Legal Basis:* Sections 201(s), 409, 701(a), 52 Stat. 1055, 72 Stat. 1784-1788, as amended (21 U.S.C. 321(s), 348, 371(a)) of the Federal Food, Drug and Cosmetic Act. F. *Chronology:* The proposed rule published on May 31, 1977 (42 FR 27603). The comment period closed July 26, 1977	Dr. Corbin Miles, GRAS Review Branch (HFF-335), Bureau of Foods, Food and Drug Administration, 330 Independence Avenue, S.W., Washington, D.C. 20201, (202) 472-4750
FDA 36—Procedural Regulations for the Cyclic Review and Priority Listing of Food and Color Additives.	A. *Description:* This proposed rule would establish the procedure for the cyclic review and priority listing of food additives. B. *Why Significant:* The FDA believes that industry should be put on notice as to the procedures to be followed and priorities to be set regarding the cyclic review of food and color additives. C. *Regulatory Analysis:* Decisinn pending on completion of preliminary study. D. *Need:* To give notice as to the order in which food additives will be reviewed under the cyclic review process. E. *Legal Basis:* Sections 201(s), 409, 701(a), and 706, 52 Stat. 1055; 72 Stat. 1784-1788, as amended (21 U.S.C. 321(s), 348, 371(a), 376) of the Federal Food, Drug, and Cosmetic Act. F. *Chronology:* The proposed rule is currently under review	Gerald McCowin, Director, Division of Food and Color Additives (HFF-300), Bureau of Foods, Food and Drug Administration, 330 Independence Avenue, S.W., Washington, D.C. 20201, (202) 472-5676
FDA 37—Net Weight.....	A. *Description.* This final rule will quantify reasonable variations for foods subject to moisture loss. B. *Why Significant:* There is substantial public interest because of possible economic deception. C. *Regulatory Analysis:* Decision pending on completion of preliminary study. D. Need: To protect the consumer from economic deception. E. *Legal Basis:* Sections 201(n), 403, 701, 52 Stat. 1041, as amended, 1046-1048, as amended; 1055-1056, as amended by 70 Stat. 919; and 72 Stat. 948 (21 U.S.C. 231(n), 343, and 371) of the Federal Food, Drug, and Cosmetic Act. F. *Chronology:* The proposed rule published on August 8, 1980 (45 FR 53023). The comment period closed November 6, 1980.	Elizabeth Campbell, Guidelines and Compliance Research Branch (HFF-312), Bureau of Foods, Food and Drug Administration, 200 C Street, S.W., Washington, D.C. 20204, (202) 245-3092
FDA 38—Caffeine.....	A. *Description:* FDA intends to issue a final rule concerning the status of caffeine in soft drinks. B. *Why Significant:* This issue concerns a matter on which there is substantial public interest. C. *Regulatory Analysis:* Decision pending on completion of preliminary study D. *Need:* The Select Committee on GRAS Substances of the Federation of American Societies for Experimental Biology (FASEB) has recommended that the FDA interim list direct food uses. E. *Legal Basis:* Sections 201(s), 409, 701(a), 52 Stat. 1055; 72 Stat. 1784-1788, as amended; 52 Stat. 1055 (21 U.S.C. 321(s), 348, 371(a)) of the Federal Food, Drug, and Cosmetic Act. F. *Chronology:* The proposed rule published on October 1, 1980 (45 FR 69816). The comment period closes December 22, 1980.	Dr. Corbin Miles, GRAS Review Branch (HFF-335), Bureau of Foods, Food and Drug Administration, 330 Independence Avenue, S.W., Washington, D.C. 20201, (202) 472-4750
FDA 39—GRAS Whey—Whey Products and Hydrogen Peroxide Used in Whey Treatments	A. *Description:* This final rule will establish common or usual names and affirm the GRAS status for whey and whey products. This is a result of ten GRAS petitions. These dried whey products have numerous potential uses in food including sources of milk protein and use as milk solids where not exempted by food standards. B. *Why Significant:* There is substantial public interest in establishing uniform nomenclature and safe uses for these milk protein products. C. *Regulatory Analysis:* Not required. D. *Need:* To establish safe uses of certain milk proteins. E. *Legal Basis:* Sections 201(s), 409, 701(a), 52 Stat. 1055, 72 Stat. 1784-1788, as amended (21 U.S.C. 321(s), 348, 371(a)) of the Federal Food, Drug, and Cosmetic Act. F. *Chronology:* The proposed rule published on June 22, 1979 (44 FR 36416). The comment period closed on October 29, 1979.	Dr. Corbin Miles, GRAS Review Branch (HFF-335), Bureau of Foods, Food and Drug Administration, 330 Independence Avenue, S.W., Washington, D.C. 20201, (202) 472-4750
FDA 40—Retortable Pouch.....	A. *Description:* This final rule will provide for safe use of components of laminated pouch intended to contact food under retort conditions. B. *Why Significant:* The retortable pouch could be used in place of the "tin can" in the marketing of many foods. C. *Regulatory Analysis:* Not required. D. *Need:* To protect the public health. E. *Legal Basis:* Section 409, 72 Stat. 1786 (21 U.S.C. 348) of the Federal Food, Drug, and Cosmetic Act. F. *Chronology:* The notice of filing for several petitions published on November 7, 1975 (40 FR 52076), February 10, 1976 (41 FR 5861), September 13, 1976 (41 FR 38802), February 10, 1978 (43 FR 5891), April 7, 1978 (43 FR 14737), and June 23, 1978 (43 FR 27236). The final rule was published on January 15, 1980 (45 FR 2842). The objection period closed on February 14, 1980. The objections are under review.	Gerald McCowin, Director, Division of Food and Color Additives (HFF-300), Bureau of Foods, Food and Drug Administration, 330 Independence Avenue, S.W., Washington, D.C. 20201, (202) 472-5676.
FDA 41—Xylitol.....	A. *Description:* This proposed rule would determine the status of the use of Xylitol in specific dietary products. B. *Why Significant:* Xylitol is a sweetener. There is much industry and consumer interest in sucrose substitutes.	Gerald McCowin, Director, Division of Food and Color Additives (HFF-300), Bureau of Foods, Food and Drug Administration, 330 Independence Avenue, S.W., Washington, D.C. 20201, (202) 472-5676.

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Title	Summary	Contact
	C. *Regulatory Analysis:* Not required. D. *Need:* Data has been submitted to the FDA suggesting that Xylitol may not be safe. E. *Legal Basis:* Sections 409, 701(a), 52 Stat. 1055; 72 Stat. 1785–1788 (21 U.S.C. 348, 371(a)) of the Federal Food, Drug, and Cosmetic Act. F. *Chronology:* This proposed rule is currently under review.	
FDA 43—Trichloroethylene	A. *Description:* This final rule will prohibit trichloroethylene in human food because it may pose a risk of cancer. B. *Why Significant:* There is substantial FDA interest due to public health concerns indicated above. C. *Regulatory Analysis:* Not required D. *Need:* To protect the public health. E. *Legal Basis:* Sections 201(s), 402, 409, 701, 52 Stat. 1046–1047, as amended; 72 Stat. 1784–1788, as amended (21 U.S.C. 321(s), 342, 348, 371) of the Federal Food, Drug, and Cosmetic Act. F. *Chronology:* The proposed rule published on September 27, 1977 (42 FR 49465). The comment period closed on November 28, 1977.	Gerald McCowin, Director, Division of Food and Color Additives (HFF–300), Bureau of Foods, Food and Drug Administration, 330 Independence Avenue, S.W., Washington, D.C. 20201, (202) 472–5676.
FDA 44—Use of Chlorine Gas in an Aqueous Solution	A. *Description:* This proposed rule would establish GRAS conditions of use for chlorine food sanitizers. This is the result of twelve GRAS petitions for uses of chlorine, hypochlorous acid, and chlorine dioxide as food sanitizing solutions. B. *Why Significant:* There is a substantial public health issued involved C. *Regulatory Analysis:* Not required. D. *Need:* To establish safe uses of chlorine in a sanitizing agent. E. *Legal Basis:* Sections 201(s), 409, 701(a), 52 Stat. 1055; 72 Stat. 1784–1788, as amended (21 U.S.C. 321(s), 348, 371(a)) of the Federal Food, Drug, and Cosmetic Act. F. *Chronology:* The proposed rule is currently under review.	Dr. Corbin Miles, GRAS Review Branch (HFF–335), Bureau of Foods, Food and Drug Administration, 330 Independence Avenue, S.W., Washington, D.C. 20201, (202) 472–4750.
FDA 45—Nitrite as a Color Additive in Bacon	A. *Description:* This final rule will resolve the issue regarding nitrite as a color additive in bacon. B. *Why Significant:* There is substantial public interest and controversy regarding the use of nitrite in bacon. C. *Regulatory Analysis:* Decision pending on completion of preliminary study D. *Need:* To clarify the status of nitrite as a color additive in bacon. E. *Legal Basis:* Sections 201(s), 201(t)(1), 402(a), 701(a), 706, 72 Stat. 1784, 74 Stat. 397, 52 Stat. 1046, 1055–1056, as amended (21 U.S.C. 321(s), 321(t)(1), 342(a), 371(a), 376) of the Federal Food, Drug, and Cosmetic Act. F. *Chronology:* The proposed rule was published December 21, 1979 (44 FR 75659) The comment period closed on May 19, 1980.	Gerald McCowin, Director, Division of Food and Color Additives (HFF–300), Bureau of Foods, Food and Drug Administration, 330 Independence Avenue, S.W., Washington, D.C. 20201, (202) 472–5676
FDA 46—Prior Sanction Status of Nitrites in Poultry Products.	A. *Description:* this proposed rule would resolve the issue regarding whether there is a prior sanction for nitrites in poultry products. B. *Why Significant:* There is substantial interest and controversy in the legal status of nitrites. C. *Regulatory Analysis:* Not required D. *Need:* To protect the public health E. *Legal Basis:* Sections 201(s), 201(t)(1), 402(a), 701(a), 706, 72 Stat. 1784; 74 Stat. 397, 52 Stat. 1046, 1055–1056, as amended (21 U.S.C. 321(s), 321(t)(1), 342(a), 376) of the Federal Food, Drug, and Cosmetic Act F. *Chronology:* The proposed rule was published on December 21, 1979 (44 FR 75662). The comment period closes on June 18, 1980	Gerald McCowin, Director, Division of Food and Color Additives (HFF–300), Bureau of Foods, Food and Drug Administration, 330 Independence Avenue, S.W., Washington, D.C. 20201, (202) 472–5676
FDA 47—Safety of Food Ingredients Sucrose and Corn Sugar	A. *Description:* The proposed rule would rule on the GRAS status of sucrose and corn sugar. B. *Why Significant:* There is much consumer concern about the health implications of consumption of sucrose and corn syrup C. *Regulatory Analysis:* Not required. D. *Need:* To re-evaluate the safety of all GRAS ingredients. E. *Legal Basis:* Sections 201(s), 409, 701(a), 52 Stat. 1055 (21 U.S.C. 321(s), 348, 371(a)) of the Federal Food, Drug, and Cosmetic Act. F. *Chronology:* This proposed rule is currently under review.	Dr. Corbin Miles, GRAS Review Branch (HFF–335), Bureau of Foods, Food and Drug Administration, 330 Independence Avenue, S.W., Washington, D.C. 20201, (202) 472–4750
FDA 48—Optional Ingredient Labeling Regarding Certain Food Standards	A. *Description:* This proposed rule would revise certain food standards to require that all optional ingredients be labeled in accord with 21 CFR 101. B. *Why Significant:* There is substantial public interest in having all optional ingredients properly labeled. C. *Regulatory Analysis:* Decision pending on completion of preliminary study D. *Need:* To promote honesty and fair dealing in the interest of consumer. E. *Legal Basis:* Sections 401, 701(e), 52 Stat. 1046, as amended; 70 Stat. 919, as amended (21 U.S.C. 341, 371(e)) of the Federal Food, Drug, and Cosmetic Act. F. *Chronology:* The proposed rule is currently under review.	Dr. Prince Harrill, Deputy Director, Division of Food Technology, (HFF–211), Bureau of Foods, Food and Drug Administration, 200 C Street, S.W., Washington, D.C. 20204, (202) 245–1164
FDA 49—National Shellfish Safety Program.	A. Description: A notice to withdraw the proposed National Shellfish Safety Program regulation and a proposal to continue the voluntary National Shellfish Program B. *Why Significant:* An improved voluntary National Shellfish Program would help ensure the safety and wholesomeness of shellfish harvested in waters of participating states C. *Regulatory Analysis:* Not required. D. *Need:* To improve the voluntary National Shellfish Program. E. *Legal Basis:* Sections 402, 403, 701(a), Pub. L. 717; 52 Stat. 1046–1048, 1055, as amended (21 U.S.C. 342, 343, 371(a)) of the Federal Food, Drug, and Cosmetic Act, Sections 001, 303, 311, 361, Pub. L. 410; 58 Stat. 691, 693, 703; 74 Stat. 364, as amended (42 U.S.C. 241, 242, 243, 246) of the Public Health Service Act. F. *Chronology:* The proposed rule published on June 19, 1975 (40 FR 25916). The comment period closed November 13, 1975.	David Clem, Shellfish Sanitation Branch, (HFF–417), Bureau of Foods, Food and Drug Administration, 200 C Street, S.W., Washington, D.C. 20204, (202) 245–1557
FDA 50—Dietary Supplement of Vitamins and Minerals	A. *Description:* This proposed rule would establish a regulation for vitamin/mineral nutritional supplements and the labeling requirements. B. *Why Significant:* There is substantial public concern over the possibility that the availability of vitamin and mineral supplements may be in some way restricted by this regulation. C. *Regulatory Analysis:* Not required. D. *Need:* To make available products and labeling information adequate for consumers to regulate their own intake of vitamins and minerals. E. *Legal Basis:* Section 201(n), 403 (a) and (j), 701 (a) and (e), 52 Stat. 1041, as amended; 1047–1048, as amended (21 U.S.C. 321(n), 343 (a) and (j), 371(n) and (e) of the Federal Food, Drug, and Cosmetic Act.	Dr. Allen Forbes, Associate Director, Nutrition and Food Sciences, (HFF–200), Bureau of Foods, Food and Drug Administration, 200 C Street, S.W., Washington, D.C. 20204, (202) 245–1561

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Title	Summary	Contact
	F. *Chronology:* The proposed rule is currently under review.	
FDA 51—Labeling of Sodium and Potassium Content of Foods.	A *Description:* This proposed rule would amend § 105.69 ("foods used to regulate sodium- and potassium-intake") to change the present mode of declaring sodium content and to add a description of how potassium content is also to be declared. There shall also be a new paragraph in § 101.17 ("Food Labeling Warning statements") to provide for warnings regarding potassium content on labels of some salt substitutes. B. *Why Significant:* There is substantial public interest in and a health need for consumers being able to regulate their own intake of salts. C. *Regulatory Analysis:* Not required. D. *Need:* To give consumers an opportunity to regulate their intake of sodium acid potassium. E. *Legal Basis:* Sections 201 (n) and (s), 402(a)(2)(c), 403(a), 409(c)(1)(a), and 701(a) (U.S.C. 321 (n) and (s), 342(a)(2)(c), 343(a), 348(c)(1)(a), and 371(a)) of the Federal Food, Drug, and Cosmetic Act. F. *Chronology:* The proposed rule is currently being drafted in the Bureau of Foods.	Dr. Allen Forbes, Associate Director, Nutrition and Food Sciencas, (HFF-200), Bureau of Foods, Food and Drug Administration, 200 C Street, S.W., Washington, D.C. 20204, (202) 245-1561.
FDA 55—Procedural Regulations for Cyclic Review of Animal Drugs.	A. *Description:* This proposed rule would establish procedures and priorities for cyclic review. B. *Why Significant:* The FDA believes it is important that industry be put on notice, as to the proceduras to be followed and priorities to be set regarding the cyclic review of animal drugs. C. *Regulatory Analysis:* Decision pending on completion of preliminary study. D. *Need:* To set procedures and priorities for cyclic review. E. *Legal Basis:* Sections 512, 701(a), 52 Stat. 343-351 (21 U.S.C. 360, 371(a)) of the Federal Food, Drug, and Cosmetic Act. F. *Chronology:* The proposed rule is currently being reviewed.	Dr. Bob Scheuplein, Chief, Food Animal Additive Staff (HFF-154), Bureau of Foods, Food and Drug Administration, 200 C Street, S.W., Washington, D.C. 20204, (202) 472-5760.
FDA 56—Sensitivity of Method.....	A. *Description:* This final rule would establish criteria and proceduras for evaluating assays for carcinogenic residues in animal-derived food. B. *Why Significant:* Industry needs guidelines as to what human safety data is required by FDA for new animal drug approval. C. *Regulatory Analysis:* Yes, being conducted. D. *Need:* To facilitate a determination of the safety of drugs intended for food producing animals. E. *Legal Basis:* Sections 402, 403, 409, 512, 701(a), 706, 52 Stat. 1046-1048, as amended; 1055, 72 Stat. 1785-1788, as amended; 74 Stat. 399-403, as amanded, 82 Stat. 343-351 (21 U.S.C. 342, 343, 348, 360(b), 371(a), 376) of the Federal Food, Drug, and Cosmetic Act. F. *Chronology:* The proposed rule was published on March 20, 1979 (44 FR 17070). The comment period closed on July 18, 1979. Notice of hearing published on April 20, 1979 (44 FR 23538). Hearing was held on June 4, 1979.	Bob Scheuplein, Chief, Food Animal Additive Staff (HFF-154), Bureau of Foods, Food and Drug Administration, 200 C Street, S.W., Washington, D.C. 20204, (202) 472-5760.
FDA 58—Classification of Preenactment Devices.	A. *Description:* These regulations classify all medical devices marketed prior to May 28, 1976 into three regulatory control categories. The classifications are based on the recommendations of eight expert advisory panels. B. *Why Significant:* The classification regulations will determine the extent to which a device must be regulated to assure its safety and effectiveness. The classification regulations advise manufacturers whether their devices are subject to general controls, performance standards, or premarket approval. C. *Regulatory Analysis:* Not required. D. *Need:* To implement sections 513 (c) and (d) of the Medical Device Amendments of 1976. E. *Legal Basis:* 21 U.S.C 360c (c) and (d). F. *Chronology:* Final Regulations published: Neurological Devices, September 4, 1979 (44 FR 51726); Cardiovascular, February 5, 1980 (45 FR 7904); OB/GYN, February 26, 1980 (45 FR 12682). Hematology/Pathology, September 12, 1980 (45 FR 60576); General Hospital, October 21, 1980 (45 FR 69678). Proposed rules published: Physical medicine, August 28, 1979 (44 FR 50458), comment period closed October 29, 1979; Anesthesiology, November 2, 1979 (44 FR 63292), comment period closed January 2, 1980; Microbiology/Immunology, April 22, 1980 (45 FR 27204), comment period closes June 23, 1980.	Robert S. Kennedy, Associate Director for Device Evaluation (HFK-400), Bureau of Medical Devices, Food and Drug Administration, 8757 Georgia Avenue, Silver Spring, MD 20910, (301) 427-7230.
FDA 60—Premarket Approval Procedural Regulation.	A. *Description:* This regulation will provide procedural requirements for submission of premarket approval applications, including safety and effectiveness requirements for all Class III medical devices. B. *Why Significant:* The regulation is essential to ensure that FDA receives adequate information on the safety and effectiveness of all Class III devices. C. *Regulatory Analysis:* Decision pending on completion of preliminary study. D. *Need:* To implement section 515 of the Medical Device Amendments of 1976. E. *Legal Basis:* 21 U.S.C. 1360e. F. *Chronology:* The proposal is currently under review.	Keith Lusted, Premarket Approval Coordinator (HFK-402), Bureau of Medical Devices, Food and Drug Administration, 8757 Georgia Avenue, Silver Spring, MD 20910, (301) 427-8162.
FDA 64—Restricted Device Regulation.....	A. *Description:* This regulation will establish a criteria for manufacturers to determine whether a device is a restricted device and thus subject to certain labeling requirements as set forth in the regulation. B. *Why Significant:* The regulation will ensure that all restricted devices are subject to uniform labeling requirements. Once the regulation becomes a final rule, FDA inspectors will have access to manufacturing files concerning restricted devices. C. *Regulatory Analysis:* Not required. D. *Need:* To implement section 520(e) of the Medical Device Amendments of 1976 and adhere to the decision of the Courts in: *Bacton, Dickinson and Company v. FDA*, 589 F.2d 1175 (2d Cir. 1978); and *In the Matter of Establishment Inspection of Portex, Inc., FDA, Appellant*, 595 F.2d 84 (1st Cir. 1979). E. *Legal Basis:* 21 U.S.C. 360j(e). F. *Chronology:* Proposed rule was published October 3, 1980 (45 FR 65619). The comment period closes January 16, 1981.	Michael Lidsky, Office of ADRP (HFK-70), Bureau of Medical Devices, Food and Drug Administration, 8757 Georgia Avenue, Silver Spring, MD 20910, (301) 427-7114.
FDA 65—Mandatory Experience Reporting.....	A. *Description:* The regulation will set forth mandatory reporting requirements for manufacturers and distributors concerning devices which cause or could cause deaths or injuries, or are the subject of a corrective action. B. *Why Significant:* The regulation will provide greater patient protection by ensuring that FDA receives information on devices that are unsafe or ineffective. C. *Regulatory Analysis:* Not required. E. *Legal Basis:* 21 U.S.C. 360i. F. *Chronology:* Proposed rule was published November 18, 1980 (45 FR 76183). The comment period closes February 17, 1981. D. *Need:* To implement section 519 of the Medical Device Amendments of 1976 and enable FDA to monitor the safety of devices.	Chester Reynolds, Chief, Device Experience Branch (HFK-125); Bureau of Medical Devices; Food and Drug Administration, 8757 Georgia Avenue; Silver Spring, MD 20910, (301) 427-8100.

Food and Drug Administration—Significant Regulations—Continued

Title	Summary	Contact
FDA 66—Maximum Residue Limits for Ethylene Oxide, Ethylene Chlorhydrin, and Ethylene Glycol.	A. *Description:* This regulation will impose residue limits on the use of ethylene oxide as a sterilent for certain drugs and devices by: (1) Establishing maximum residue limits for ethylene oxide and its two major reaction products; and (2) Maximum daily levels of exposure for drug products for ethylene oxide and its two major reaction products. B. *Why Significant:* The regulation addresses an issue of substantial public interest and controversy—the continued use of ETO at the levels of use proposed by FDA. C. *Regulatory Analysis:* Decision pending on completion of preliminary study. D. *Need:* To develop safe levels of use for ethylene oxide, ethylene chlorhydrin, and ethylene glycol. E. *Legal Basis:* 21 U.S.C. 351, 355, 356, 367, 360b, 360c, 360k, 371(a). F. *Chronology:* Proposed rule was published June 23, 1978 (43 FR 27474). The comment period closed August 22, 1978.	Carl Bruch, Deputy Associate Director for Device Evaluation (HFK–400), Bureau of Medical Devices, Food and Drug Administration, 8757 Georgia Avenue, Silver Spring, MD 20910, (301) 427–7230.
FDA 70—Recommendations for State and Local Agencies Concerning Accidental Radioactive Contamination of Human Food and Animal Feeds.	A. *Description:* The recommendations would consist of Protective Action Guides (PAGs), defined as the projected radiological dose equivalent or dose commitment to individuals in the general population that warrants protective action following a release of radioactive material. The Department of Health, Education, and Welfare was assigned agency responsibility for this task in the FEDERAL REGISTER of December 24, 1975 (40 FR 59494) by the Federal Preparedness Agency, General Services Administration. Within HEW, this function has been delegated to the Commissioner of Food and Drugs. B. *Why Significant:* Provides guidance following radiological incidents, including nuclear power plant accidents. C. *Regulatory Analysis:* Not required. D. *Need:* To develop necessary guidance under responsibility assigned by Federal Preparedness Agency. E. *Legal Basis:* Federal Preparedness Agency Notice in 40 FR 59494 and Public Health Service Act, 42 U.S.C. 241, 242o 243. F. *Chronology:* Proposed rule published on December 15, 1978 (43 FR 58790). Comment period closed on February 13, 1979.	Gail D. Schmidt, Standards and Regulations Branch (HFX–460), Bureau of Radiological Health, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, (301) 443–3426.
FDA 71—Recommendations for National Standards for Medical Radiation Technologists.	A. *Description:* The Notice of Intent announced that the Bureau of Radiological Health will be establishing recommended qualifications for medical radiation technologists. The Notice solicited professional and public input about existing practices of credentialing, the need for uniform national standards, and possible approaches for ensuring that all medical radiation technologists demonstrate a certain level of competence in conducting medical radiation examinations. B. *Why Significant:* The issue concerns a matter on which there is substantial public interest as evidenced by the more than 500 comment letters received on the Notice of Intent. C. *Regulatory Analysis:* Not required. D. *Need:* Medical radiation technologists exercise considerable influence over patient exposure during radiological procedures and so criteria for their credentialing are essential. E. *Legal Basis:* Public Health Service Act, 42 U.S.C. 241, 243, 263d. F. *Chronology:* Notice of intent published on March 13, 1979 (44 FR 14637). Comment period closed on July 11, 1979.	Charles P. Froom, Standards and Regulations Branch (HFX–460), Bureau of Radiological Health, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, (301) 443–3426.
FDA 72—Recommendations on Exposures from Diagnostic X-Ray Examinations.	A. *Description:* There exists a considerable range in the entrance skin exposure and the resulting organ doses for the same X-ray procedure conducted at different medical facilities and often within the same facility. Radiation exposure recommendations are being investigated that will permit radiologists, radiation protection personnel, and others to evaluate exposure values used in a given facility. Following the analysis of the comments generated by the Notice of inquiry, a program decision will be made as to the course of action the Bureau will pursue. B. *Why Significant:* The recommendations could have a great impact on reducing human exposure from medical X-ray examinations which accounts for ninety percent of public exposure to man-made ionizing radiation. C. *Regulatory Analysis:* Not required. D. *Need:* This recommendation will encourage facilities which are delivering excessive exposures compared to the usual exposures for specific examinations to reevaluate their procedures and lower their exposures. E. *Legal Basis:* Public Health Service Act, 42 U.S.C. 263d. F. *Chronology:* Notice of inquiry published on August 17, 1979 (44 FR 48354). Comment period closes on December 17, 1979.	Raymond F. Coakley, Jr., Standards and Regulations Branch (HFX–460), Bureau of Radiological Health, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, (301) 443–3426.
FDA 73—Recommendations for Referral Criteria for Diagnostic Radiological Examinations.	A. *Description:* An often cited reason for the overuse of diagnostic radiological examinations is the lack of referral criteria for specific examinations. The National Conference on Referral Criteria for X-Ray Examinations addressed this problem. One of the most important recommendations resulting from the Conference, publicly ratified by the Commissioner, was that which established the Government as a facilitator in the cooperative medical professional organizations. The purpose of this announcement is: (1) To state FDA's intent to facilitate the development of referral criteria through expert panels of physicians, grants, and contracts, (2) To provide a listing of candidate radiologicel (including nuclear medicine) examinations; and (3) To announce means through which public participation in the process can be assured. B. *Why Significant:* These recommendations should sharply reduce the use of diagnostic X-ray procedures in those circumstances where experience has shown that such examinations do not significantly improve the patient's recovery from disease or injury. C. *Regulatory Analysis:* Not required. D. *Need:* To reduce human exposure to medical X-ray in those instances where no significant medical benefit would result. E. *Legal Basis:* Public Health Service Act, 42 U.S.C. 241, 242, 243. F. *Chronology:* The notice is currently under development.	Robert A. Phillips, Standards and Regulations Branch (HFX–460), Bureau of Radiological Health, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.
FDA 75—Sulfonamide Containing Animal Drugs.	A. *Description:* To amend 21 CFR 510.450 setting out prescribed requirements for studies to establish safe and effective conditions of use for sulfonamida containing drugs in food producing animals. B. *Why Significant:* All sponsors of sulfonamide containing drugs for use in food producing animals will be required to submit adequate information to establish safe and effective conditions of use including tolerances for safe residues in the edible products. C. *Regulatory Analysis:* Decisions pending on completion of preliminary study.	

Food and Drug Administration—Significant Regulations—Continued

Title	Summary	Contact
	D. *Need:* Data currently available is not adequate to establish safe tolerances for residues of sulfonamide drugs in edible products of food producing animals. E. *Legal Basis:* Sections 512, 701(a), 52 Stat. 1055, 82 Stat. 343–351 (21 U.S.C. 360b, 371(a)). F. *Chronology:* 21 CFR 510.450 was initially promulgated October 23, 1970 (35 FR 16598). It was amended to require interim studies on July 22, 1974 (39 FR 26693).	Dr. Emilio E. Viera, Division of Drugs for Swine and Minor Species (HFV–138), Bureau of Veterinary Medicine, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–3410.
FDA 76—Medicated Feed Task Force Implementation.	A. *Description:* Amends the regulations to provide revised criteria for the need of an approved medicated feed application for the manufactura of medicated feeds. B. *Why Significant:* This proposal would materially change the current requirements for approval for the use of drugs in the manufactura of medicated feeds. C. *Regulatory Analysis:* Not required. D. *Need:* The proposal would establish sound and consistent criteria for approval of medicated feed applications. E. *Legal Basis:* Secs 512, 701(a), 52 Stat. 1055, 82 Stat. 343–351 (21 U.S.C. 360b, 371(a)). F. *Chronology:* Revised feed definitions proposed January 17, 1978 (43 FR 2526). Task Force Report made available by FR Notice December 15, 1978 (43 FR 58634). FEDERAL REGISTER of March 8, 1979 (44 FR 12208) deferred action on definitions proposal to become a part of the Medicated Feed Task Force Implementation.	Dr. Gaorge Graber, Division of Animal Feeds (HFV–220), Bureau of Veterinary Medicine, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4438.
FDA 77—Teat Dips	A. *Description:* To establish a regulation prescribing data requirements to establish safe and affective use of teat dips in the dairy industry. B. *Why Significant:* The regulation will require that all articles offered for use as teat dips are new animal drugs and will require that they be the subject of an approved new animal drug application. C. *Regulatory Analysis:* Not required. D. *Need:* Such products have been shown not to be safe and effective for this use. E. *Legal Basis:* Sections 512, 701(a), 52 Stat. 1055, 82 Stat. 343–351 (21 U.S.C. 360b, 371(a)). F. *Chronology:* A notice of proposed rulemaking issued in the FEDERAL REGISTER of August 9, 1977 (42 FR 40217). Comment period closed on March 10, 1978.	Dr. Howard Meyers, Division of Surveillance (HFV–216), Bureau of Veterinary Medicine, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1846.
FDA 78—Animal Drugs for Minor Species	A. *Description:* To modify the safety and effectiveness requirements for approval of new animal drug applications for use of a drug in a minor species or the minor use of a drug in a major species. B. *Why Significant:* To assure the availability of new animal drugs for use in minor species or for a minor use in a major species. C. *Regulatory Analysis:* Not required. D. *Need:* Because of little economic incentive to drug manufacturers. Under current criteria few drugs have been approved for use in minor species. E. *Legal Basis:* Sections 512, 701(a), 52 Stat. 1055, 82 Stat. 343–351 (21 U.S.C. 360b, 371(a)). F. *Chronology:* A notice of proposed rulemaking issued in the FEDERAL REGISTER of July 20, 1979 (44 FR 42714). Comment period closed on October 19, 1979.	Dr. Thomas V. Raines, Division of Drugs for Avian Species (HFV–149), Bureau of Veterinary Medicine, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4913.
FDA 79—Sterility and Pyrogenicity of Animal Drugs.	A. *Description:* To amend the current good manufacturing practice regulations for injectable animal drugs to require that they be sterile and free of extrinsic pyrogenic material. B. *Why Significant:* May require firms currently manufacturing such drugs to revise and update manufacturing facilities. C. *Regulatory Analysis:* Decision pending on completion of preliminary study. D. *Need:* Parenteral drugs that are not sterile and free of extrinsic pyrogenic material are potentially unsafe for such use. E. *Legal Basis:* Sections 501, 502, 512, 701(a) 52 Stat. 1049–1053 as amended, 1055 82 Stat. 343–351 (21 U.S.C. 351, 352, 360b, 371(a)). F. Chronology: A notice of intent was published in the FEDERAL REGISTER of December 15, 1978 (43 FR 58591). Comment period closed on June 13, 1979.	Ms. Pat Cushing, Division of Compliance (HFV–234), Bureau of Veterinary Medicine, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–3460.
FDA 80—Approval of Supplemental New Animal Drug Applications.	A. *Description:* Conditions are set forth under which a supplemental new animal drug application may be approved with or without a complete reevaluation of all safety and effectiveness data in the parent application. B. *Why Significant:* The regulation constitutes a change in agency policy regarding such approvals. C. *Regulatory Analysis:* Not required. D. *Need:* The regulation will facilitate approval of minor changes in approved applications including improving safety and effectiveness of the drug on an expeditious basis. E. *Legal Basis:* Sections 512, 701(a), 52 Stat. 1055, 82 Stat. 343–351 (21 U.S.C. 360b, 371(a)). F. *Chronology:* Notice of intent published November 12, 1976 (41 FR 50003) and notice of proposed rulemaking on December 23, 1977 (42 FR 64367). Comment period closed on March 23, 1978.	John R. Markus, Chief Chemist, Scientific Evaluation, (HFV–104), Bureau of Veterinary Medicine, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4313.
FDA 81—Prohibited Substances; Deodorizer Distillates.	A. *Description:* The regulation would prohibit the use of deodorizer distillate substances in animal feed. B. *Why Significant:* Such substances have been implicated in the contamination of animal feed resulting in the destruction of contaminated food producing animals. C. *Regulatory Analysis:* Not required. D. *Need:* Deodorizer distillate substances contain concentrated pesticide and other chemical residues from their application to growing crops. E. *Legal Basis:* Sections 201(g), 402, 409, 701(a), 52 Stat. 1046–1047 as amended 1055, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 342, 348, 371(a)). F. *Chronology:* Notice of Proposed Rulemaking published September 9, 1975 (40 FR 41797). Comment period closed on December 10, 1975. Tentative final rule was published April 29, 1980 (45 FR 28349).	John R. McDowell, Division of Animal Feeds (HFV–222), Bureau of Veterinary Medicine, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5362.
FDA 82—Descending Order of Predominance Ingredient Statement.	A. *Description:* This is a proposal to establish a requirement that the labels of food bear a statement that ingredients are listed in descending order of predominance by weight so that consumers can better evaluate the ingredients and nutritional value of foods and select products that meet their individual needs and preferences. B. *Why Significant:* This issue concerns a matter on which there is substantial public interest. C. *Regulatory Analysis:* Not required. D. *Need:* To increase consumer awareness of the fact that ingredients are listed in their order of predominance. E. *Legal Basis:* Sections 201(n), 403(a), 701(a), 52 Stat. 1041, as amanded; 1047 as amended, 1055 (21 U.S.C. 321(n), 343(a), and 371(a)) of the Federal Food, Drug and Cosmetic Act. F. *Chronology:* This proposed rule is currently under review.	Taylor M. Quinn, Associate Director of Compliance (HFF–300), Bureau of Foods, Food and Drug Administration, 200 C Street, S.W., Washington, D.C. 20204 (202) 245–1243.

Food and Drug Administration—Significant Regulations—Continued

Title	Summary	Contact
FDA 83—Restrictions on Alpha-fetoprotein Test Kits.	A. This regulation establishes restriction on the sale distribution and use of alpha-fetoprotein (AFP) test kits for neural tube defects (NTDs). B. *Why Significant:* This regulation will provide for the safe and effective use of AFT test kits in prenatal detection of NTD's. C. *Regulatory analysis:* Not required. D. *Need:* The restrictions in this regulation are necessary for the safe and effective use of AFP test kits. E. *Legal Basis:* 21 U.S.C. 360j(e). F. Chronology: Notice of Proposed Rulemaking published November 7, 1980 (45 FR 74158). Commentperiod closes January 8, 1981.	Joseph M. Sheehan, Office of the Assistant Director for Regulations Policy, (HFK-70), Bureau of Medical Devices, Food and Drug Administration, 8757 Georgia Avenue, Silver Spring, MD 20910, (301) 427-8162.
FDA 84—Patient Information	A. This notice will set forth FDA's statement of policy on the development of patient information for medical devices. This notice identifies the criteria for selecting devices for development of patient information and describes the processes that will be used to determine when patient information should be provided for medical devices and the procedures associated with their use. B. *Why significant:* This policy will help to ensure that patients have an opportunity to be well informed participants in their health care. C. *Regulatory Analysis:* Not required. D. *Need:* Publication of this notice will enable FDA to obtain comments on this policy from consumers, industry and health professionals. E. *Legal Basis:* 21 U.S.C. 352. F. *Chronology:* The notice is currently under review.	Carol A. Vetter, Consumer Affairs Officer (HFK-131), Bureau of Medical Devices, Food and Drug Administration, 8757 Georgia Avenue, Silver Spring, MD 20910, (301) 427-8120.
FDA 88—Infant Formulas Quality Control Labeling Regulation.	A. *Description:* This is a proposal to require a warning statement on the label where specified quality control requirements are not met. B. *Why Significant:* The nutritional adequacy of infant formulas is a public health issue on which there is substantial public interest. C. *Regulatory Analysis:* Not Required. D. *Need:* To assure that the required levels of nutrients are present. E. *Legal Basis:* Sections 201(n), 403(a), 701(a), 52 Stat. 1041 as amended, 1047-1048 as amended, 1055 (21 U.S.C. 321(n), 343(a)), 371(a) of the Federal Food, Drug and Cosmetic Act. F. *Chronology:* The proposed rule is currently under review.	Melvin R. Johnston, Plant and Protein Technology Branch (HFF-214), Bureau of Foods, Food and Drug Administation, 200 C St., S.W., Washington, DC. 20204, (202) 245-1504.
FDA 87—Current Good Manufacturing Practice Relating to Poisonous and Deleterious Substances in Food, Feed, and Food-Packaging Materials Plants.	A. *Description:* This is a proposal to amend several of FDA regulations to prohibit or limit the amount of poly-chlorinated biphenyls (PCB's) in sealed electrical transformers and capacitors used or stored in or around food, feed, and food- and feed-packaging materials plants or storage facilities. B. *Why Significant:* This is a public health issue on which there is substantial public interest. C. *Regulatory Analysis:* Required. D. *Need:* To protect the public health. E. *Legal Basis:* Sections 402(a), 406, 409, 701(a), 52 Stat. 1046 as amended, 1049 as amended, 1055, 72 Stat. 1785-1788 as amended, (21 U.S.C. 342(a), 346, 348, 371(a)) of the Federal Food, Drug and Cosmetic Act and Section 361, 58 Stat. 703 (42 U.S.C. 264) of the Public Health Service Act. F. *Chronology:* The proposed rule published on May 9, 1980 (45 FR 30984). Comment period ends July 7, 1980.	F. Leo Kauffman, Plant and Protein Technology Branch (HFF-214), Bureau of Foods, Food and Drug Administration, 200 C Street, SW., Washington, D.C. 20204, (202) 245-1164.
FDA 88—Infant Formula; Recall Procedures	A. Description: This proposed rule would establish recall procedures for removing adulterated infant formula from the marketplace. B. Why Significant: There is considerable public interest in infant formulas due to medical problems in infants resulting from inadequate amounts of essential nutrients. C. Regulatory Analysis: Not required. D. Need: To protect the public health. E. Legal Basis: Sec. 1 et seq., Pub. L. 717, 52 Stat. 1040-1059, as amended (21 U.S.C. 301 et seq.) of the Federal Food, Drug, and Cosmetic Act. F. Chronology: The proposed rule is currently under review.	Howard Pippin, Guidelines and Compliance Research Branch (HFF-312), Bureau of Foods, Food and Drug Administration, 200 C St., S.W., Washington, D.C. 20204, (202) 245-3092.
FDA 89—Device Risk Notification	A. Description: This regulation sets forth procedures to be followed whenever FDA requires manufacturers, distributors, or other responsible parties to notify health professionals or other persons of an unreasonable risk to health presently by a medical device. B. Why Significant: Will enable health professionals and other users to reduce or eliminate unreasonable risks presented by devices. C. Regulatory Analysis: Not required. D. Need: To implement § 518(a) of the Medical Device Amendments of 1976 and to enable FDA to assure the safety and effectivenss of medical devices. E. Legal Basis: 21 U.S.C. 360h(a). F. Chronology: The proposal is currently under review.	Robert A. Forst, Office of the Assistant Director for Regulations Policy (HFK-70), Bureau of Medical Devices, Food and Drug Administration, 8757 Georgia Avenue, Silver Spring, MD 20910, (301) 427-7114.
FDA 90—Prosthetic Fiber for Implantation into the Human Scalp; Banning	A. Description: The regulation will ban all prosthetic fibers intended for implantation into the human scalp to conceal baldness. B. Why Significant: There is public health danger resulting from the side effects associated with the prosthetic fibers. C. Regulatory Analysis: Not required. D. Need: To protect the public from dangerous side effects associated with prosthetic hair fibers. E. Legal Basis: 21 U.S.C. 360f. F. Chronology: The proposed rule is currently under review.	Pamela F. Wojtowicz, Division of Compliance (HFK-114), Bureau of Medical Devices, Food and Drug Administration, 8757 Georgia Avenue, Silver Spring, MD 20910, (301) 427-7218.

Office of Human Development Services

Title	Summary	Contact
HDS-4—Developmental Disabilities Program: General Rules.	A. *Description:* This regulation would revise existing regulations to clarify current policies and implement changes in the following areas: Definition of developmental disability; rights of the developmentally disabled; protection and advocacy systems; state planning councils; the state plan; allotments; and special project grants. B. *Why Significant:* This regulation would change the state plan requirements and concentrate funds on a limited number of priority service areas for the developmentally disabled. C. *Regulatory Analysis:* Not required. D. *Need:* To implement the 1978 Amendments to the Developmental Disabilities Assistance and Bill of Rights Act. E. *Legal Basis:* 42 U.S.C. 6008. F. *Chronology:* None.	Ann Queen, Administration on Developmental Disabilities, Rm. 3650, HHS North Bldg., 330 Independence Ave., S.W., Washington, D.C. 20201, (202) 472-7213.

Office of Human Development Services—Continued

Title	Summary	Contact
HDS-5—Social Service Programs: Consolidated Grants to Insular Areas.	A. *Description:* This regulation would specify the procedures for application and use of a single grant award consolidating the formula grant funds available for social services to the Insular Areas under Titles I, IV-A, IV-B, X, XIV, XVI and XX of the Social Security Act. B. *Why Significant:* This regulation will allow the Insular Areas greater flexibility for setting social services priorities and in responding to the needs of their populations. C. *Regulatory Analysis:* Not required. D. *Need:* To implement a 1977 Amendment to the Omnibus Territories Act. E. *Legal Basis:* 48 U.S.C. 1469(a). F. *Chronology:* None.	Warren Master, Rm. 736-E, H. H. Humphrey Bldg., 200 Independence Ave., S.W., Washington, D.C. 20201, (202) 245-6275.
HDS-6—Native American Program: General Rules.	A. *Description:* This regulation would simplify and clarify existing regulations and implement significant changes in policies and operation to reflect experience in operating the program. B. *Why Significant:* The Native American Grants provide valuable resources to Native Americans in their efforts to achieve economic and social self-sufficiency. C. *Regulatory Analysis:* Not required. D. *Need:* Regulations are needed to provide detailed requirements for the receipt and use of grants under the Native Americans Program Act of 1974. E. *Legal Basis:* 42 U.S.C. 2991. F. *Chronology:* None.	Casimer Wichlacz, Director, Policy Planning and Budget Division, Administration for Native American, Rm. 5300, HHS North Bldg., 330 Independence Ave., S.W., Washington, D.C. 20201, (202) 245-7776.
HDS-7—Child Abuse and Neglect Prevention and Treatment Program: General Rules.	A. *Description:* This regulation will implement statutory amendments to the Child Abuse Prevention and Treatment Act, which provides discretionary grants for demonstration and service projects and research projects to private, nonprofit organizations. In addition, it provides special grants to States who meet the eligibility criteria for child abuse prevention and treatment projects. B. *Why Significant:* This regulation will revise the definition of child abuse and neglect to include sexual abuse and sexual exploitation as required by the statute. This will broaden the scope of services provided by the Act. C. *Regulatory Analysis:* Not required. D. *Need:* To implement the Child Abuse Prevention and Treatment and Adoption Reform Act of 1978. E. *Legal Basis:* 42 U.S.C. 5101 et seq. F. *Chronology:* Notice of Decision to Regulate was published on September 6, 1978 (43 FR 39593).	Frank Ferro, Associate Chief, Children's Bureau, Administration for Children, Youth, and Families, Donohoe Bldg., Room 2030, 400 6th St., S.W., Washington, D.C. 20013, (202) 755-7418.
HDS-15—Eligibility Requirements and Limitations for Enrollment in Head Start.	A. *Description:* Will implement a new legislative requirement of P.L. 95-568 which allows a Head Start program to establish more liberal eligibility criteria if the community in which it is operating meets certain statutory requirements. B. *Why Significant:* This amendment will allow more than 15% over income children to enroll in Head Start programs located in communities which meet criteria established in the statute. C. *Regulatory Analysis:* Not required. D. *Need:* To implement a 1978 amendment to the Headstart-Follow Through Act. E. *Legal Basis:* 42 U.S.C. § 2928g(a)(2). F. *Chronology:* None.	Henlay Foster, Associate Director, Head Start Bureau, Administration for Children, Youth, and Families, Room 5163, Donohoe Bldg., 400 6th St., S.W., Washington, D.C. 20013, (202) 755-7782.
HDS-16—Adoption Assistance and Child Welfare Act of 1980.	A. *Description:* To implement the provisions of Pub. L. 96-272 to establish a program of adoption assistance, to strengthen the program of foster care assistance for needy and dependent children, to improve the child welfare social services, and aid to families with dependent children programs, and for other purposes. B. *Why Significant:* This regulation will help to shorten the term of children in foster care and to give them permanency. C. *Regulatory Analysis:* Threshold study completed. D. *Need:* To implement Sections 101-103 of Pub. L. 96-272. E. *Legal Basis:* Pub. L. 96-272; 94 Stat. 500 et seq. F. *Chronology:* None.	Ms. Beatrice Moore, Director, Child Welfare Services State Grant Division, Children's Bureau, Administration for Children, Youth, and Families, Room 2749, Donohoe Building, 400 Sixth St., S.W., Washington, D.C. 20201, (202) 755-8888.
HDS-17—Medical and Social Services for Certain Handicapped Persons, Section 201(c) of Pub. L. 96-265.	A. *Description:* This regulation establishes the policies and procedures for the implementation of a three year pilot program for the provision of medical and social services to severely handicapped individuals under certain circumstances. Under this pilot program States will receive a share of $6 million (to be matched at the 75%-25% rate) yearly, beginning Sept. 1, 1981, based on their SSI disabled and blind population. To participate in the program, States must designate an agency to administer or supervise the administration of the pilot program, and either submit a State plan or amend their title XX administrative plan. B. *Why Significant:* This pilot program will give States flexibility in the provision of services to handicapped persons who are ineligible for SSI and Medicaid, and who without the benefits under this program might not be able to continue employment. C. *Regulatory Analysis:* A threshold study is being developed. D. *Need:* To implement Section 1620 of the Social Security Act, as established by Section 201(c) of Pub. L. 96-265, the Social Security Disability Amendments of 1980. E. *Legal Basis:* Pub. L. 96-265; 94 Stat. 446-449. F. *Chronology: None.*	Warren Master, Director, Office of Policy Development, Room 736-E, Humphrey Bldg., 200 Independence Ave., S.W., Washington, D.C. 20201, (202) 245-6275.
HDS-18—Social Services Programs under Titles IV-A and XX of the Social Security Act—Safeguarding of Information.	A. *Description:* This regulation amends the Safeguarding of Information provisions under title IV-A in the Territories and title XX in the States, to allow for disclosure of information (including clients' names and addresses), to legislative bodies legally authorized to conduct audits. B. *Why Significant:* The regulation provides access to client information which will assist in the conducting of an audit. C. *Regulatory Analysis:* Not required. D. *Need:* To implement Section 403 of Pub. L. 96-265, The Social Security Disability Amendments of 1980. E. *Legal Basis:* Pub. L. 96-265; 94 Stat. 462. F. *Chronology: None.*	Warren Master, Director, Office of Policy Development, Room 736-E, Humphrey Bldg., 200 Independence Ave., S.W., Washington, D.C. 20201, (202) 245-6275.

OFFICE OF HUMAN DEVELOPMENT SERVICES, HHS SEMI ANNUAL AGENDA

HDS-19—Social Service Program Under Title XX of the Social Security Act. Joint Regulation to Implement Sections 201(a) and (b) of Pub. L. 96-265.	A. *Description:* These regulations implement the provisions in law that require States to "deem" certain employed disabled individuals eligible for social services under title XX and medical care under title XIX as if they were SSI recipents. These individuals no longer receive cash payments under the regular SSI program. These regulations are being developed jointly with HCFA and SSA. B. *Why Significant:* As an incentive to encourage disabled individuals to remain employed after their earnings make them ineligible for a regular SSI payment, this regulation provides continuation of Medicaid and title XX eligibility.	

OFFICE OF HUMAN DEVELOPMENT SERVICES, HHS SEMI ANNUAL AGENDA—Continued

Title	Summary	Contact
	C. *Regulatory Analysis:* A threshold study is being prepared. D. *Need:* To implement the provisions in Sections 201(a) and (b) of Pub. L. 96–265, the Social Security Disability Amendments of 1980. E. *Legal Basis:* Pub. L. 96–265; 94 Stat. 445–446. F. *Chronology:* None.	Warren Master, Director, Office of Policy Development, Room 736–E, Humphrey Bldg., 200 Independence Ave., S.W., Washington, D.C. 20201, (202) 245–6275.
HDS–20—Social Service Programs under Titles I, IV–A, X, XIV, XVI, and XX of the Social Security Act—Implementation of provisions in Title II of Pub. L. 96–272 and Revision of the Title XX Training Regulations	A. *Description:* This regulation would implement provisions of Title II of Pub. L. 96–272 which amend title XX of the Social Security Act in several areas as follows: raises the statutory ceiling; provides a separate allocation for the Territories; allows 100% FFP for child day care; allows, at State option, the provision of emergency shelter to adults, grants to day care providers to hire welfare recipients and a multi-year service program plan; allows restricted donations for training; for FY 1980 and 81; establishes a 2-yeer ceiling on training funds and a requirement for a training plan es of FY 1982; eliminates certain restrictions in the provision of specified services to alcoholics and drug addits. The regulation also would revise the training rules and clarify existing requirements. B. *Why Significant:* These regulations would make permanent certain former temporery programmatic provisions, end also implement the other amendments to title XX. In addition they would provide the States with more options in operating their training programs, and establish requirements related to the requirement for an HHS approved training plan. C. *Regulatory Analysis:* A threshold study is in progress. D. *Need:* To implement the amendments to title XX as contained in Pub. L. 96–272, the Adoption Assistance and Child Welfare Act of 1980. E. *Legal Basis:* 42 USC 1397(a)–(f); 94 Stat. 521–527. F. *Chronology:* None	Warren Master, Director, Office of Policy Development, Room 736–E, Humphrey Bldg., 200 Independence Ave., S.W., Washington, D.C. 20201, (202) 245–6275.
HDS–21—Joint Recodification Project—Fair Hearings.	A. *Description:* These regulations would revise the requirements for a fair hearing system for applicants and recipients to appeal certain State end provider agency ections in delivering services. They are being developed jointly with regulations in this area for the AFDC and Medicaid programs. B. *Why Significant:* These regulations cover important issues such as the individual's right to a fair hearing; time limits and procedures for holding a hearing and implementing a hearing decision. The rules will apply to service programs under titles I, IV–A and B, X, XIV, XVI(AABD) and XX of the Social Security Act. C. *Regulatory Analysis:* A threshold analysis is being conducted. D. *Need:* This will represent the first time that regulations for fair hearings have policies and procedures that specifically pertain to the social services programs. E. *Legal Basis:* 42 USC 1302, 302–303, 1202–1203, 1352–1353, 1382–1383, 1397. F. *Chronology:* Disclosure Draft Notice—June 13, 1979 (44 *FR* 33913).	Warren Master, Director, Office of Policy Development, Room 736–E, Humphrey Bldg., 200 Independence Ave., S.W., Washington, D.C. 20201, (202) 245–6275.
HDS–22—Joint Recodification Project-Application Determination.	A. *Description:* These regulations would revise the procedural requirements that States must follow in taking applications, end making eligibility determinations. These regulations are being revised jointly with those for the AFDC and Medicaid programs. B. *Why significant:* These regulations cover important issues including the eligibility and application process; the rights of applicants and recipients; and time limits for providing services. C. *Regulatory Analysis.* A threshold study is in preperation. D. *Need:* To clarify application and eligibility requirements for the social services program under title XX in the States and under titles I, IV-A, X, XIV, and XVI(AABD) in the Territories. These proposed rules would establish common policies for the AFDC, Medicaid and Social Services programs which are administered by the same agency in most States. E. *Legal Basis:* 42 U.S.C. 1302, 302–303, 1202, 1203, 1352–1353, 1382–1383, 1397. F. *Chronology:* Notice of decision to develop regulations—March 19, 1979 (44 *FR* 16449). Disclosure Draft Notice—April 9, 1979 (44 *FR* 21044).	Warren Master, Director, Office of Policy Development, Room 736–E, Humphrey Bldg., 200 Independence Ave., S.W., Washington, D.C. 20201, (202) 245–6275.
HDS–23—Work Incentive Program: Technical Amendments and Relocation to Chapter XIII of 45 CFR.	A. *Description:* These regulations amend the regulations relating to the Work Incentive Programs for AFDC recipients in order to make them conform with legislative amendments. They also would relocate the WIN regulations from Part 224 of Chapter II to Chapter XIII of 45 CFR. The revised regulations would contain current agency designations. B. *Why significant.* These regulations would implement legislative changes affecting some aspects of Work Incentive Program operations. C. *Regulatory Analysis:* Not required. D. *Need:* These regulations are needed to implement legislative changes mandated by Pub. L. 96–265 and to consolidate in Chapter XIII of 45 CFR all regulations administered by the Office of Human Development Services. E. *Legal Basis:* 42 U.S.C. 630 et seq. F. *Chronology:* None.	Merwin S. Hans, Executive Director, National Coordination Committee Work Incentive Program, Room 5102, Patrick Henry Bldg., 601 D. St., N.W., Washington, D.C. 20201, (202) 387–6694.
HDS–24—Work Incentive Program: Period within which State Claims must be filed.	A. *Description:* This regulation would establish a 2-year time limit for the payment of claims by the State guaranties under the Work Incentive Program in accordance with new legislation. B. *Why significant:* These regulations are intended to improve the financial management programs under the Social Security Act. C. *Regulatory Analysis:* Not required. D. *Need:* The regulation is required by new legislation. E. *Legal Basis:* Section 1132 of the Social Security Act as amended by Pub. L. 96–272 F. *Chronology:* None.	Merwin S. Hans, Executive Director, National Coordination Committee Work Incentive Program, Room 5102, Patrick Henry Bldg., 601 D. St., N.W., Washington, D.C. 20201, (202) 387–6694

Social Security Administration

Title	Summary	Contact
SSA–4—Aid to Families With Dependent Children Program—Quality Control Reviews—General Administretion, 45 CFR Part 205.	A. *Description:* The proposed regulations will require States to submit findings from their monthly AFDC review sample to SSA within 75 days after the sample month. Also, States will be required to submit findings on not less than 98 percent of the cases selected for the monthly review sample unless an alternative completion plan for that State is approved by the Secretary. The anticipated result is that the monthly review findings will be promptly submitted and not delayed until the end of the 6-month sample period.	Sean Hurley, (202) 245–8999, Program Specialist, Office of Family Assistance, Room 1416, Switzer Bldg., 330 C Street, S.W., Washington, D.C. 20201.

Social Security Administration—Continued

Title	Summary	Contact
	B. *Why Significant:* This change would assura mora rapid availability of quality control data. This would anabla SSA to complete our reports on a mora timaly and updatad basis. Timely data on payment error rates will assist administrators in determining whera funds ara being lost and in taking action to correct problams. C. *Regulatory Analysis:* Not required. D. *Need:* Thesa proposed regulations implement an administrative decision that was mada. E. *Legal Basis:* 42 U.S.C. 302, 602, 1202, 1352 and 1382. F. *Chronology:* A Notice of Decision to Ragulate was published on June 15, 1979 (44 FR 34606). An NPRM was published on Oct. 24, 1980 (45 FR 70521).	
SSA-7—Aid to Families With Dependent Children Program—Redetermining Eligiblity and Computing Supplementary Payment, 45 CFR Parts 232, 233, and 302.	A. *Description:* Thesa regulations will requira that aligibility be based on the current month's reportad support payments, and each month's supplemental payment be based on the largest part of the amount collected in tha current month that would not cause inaligibility. They will provide uniform and equitabla redeterminations of eligiblity and paymant amounts. B. *Why Significant:* These regulations would affect AFDC and Child Support Enforcemant programs in 14 States and in Puerto Rico, Guam, Virgin Islands, and tha District of Columbia. C. *Regulatory Analysis:* Not required. D. *Need:* These regulations will assura that no family receiving child support payments will suffer a loss in disposable income as a result of tha initiation of the Child Support Enforcement Program. E. *Legal Basis:* 402(a) (7), (8), (10), and (28) and 1102 of the Social Security Act as amended; 42 U.S.C. 607 (a)(7), (8), (10) and (28) and 1302 as amended, Section 202 of Pub. L. 94-88. F. *Chronology:* A Notice of Decision to Regulate was published on May 18, 1979 (44 FR 29122). Notice of proposed rulemaking was published on February 15, 1980 (45 FR 8322)	Alica Stewart, (202) 245-2010, Program Specialist, Offica of Family Assistanca, Room B411, Trans Point Bldg., 2100 Second St., S.W., Washington, D.C. 20024.
SSA-9—Aid to Familes With Dependant Children Program—Inclusion of Child Receiving Old-Aga, Survivors' and Disability Insuranca Benefits into an AFDC Assistanca Unit, 45 CFR Part 233.	A. *Description:* The proposed regulations will raaffirm an AFDC caratakar's option to include in the AFDC assistance unit a child who receives OASDI benefits under Title II of the Social Security Act, even when such benefits are sufficient to meet tha child's needs under the State's AFDC payment standard. B. *Why Significant:* The proposed regulations will codify internal policy memoranda in affect between the Federal Government and the States. C. *Regulatory Analysis:* Not required. D. *Need:* Policy clarification is required between State Lettar 1088 and subsequent policy issuance in order to resolve two conflicting interpretations. E. *Legal Basis:* 42 U.S.C. 602 and 1302. F. *Chronology:* A Notice of Decision to Regulata was published on March 6, 1979 (44 FR 12214). An NPRM was published on June 26, 1980 (45 FR 43235).	Connie Katz, (202) 245-2015, Program Specialist, Office of Family Assistance, Room B416, Trans Point Bldg., 2100 Second Street, S.W., Washington, D.C. 20024.
SSA-15—Social Security Administration—Availability of Information and Records to the Public, 20 CFR Parts 401 and 422.	A. *Description:* These proposed regulations will revise SSA's rules on tha Preedom of Information Act to make them consistent with HEW's regulations in 45 CFR part 5, transfer material concerning HCFA's Medicare program and relocate certain rules to bring SSA's rules on disclosure and tha availability of information together in one part. B. *Why Significant:* These ara basically technical revisions to make SSA's rules consistent with those in 45 CFR part 5. C. *Regulatory Analysis:* Not raquired. D. *Need:* There is a need to review SSA's rules on the availability of information for consistency with HEW's, revise our rules to raflect creation of Health Cara Financing Administration, and to transfer certain Medicara information which no longer applies to SSA activities to 42 CFR part 405. E. *Legal Basis:* 42 U.S.C. 405 and 1302. F. *Chronology:* A Notice of Daeision to Regulata was published on May 18, 1979 (44 FR 29102).	Armand Esposito, (301) 594-7455, Legal Assistant, Office of Regulations, 6401 Security Blvd., Baltimore, Md. 21235.
SSA-18—Old-Age, Survivors, Disability Insurance Program—Basic Computation of Benefits and Lump Sums, 20 CFR Part 404, Subpart C.	A. *Description:* These proposed regulations will contain the rules on computations of primary insurance amounts (PIA) under the old-age, survivors, and disability insuranca programs. (An individual's PIA is the basic tool we use to find the amount of tha individual's monthly benefit as well as the monthly benefits of his or her family.) B. *Why Significant:* These proposed regulations will simplify the complex provisions for computing benefits. C. *Regulatory Analysis:* Not required. D. *Need:* These regulations are being rewritten to meet the Department's "Operation Common Sense" standards. E. *Legal Basis:* Sec. 215 of tha Social Security Act; 42 U.S.C. 415. F. *Chronology:* A Notice of Decision to Regulate was published on March 6, 1979 (44 FR 12205). An NPRM was published on June 25, 1980 (45 FR 42647).	Jack Schanberger, (301) 594-6785, Legal Assistant, Offica of Regulations, 6401 Security Blvd., Baltimora, Md. 21235.
SSA-21—Old-Age, Survivors, Disability Insurance Program—Deductions, Reduction; and Nonpayment of Benefits, 20 CFR Part 404, Subpart E.	A. *Description:* This proposal is a recodification of the rules for making deductions from benefits, reducing benefits, and for nonpayment of benefits in the old-age, survivors, and disability insurance programs. B. *Why Significant:* The recodified ragulations will ba easier for tha public to usa and will update amendment material not contained in current regulations. C. *Regulatory Analysis:* Not required. D. *Need:* Wa proposa to remove seldom used provisions, obsolete examples, and long, rambling paragraphs. The rules are rewritten in simpler terms under HEW's "Operation Common Sense." E. *Legal Basis:* 42 U.S.C. 405 and 1302; Sections 203, 205, and 224 of the Social Security Act. F. *Chronology:* A Notice of Decision to Regulate was published on July 11, 1979 (44 FR 40531).	Marval Cazer, (301) 594-7453, Legal Assistant, Office of Regulations, 6401 Security Blvd., Baltimore, Md. 21235 .
SSA-22—Old-Age, Survivors, Disability Insurance and Supplemental Security Income Programs—Limitation for Holding Hearings, Issuing Hearing Decisions and Issuing Appeals Decisions, 20 CFR Part 404 Subpart J and Part 416 Subpart N.	A. *Description:* These regulations will provide time frames for the holding of hearings, issuance of hearing decisions and Appeals Council reviews for all Title II and Title XVI disability cases. Good cause exceptions which generally benefit claimants ara also described. B. *Why Significant:* This regulation provides regulatory assurance to claimants that appeals will be heard promptly and decisions issued promptly. C. *Regulatory Analysis:* Not requirad. D. *Need:* These ragulations are needed because, over the last saveral years, Congress, the Courts, representatives of individuals in social security matters, and the general public have expressed concarn over delays in holding hearings, issuing hearing decisions and the reviews of these decisions. In addition, the Court of Appeals in *Blankenship v. Califano* ordered the Secretary to prepare and submit regulations for the	Phil Berge, (301) 594-7452, Legal Assistant, Office of Regulations, 6401 Security Blvd., Baltimore, Md. 21235.

Social Security Administration—Continued

Title	Summary	Contact
	Court's approval to remedy the problem of unreasonable delays in conducting hearings for the OASDI and SSI programs. E. *Legal Basis:* 42 U.S.C. 405, 1302, 1320(c)(8), 1383, 1395ff, and 1395(ii). F. *Chronology:* A notice of proposed rulemeking was published on March 12, 1980 (45 FR 12837).	
SSA-25—Old-Age, Survivors, Disability Insurance Program—Coverage of Employees of State and Local Governments, 20 CFR Part 404, Subpart M.	A. *Description:* These proposed regulations will expand the current rules on including employees of State and local governments and interstate instrumentalities in the social security program. B. *Why Significant:* These proposed regulations will reflect the policies States must follow in applying for coverage of its employees and those of its local subdivisions, how to terminate its agreements, when it must pay its social security contributions, file wage reports, etc. C. *Regulatory Analysis:* Not required. D. *Need:* The current regulations need to be organized into a logical sequence and to be updated to reflect many policies which all parties have been following for many years. We will be reviewing all policies in this area to reduce recordkeeping burdens and to assess their import in the trust funds. E. *Legal Basis:* 42 U.S.C. 418. F. *Chronology:* A Notice of Decision to Regulate was published on September 28, 1979 (44 FR 55839).	Armand Esposito, (301) 594-7455, Legal Assistant, Office of Regulations, 6401 Security Blvd., Baltimore, Md. 21235.
SSA-28—Old-Age, Survivors, Disability Insurance and Supplemental Security Income Programs—Determining SGA: Earnings Guidelines for Years Beginning 1980, 20 CFR Part 404 Subpart P and Part 416 Subpart I.	A. *Description:* Under the law, a person who is able to do substantial gainful activity is not disabled for payment purposes. These interim regulations will specify the monthly earnings amounts that are used as guidelines to determine whether a person has done Substantial Gainful Activity. B. *Why Significant:* The increased guideline amounts reflect the general rise in earnings level of workers in the national economy. C. *Regulatory Anelysis:* Not required. D. *Need:* Revised guidelines are needed for 1980 and the regulations should be in place by calendar year 1980. E. *Legal Basis:* 42 U.S.C. 405, 423, 1302, 1382c and 1383. F. *Chronology:* None. An interim regulation was published on March 18, 1980 (45 FR 17131).	David Smith, (301) 594-7336, Legal Assistant, Office of Regulations, 6401 Security Blvd., Baltimore, Maryland 21235.
SSA-29—Old-Age, Survivors, Disability Insurance and Supplemental Security Income Programs—Representative Payee, 20 CFR Part 404 Subpart Q and Part 416 Subpart F	A. *Description.* The proposed regulations will state the rules used in determining when a beneficiary needs a representative payee, how a representative payee is selected, and how we assure that the representative payee uses payments in the best interest of the beneficiary. B. *Why Significant:* The proposed regulations will be simpler and easier for the public to understand. The guidelines for the use of representative payees are important for members of the public to know. C. *Regulatory Analysis:* Not required. D. *Need:* These regulations are being rewritten to meet the Department's "Operation Common Sense" standards. E. *Legal Basis:* 42 U.S.C. 405, 1302, 1383. F. *Chronology:* A Notice of Decision to Regulate was published on June 19, 1979 (44 FR 35241). An NPRM was published in November, 1980.	Ken Dyer, (301) 594-7454, Legal Assistant, Office of Regulations, 6401 Security Blvd., Baltimore, Marylend 21235.
SSA-30—Supplemental Security Income Program—Eligibility, 20 CFR Part 416, Subpart B	A. *Description:* These proposed regulations will state requirements for individuals to be eligible for SSI benefits. B. *Why Significant:* The proposed regulations simplify the language of existing regulations. Also, they expand the definition of a resident of an institution to agree with that in operating procedures. C. *Regulatory Analysis:* None. D. *Need:* These regulations are being rewritten to meet the Department's "Operation Common Sense" standards. E. *Legal Basis:* 42 U.S.C. 1302, 1381a, 1382, 1382c, 1383 and 1383b. F. *Chronology:* A Notice of Decision to Regulate was published March 27, 1979 (44 FR 18237). An NPRM was published on Sept. 4, 1980 (45 FR 58503).	Rita Hauth, (301) 594-7112, Legal Assistant, Office of Regulations, 6401 Security Blvd., Baltimore, Maryland 21235
SSA-33—Supplemental Security Income Program—Amount of Benefits, 20 CFR Part 416, Subpart D.	A. *Description:* This proposed recodification under Operation Common Sense revises and reorganizes rules on how the Social Security Administration figures amounts of monthly benefits payable to eligible individuals and eligible couples under the Supplemental Security Income (SSI) program. B. *Why Significant:* This recodification will clarify the rules and make them easier to understand. No policy change is involved. C. *Regulatory Analysis:* Not required. D. *Need:* Social Security Administration wants to provide the public with clearer regulations. E. *Legal Basis:* Secs. 1611 and 1612, secs. 210 and 211, Pub. L. 93-66, as emended, 88 Stat. 1466-1469, 87 Stat. 154, 42 U.S.C. 1382 end 1382a. F. *Chronology:* A Notice of Decision to Regulate was published on July 11, 1979 (44 FR 40531).	Jack Schanberger, (301) 594-6795, Legal Assistant, Office of Regulations, 6401 Security Blvd., Baltimore, Maryland 21235
SSA-35—Supplemental Security Income Program—Reports Required 20 CFR Part 416, Subpart G	A. *Description:* This proposed recodification under Operation Common Sense revises end reorganizes rules on reports required from each applicent, eligible individual, eligible spouse, and eligible child under the Supplemental Security Income program. The rules cover provisions regarding reports required and explain the penalties for failures to report on time. B. *Why Significant:* This recodification will clarify the rules and make them easier to understand. No policy change is involved. C. *Regulatory Analysis:* Not required. D. *Need:* Social Security Administration wants to provide the public with clearer regulations. E. *Legal Basis:* Secs. 1102, 1611, 1612, 1613, 1614, end 1631 of the Social Security Act, as emended; Sec. 211 of Pub. L. 93-66; 49 Stat. 647, as amended; 86 Stat. 1466, 1468, 1470, 1471, and 1475; 87 Stat. 154; 42 U.S.C. 1302, 1382, 1382a, 1382b, 1382c, and 1383. F. *Chronology:* Notice of Decision to Regulete wes published on July 11, 1979 (44 FR 40531). An NPRM wes published on June 19, 1980 (45 FR 41453).	Marval Cazer, (301) 594-7463, Legal Assistant, Office of Regulations, 6401 Security Blvd., Baltimore, Maryland 21235.
SSA-38—Supplemental Security Income Program—Resources, 20 CFR Part 416, Subpart L	A. *Description:* These proposed regulations will describe what we count as resources in determining eligibility for supplemental security income. B. *Why Significant:* The purpose of these recodified reguletions is to meke the rules clearer and easier for the public to understand. C. *Regulatory Analysis:* Not required. D. *Need:* These reguletions are being rewritten to meet the Department's "Operation Common Sense" standards.	Henry Lerner, (301) 594-7414, Legal Assistant, Office of Regulations, 6401 Security Blvd., Baltimore, Maryland 21235.

Social Security Administration—Continued

Title	Summary	Contact
	E. *Legal Basis:* 42 U.S.C. 1302, 1382, 1382b, 1382c, and 1383. F. *Chronology:* A Notice of Decision to Regulate was published on March 27, 1979 (44 FR 12837).	
SSA-39—Supplemental Security Income Program—Reductions, Suspensions, and Terminations, 20 CFR Part 416, Subpart M.	A. *Description:* These proposed regulations will contain the rules for reducing, suspending and terminating an SSI recipient's benefits. They are being rewrittan to provida graatar clarity to the raader and to consider policy additions, ravisions, and clarification. B. *Why Significant:* The rules will be clearer and aasier for the public to read. C. *Regulatory Analysis:* Not required. D. *Need:* These regulations ara being rewritten to meet the Department's "Operation Common Sensa" standards. E. *Legal Basis:* 42 U.S.C. 1302, 1382, 1382c, 1382d, and 1383. F. *Chronology:* A Notica of Decision to Regulata was published on June 19, 1979 (44 FR 35241).	Charles Campbell, (301) 594-7453, Legal Assistant, Office of Regulations, 6401 Security Blvd., Baltimore, Maryland 21235.
SSA-41—Supplemental Security Incoma Program—Interim Assistanca Provisions, 20 CFR Part 416, Subpart S.	A. *Description:* This recodification under Operation Common Sensa ravisas and reorganizes rules on intarim assistance provisions under the Supplemental Security Incoma program. Tha rules permit the Social Security Administration to anter into an agreement with a State to repay the State for interim assistanca it givas an individual whila an application for SSI is pending. B. *Why Significant:* This recodification will clarify the rules and maka them easier to understand. Tha rules permit SSA to withhold an individual's SSI benefit payment and send it to the Stata as repayment for interim assistance, upon tha individual's written authorization. A policy changa will allow the authorization to go into effect upon notice to SSA of receipt by the Stata. C. *Regulatory Analysis:* Not required. D. *Need:* Social Security Administration wants to provide tha public with clearer regulations and to update policy to take advantage of modern electronic communications facilities. E. *Legal Basis:* Secs. 1102 and 1631 of the Social Security Act as amended; 49 Stat. 647 as amended; 86 Stat. 1475 as amended; 42 U.S.C. 1302 and 1383. F. *Chronology:* A Notice of Decision to Regulate was published on July 11, 1979 (44 FR 40531). A notice of proposed rulamaking was published on April 21, 1980 (45 FR 26719).	Clara Powell, (301) 594-7459, Legal Assistant, Offica of Regulations, 6401 Security Blvd., Baltimora, Maryland 21235.
SSA-43—Supplemental Security Income Program—Medicaid Eligibility Datarminations, 20 CFR Part 416, Subpart U.	A. *Description:* The proposed regulations will giva the rules undar which Social Security Administration agrees to make determinations of Medicaid eligibility for SSI beneficiaries on behalf of States and to give Statas othar assistance in Medcaid program administration. B. *Why Significant:* The agreements avoid duplication of effort between State and Federal govarnments and simplify the Medicaid application process for applicants. This revision makas the rules clearer and easier to raad. C. *Regulatory Analysis:* Not required. D. *Need:* Tha regulations are being rewrittan under "Operation Common Sense" to make the rules claarar and easier to use. E. *Legal Basis:* 42 U.S.C. 1302, 1383, 1383c and 4222. F. *Chronology:* A Notice of Decision to Regulata was published on June 19, 1979 (44 FR 35241).	Cliff Terry, (301) 594-7519, Legal Assistant, Office of Regulations, 6401 Security Blvd., Baltimore, Maryland 21235.
SSA-44—AFDC Program Determination of Assistanca Paymant When Ona or More Family Members are SSI Boneficiarias, 45 CFR Parts 233.20 and 233.90.	A. *Description:* Tha proposed regulations raquira a State to pay AFDC to tha parent of a child SSI recipiant whera tha parent would otharwise be ineligible because tha child is eligible for SSI. B. *Why Significant:* These regulations will implement a new provision of law which is intended to sea that a potential AFDC family is not adversely affected by a child's SSI eligibility. C. *Regulatory Analysis:* Not required. D. *Need:* These regulations ara needed to implament a naw provision of the Social Security Act, i.a., Section 402(a)(24) as added by Section 414 of Public Law 92-603. E. *Legal Basis:* 42 U.S.C. 602 of the Social Security Act, as amended; Pub. L. 92-603.	Chapin Wilson, (202) 245-2015, Program Specialist, Office of Family Assistanca, Room B-416 Trans Point Building, 2100 Second Street, S.W., Washington, D.C. 20024.
SSA-45—AFDC Program Fair Hearings, 45 CFR Part 205.10.	A. *Description:* The proposed regulations recodify the rules on fair hearing procedures for financial assistance programs. B. *Why Significant:* The proposed regulationa set forth what notices ara required to applicants and recipients and prescribe the hearings procedures to allow thosa individuals to contest an action or delay by the administering agency. C. *Regulatory Analysis:* Not required. D. *Need:* These regulations are being rewritten to meet the Department's "Oparation Common Sense" standards. E. *Legal Basis:* 42 U.S.C. 302(a)(4), 602(a)(4), 1202(a)(4), 1352(a)(4), 1382. F. *Chronology:* A Notice of Decision to Regulata was published on March 19, 1979 (44 FR 16449). Thera will be companion HDS and HCFA regulations.	Fred Kelly, (202) 245-2025, Deputy Director, Office of Policy, Office of Family Assistance, Room B-428 Trans Point Building, 2100 Second Street., S.W., Washington, D.C. 20024.
SSA-46—AFDC Program Application Eligibility Determinations, and Furnishing Assistance, 45 CFR Part 206.	A. *Description:* Thesa proposed regulations recodify tha rules under which Stata and local agencies process applications and determine aligibility in the Aid to Families with Dependent Childran and adult financial assistance programs. B. *Why Significant:* The proposed regulations clarify and amend existing rules. They set out the rights and responsibilities of applicants, recipiants and administering agencies. C. *Regulatory Analysis:* Not required. D. *Need:* Thesa regulations ara being rewritten to meet tha Departmant's "Operation Common Sense" standards. E. *Legal Basis:* 42 U.S.C. 602(a)(10), 1202(a)(11), 1352(a)(10), 1382. F. *Chronology:* A Notice of Decision to Regulate was published March 19, 1979 (44 FR 16449). Thera will be companion HDS and HCFA regulations.	Marianna S. Pindell, (202) 245-2068, Program Specialist, Offica of Family Assistance, Room B 407 Trans Point, Building, 2100 Second Street, S.W., Washington, D.C. 20024.
SSA-48—Old Age, Survivors & Disability Insurance and Black Lung Programs Prarecovary Hearing Before Overpayment Recovery, *Califano* v. *Yamasaki*, 20 CFR Part 404, Subpart J. 20 CFR Part 410, Subpart F.	A. *Description:* These proposed regulations requira SSA to provide its ovarpaid beneficiarias with the opportunity for an oral evidentiary hearing concerning waiver belora racovering an overpayment. B. *Why Significant:* These regulations incorporata a Suprama Court decision into the regulations. C. *Regulatory Analysis:* Not required. D. *Need:* Tha Social Security regulations must incorporate interpretations of tha Social Security Act's provisions provided by tha Suprama Court. E. *Legal Basis:* The Suprame Court decision in *"Califano* v. *Yamasaki"*. F. *Chronology:* A Notice of Decision to Regulate was published on March 13, 1980 (45 FR 16201).	Charles Campbell, (301) 594-5551, Legal Assistant, Office of Regulations, 6401 Security Boulevard, Baltimore, Maryland 21235.

Social Security Administration—Continued

Title	Summary	Contact
SSA-49—Black Lung and SSI Programs Recovery of Black Lung, Overpayments from Benefits Due Survivors, 20 CFR Part 410, Subpart E, 20 CFR Part 416, Subpart E,.	A. *Description:* The proposed regulation will provide for recovery of an overpayment of black lung benefits from subsequent black lung benefits payable to the deceased beneficiary's survivors. B. *Why Significant:* The decision provides consistent recovery of overpayment policies between the Old-Age, Retirement, and Survivors Insurance programs and the Black Lung program. Recovery may be made against the decedent's survivors when not completed during the beneficiary's lifetime. C. *Regulatory Analysis:* Not required. D. *Need:* Present regulations do not adequately define liability for repayment of a black lung overpayment. Problems have arisen in determining the liability for repayment after the beneficiary's death. E. *Legal Basis:* Secs. 413(b) of Federal Coal Mine Health and Safety Act of 1969, as amended (Federal Safety and Health Act of 1977, title II); Secs. 204 and 1102 of the Social Security Act, as amended; 30 U.S.C. 921 and 42 U.S.C. 404 and 1302. F. *Chronology:* A Notice of Decision to Regulate was published on February 19, 1980 (45 FR 10809). An NPRM was published on August 22, 1980 (45 FR 56074)	Marval Cazer, (301) 594-7463, Legal Assistant, Office of Regulations, 6401 Security Boulevard, Baltimore, Maryland 21235.
SSA 50—Old-Age, Survivors and Disability Insurance Programs; Additional Dropout Years for Child Care, 20 CFR Part 404, Subpart C.	A. *Description:* When computing disability insurance benefits, we will be able to exclude (i.e., dropout) up to 3 years of low or no earnings during which the worker was living with his or her young child for a substantial period. We will define "living with" and "substantially throughout the period". B. *Why Significant:* The regulation will soften the effect of a recent cost reduction provision in the disability insurance program. That provision generally reduces the number of years of low earnings that can be dropped in computing disability benefits, whereas this regulation will permit the dropping of some child care years of low earnings. C. *Regulatory Analysis:* Not required. D. *Need:* This regulation is needed to carry out Section 102 of the Social Security Disability Amendments of 1980. E. *Legal Basis:* 94 Stat. 443, Pub. L. 96-265.	Jack Schanberger, (301) 594-6785, Legal Assistant, Office of Regulations, 6401 Security Boulevard, Baltimore, Md. 21235.
SSA 51—Aid to Families With Dependent Children Program; Proration of Shelter Utilities and Similar Expenses for AFDC Children Living With Ineligible Relatives, 45 CFR Part 233.	A. *Description:* The regulations will provide that a State may prorate the shelter, utilities, and similar needs of specified assistance units living with closely related family members who are ineligible for AFDC. States may prorate if the total income of assistance unit members and closely related family members equals or exceeds the State's AFDC need standard for an FDC assistance unit of comparable size. B. *Why Significant:* The regulation will provide that if a State chooses to prorate, it must follow a formula specified in the regulation. Under prior law, States had complete flexibility in determining need and payment standards. C. *Regulatory Analysis:* Not required. D. *Need:* The statute is extremely complex and regulations are needed to insure that all States interpret the statute in the same way. E. *Legal Basis:* 94 Stat. 528 and 529, Pub. L. 96-272.	Connie Katz, (202) 245-2021, Policy Specialist, Office of Family Assistance, Room B-416, Transpoint Building, 2100 Second St., S.W., Washington, D.C. 20024.
SSA 52—Supplemental Security Income Program; Age 18 Deeming and Alien Deeming, 20 CFR Part 416, Subpart K.	A. *Description:* (1) Deeming of parental income and resources to an eligible child ends when a child reaches age 18 unless a savings clause applies to children between 18 and 21 (effective October 1, 1980); (2) A sponsor's income and resources are deemed to an alien for a period of three years after admission for aliens who first apply after September 30, 1980. B. *Why Significant:* (1) Eliminates different treatment of children aged 18 to 21 depending on status as students; (2) Assumes that sponsors will support aliens and sets more rigid rules than apply to other deeming categories. C. *Regulatory Analysis:* None Required. D. *Need:* (1) and (2) implement sections 203 and 504 of the Social Security Disability Amendments of 1980. E. *Legal Basis:* (1) 42 U.S.C. 1382e; (2) 42 U.S.C. 1382c and 1382j. F. *Chronology:* A Notice of Decision to Regulate was published on November 14, 1980 (45 FR 75225).	Rita Hauth, (301) 594-7112, Legal Assistant, Office of Regulations, 6401 Security Boulevard, Baltimore, Maryland 21235.
SSA-53—Supplemental Security Income Program; Benefits for Severely Disabled Performing Substantial Gainful Activity, 20 CFR Part 416, Subpart B.	A. *Description:* These regulations will clarify how SSA will interpret and apply the unique eligibility factors which are necessary for status as a supplemental income recipient for purposes of Titles XIX and XX. They will also explain the eligibility factors which must be met to acquire and retain eligibility for special SSI payments while an individual is engaged in substantial gainful activity. B. *Why Significant:* This is a 3-year demonstration program which affects individuals who work despite disabling impairments. The demonstration which begins on January 1, 1981 provides Special SSI cash benefits to these people where certain requirements are met. Even when SSI cash benefits are no longer payable these people, if they meet certain eligibility factors, are considered as SSI recipients for purposes of Titles XIX and XX of the Social Security Act. C. *Regulatory Analysis.* Not required. D. *Need:* Required by the Social Security Disability Amendments of 1980. E. *Legal Basis:* Section 201(a) and (b) of Pub. L. 96-265. F. *Chronology:*	Fred Miranda, (301) 594-7341, Legal Assistant, Office of Regulations, 6401 Security Boulevard, Baltimore, Maryland 21235.
SSA-54—Old-Age, Survivors and Disability Insurance and Supplemental Security Income Program; Continued Payment of Benefits to Persons in Approved Vocational Rehabilitation Plans, 20 CFR Parts 404, Subpart P and 416, Subpart I.	A. *Description:* These proposed regulations will provide for continued payment of cash benefits to persons whose disabilities have ended if they are participating in vocational rehabilitation programs. Participation in the program must have begun before the person's disability ends and the disability must not have been expected to end prior to the expected completion date of the program. B. *Why Significant:* These proposed regulations will effect those people who medically recover from their disabilities during the course of their vocational rehabilitation programs and who, because of the loss of their benefits, are forced to discontinue their participation in the program and seek substantial gainful work activity. C. *Regulatory Analysis:* Not required. D. *Need:* These regulations are required to implement Section 301 of the Social Security Disability Amendments of 1980. E. *Legal Basis:* 42 U.S.C. 425, 1382c, and 1383. F. *Chronology:*	Harry Short, (301) 594-7337, Legal Assistant, Office of Regulations, 6401 Security Boulevard, Baltimore, Maryland 21235.
SSA-55—Old-Age, Survivors and Disability Insurance and Supplemental Security Income Program; Deduction of Work Related Expenses, 20 CFR Parts 404, Subparts P and 416, Subpart I.	A. *Description:* The proposed regulations will provide for the deduction from earnings of certain impairment related work expenses in determining: (1) Whether a disabled person has done substantial gainful activity; and (2) the amount of a disabled person's earned income for SSI purposes. B. *Why Significant:* The regulation will encourage disabled persons to work by enabling them to deduct certain work expenses. C. *Regulatory Analysis:* Not required. D. *Need:* The proposed regulation provides the criteria for determining the deductibility of impairment related work expenses. E. *Legal Basis:* 42 U.S.C. 405, 423, 1302, 1382c and 1383.	David Smith, (301) 594-7336, Legal Assistant, Office of Regulations, 6401 Security Boulevard, Baltimore, Maryland 21235.

Social Security Administration—Continued

Title	Summary	Contact
	F. *Chronology:*	
SSA 56—Old-Age, Survivors and Disability Insurance and Supplemental Security Income Program; Extension of Trial Work Period and Reinstatement of Benefits, 20 CFR Parts 404, Subpart P and 416, Subpart I.	A. *Description:* These proposed regulations will provide persons who remain disabled and who have completed a trial work period with an additional period of 15 months in which to continue to test their ability to work. During this period a person may be paid benefits for all months in which he or she does not do substantial gainful activity. The regulations also extend the trial work period provisions (and the additional period) to widows, widowers, and surviving divorced wives. B. *Why Significant:* Persons who remain disabled and who have exhausted their trial work periods will be encouraged to continue their efforts to return to work. For the first time, the trial work period provisions are extended to widows, widowers, and surviving divorced wives. C. *Regulatory Analysis:* Not required. D. *Need:* These regulations are needed to implement Section 303 of the Social Security Disability Amendments of 1980. E. *Legal Basis:* 42 U.S.C. 402, 416, 422, 423, 1382, 1382c, and 1383. F. *Chronology:* A Notice of Decision to Regulate was published on November 14, 1980. (45 FR 75225).	Harry Short, (301) 594-7337, Legal Assistant, Office of Regulations, 6401 Security Boulevard, Baltimore, Maryland 21235.
SSA 57—Aid to Families With Dependent Children Program; Incentive for AFDC Recipients to Report Earned Income, 45 CFR 206 and 233.	A. *Description:* The regulations will provide that the earned income disregard will not be applied to any earned income which the recipient failed without good cause to report timely to the State agency. B. *Why Significant:* The regulations will require agencies in States that do not have monthly reporting systems to confirm reported changes to assure that recipients are not penalized due to agency failure to take action on the reported changes. C. *Regulatory Analysis:* Not required. D. *Need:* New rulemaking is necessary to assure uniform interpretation by States and to revise existing regulations to reflect requirement of the statute. E. *Legal Basis:* 94 Stat. 528, Pub. L. 96-272. F. *Chronology:*	Connie Katz, (202) 245-2021, Program Specialist, Office of Family Assistance, Room B-416, Transpoint Building, 2100 Second St., S.W., Washington D.C. 20024.
SSA 58—Old Age, Survivors and Disability Insurance and Supplemental Security Income Program; Limitation on Prospective Life of Applications and Closing of Record After Hearing Decision, 20 CFR Parts 404, Subparts G and J and 416, Subparts C and N.	A. *Description:* Under these proposed regulations, if a person files an application for benefits before the first month he or she meets all requirements for entitlement, we will allow the claim only if he or she meets all requirements before a hearing decision or dismissal (if there is one) is issued. Also, if the person asks the Appeals Council to review the hearing decision or dismissal, the Council will not consider new evidence unless it relates to the time before the hearing decision or dismissal and there was good cause for not submitting it earlier. B. *Why Significant:* These rules should promote final resolution of cases at the hearing stage and help to reserve Appeals Council review more nearly for cases of a genuinely appellate nature. C. *Regulatory Analysis:* Not required. D. *Need:* To conform our regulations to sec. 306 of the Social Security Disability Amendments of 1980 and to carry out the express intent of Congress in enacting it. E. *Legal Basis:* 42 U.S.C. 402(j)(2), 416(i)(2)(G), and 423(b) as amended by sec. 306 of Pub. L. 96-265. F. *Chronology:* A Notice of Decision to Regulate was published on September 16, 1980 (45 FR 61315).	Cliff Terry, (301) 594-7519, Legal Assistant, Office of Regulations, 6401 Security Boulevard, Baltimore, Maryland 21235.
SSA59—Old Age, Survivors and Disability Insurance Programs; Limitation on Total Family Benefits in Disability Cases, 20 CFR Part 404, Subpart E.	A. *Description:* There is now a lower ceiling on the total amount of benefits payable to a disabled worker and his family. B. *Why Significant:* The lower benefits now payable are intended to provide an incentive for disabled individuals to continue working or return to work, and at the same time will provide an equitable level of benefits to the family of a worker who is unable to work. C. *Regulatory Analysis:* Not required. D. *Need:* This regulation is needed to carry out section 101 of the Social Security Disability Amendments of 1980. E. *Legal Basis:* 94-Stat. 442, Pub. L. 96-265. F. *Chronology:* A Notice of Decision to Regulate was published on September 15, 1980 (45 FR 60922).	Jack Schanberger, (301) 594-6785, Legal Assistant, Office of Regulations, 6401 Security Boulevard, Baltimore, Maryland 21235.
SSA60—Old-Age, Survivors and Disability Insurance and Supplemental Security Income Programs; Deductions, Reductions and Nonpayment of Benefits, 20 CFR Parts 404, Subpart E and 416, Subpart K.	A. *Description:* These regulations will provide that an individual's retroactive monthly social security will be reduced if the individual received SSI payments for the same period. B. *Why Significant:* These regulations will preclude the windfall payment of SSI benefits that would not have been made if the monthly social security benefits had been paid when regularly due rather than retroactively. C. *Regulatory Analysis:* Not required. D. *Need:* Implements section 501 of the Social Security Disability Amendments of 1980. E. *Legal Basis:* 94 Stat. 469, 470, Pub. L. 96-265. F. *Chronology:* A Notice of Decision to Regulate was published on October 20, 1980 (45 FR 69248).	Larry Dudar, (301) 594-6629, Legal Assistant, Office of Regulations, 6401 Security Boulevard, Baltimore, Maryland 21235.
SSA61—Old Age, Survivors and Disability Insurance Programs; Payment for Medical Evidence of Record, 20 CFR Part 404, Subpart P.	A. *Description:* These regulations provide that any non-Federal hospital, clinic, laboratory, or other provider of medical services, or physician who is not employed by the Federal government, and who supplies medical evidence that we ask for and need for making determinations of disability shall be entitled to payment for the reasonable cost of providing the evidence. These regulations become effective on December 1, 1980. B. *Why Significant:* Until December 1, 1980, the claimant was primarily responsible for paying for existing medical evidence submitted to us for making a title II disability determination. We will now pay the reasonable cost for existing medical evidence which we ask for and need. The information needed for disability determinations will be obtained more expeditiously and the need for further medical consultative examinations at our expense will be reduced. C. *Regulatory Analysis:* Not required. D. *Need:* These regulations are needed to update existing regulations to reflect the Social Security Disability Amendments of 1980. E. *Legal Basis:* 42 U.S.C. 405, 423 and 1302. F. *Chronology:* Interim regulations were published October 30, 1980 (45 FR 71791).	William Ziegler, (301) 594-7415, Legal Assistant, Office of Regulations, 6401 Security Boulevard, Baltimore, Maryland 21235.
SSA 62—Survivors and Disability Insurance Programs; Reduction in Dropout Years for Disabled Workers, 20 CFR Part 404, Subpart C.	A. *Description:* When computing disability insurance benefits, we will not be able to exclude (i.e., dropout) as many years of low or no earnings as we could before this recent amendment to the Social Security Act. B. *Why Significant:* The regulation will reduce the number of years of low earnings that can be dropped in computing disability benefits. Since more years of low earnings will be used, benefit levels will be generally lower, thereby reducing benefit cost to the disability program. C. *Regulatory Analysis:* Not required.	Jack Schanberger, (301) 594-6785, Legal Assistant, Office of Regulations, 6401 Security Boulevard, Baltimore, Md. 21235.

Social Security Administretion—Continued

Title	Summary	Contact
	D. *Need:* This regulation is needed to carry out section 102 of the Social Security Disability Amendments of 1980. E. *Legal Basis:* 94 Stat. 443, Pub. L. 96-265. F. *Chronology:* A Notice of Decision to regulation was published on September 15, 1980 (45 FR 60922).	
SSA 63—Supplemental Security Income Program; Sheltered Workshops (1) and Earned Income Tax Credits (2), 20 CFR Part 416, Subpart K.	A. *Description:* (1) Sheltered workshop remuneration is earned income as of October 1, 1980. (2) Earned income tax credits ere earned income es of Januery 1, 1980. B. *Why Significant:* (1) Eliminates need to determine whether sheltered workshops services are employment or therapy—thus earned or unearned income. Earned income is advantageous to beneficiary as it provides greater exclusions and higher benefits. (2) Earned income tax credits did not effect benefits prior to 1980. These credits would have been unearned income es of 1980 and would have resulted in lower benefits, if this law would not have been enacted. C. *Regulatory Analysis:* Not required. D. *Need:* The regulations will provide the criteria to carry out appropriate provisions of Social Security Disability Amendments of 1980 end the Technical Corrections Act of 1979. E. *Legal Basis:* (1) 42 U.S.C. 1382e; (2) 42 U.S.C. 1382a.	Rita Hauth, (301) 594-7112, Legal Assistant, Office of Regulations, 6401 Security Boulevard, Baltimore, Md. 21235.
SSA 64—Old Age, Survivors and Disebility Insurance and Supplemental Security Income Programs; Payment of Certain Trevel Expense, 20 CFR Parts 404, Subparts I and P and 416, Subpart N.	A. *Description:* These proposed regulations will provide for the payment of certain travel expenses to claimants who attend medical exams, end to claimants, their representatives, and witnesses who attend reconsideration interviews and proceedings before administrative law judges. B. *Why Significant:* The proposed regulations are significant beceuse they will explain when SSA will pay certain travel expenses. C. *Regulatory Analysis:* None required. D. *Need:* Previous instructions were issued in guides and manuals. Regulations ere needed so that the public will be made aware of its entitlement to certain travel expenses. E. *Legal Basis: 94 Stat. 459 and 460 Pub. L. 96-265.*	Clara Barrett Powell, (301) 594-7459, Legal Assistant, Office of Regulations, 6401 Security Boulevard, Baltimore, Md. 21235.
SSA 65—Old Age, Survivors, and Disability Insurance Programs Claims in Trust Territories, 20 CFR Parts 404, Subparts G and H	A. *Description:* The proposed regulations will provide that personnel of the U.S. Department of the Interior will accept applications and evidence in connection with claims filed under title II of the Social Security Act in the Trust Territories of the Pacific. B. *Why Significant:* The regulations will affect the Social Security program in the Trust Territories of the Pacific. C. *Regulatory Analysis:* Not Required. D. *Need:* Current reguletions do not provide a contact for social security claimants and beneficiaries in the Trust Territories of the Pacific. E. *Legal Basis:* 42 U.S.C. 402 and 405. F. *Chronology:*	David Smith, (301) 594-7336, Legal Assistant, Office of Regulations, 6401 Security Boulevard, Baltimore, Maryland 21235.
SSA 66—Old Age, Survivors, and Disability Insurance and Supplemental Security Income Programs; Personalized Notices to Be Provided Certain SSA Claimants, 20 CFR Parts 04, Subpart J and 416, Subpart N	A. *Description:* Any decision made by the Secretary which involves e determination of disability under title II or title XVI, unfevorable in whole or part to the disabled individual, shall contain a statement of the cause in understandable language setting forth e discussion of the evidence and stating the Secretary's determination end the reason or reasons upon which it is based. Where e written personalized notice has been provided, we will not repeat this information. B. *Why Significant:* The proposed regulations require that we furnish additional information to DI and SSI claimants for disability whose claims are being denied that we previously furnished. C *Regulatory Analysis:* Not required. D. *Need:* The proposed regulations implement section 305 of the Social Security Disability Amendments of 1980. E. *Legal Basis:* F. *Chronology:* A Notice of Decision to Regulate was published on September 10, 1980 (45 FR 59589).	Phil Berge, (301) 594-7452, Legal Assistant, Office of Regulations, 6401 Security Boulevard, Baltimore, Maryland 21235.
SSA 67—Supplemental Security Income Progrem; Determination of Overpayment/Underpayment Period, 20 CFR Part 416, Subpart E	A. *Description:* The amended regulations will permit the making of a determination of overpayment for a period which includes excess payment of SSI payments for the calendar quarter in which the determination of overpayment will be made. Present regulations require that we wait until efter the last month of the calendar quarter in which excess payments have been made before recovery may be attempted. B. *Why Significant:* Permits an immediate determination and notification of the recipient without waiting until the end of the calendar quarter. It contributes to better understanding and ability to repay by the recipient. C. *Regulatory Analysis:* None required. D. *Need:* The regulation will speed initiation of the determination process of overpayment and reduce excess overpayments. E. *Legal Basis:* 42 U.S.C. 1302 end 1383. F. *Chronology:* A Notice of Decision to Regulate was published on November 14, 1980 (45 FR 75226).	Marvel Cazer, (301) 594-7463, Legal Assistant, Office of Regulations, 6401 Security Boulevard, Baltimore, Maryland 21235.
SSA 68—Aid to Families With Dependent Children Program; Adjustment for Federal Share for Uncashed Checks, 45 CFR Part 205	A. Description: The regulations will reinforce present policy which requires States to return to the Federal government its share of uncashed or canceled essistance checks. The regulations will establish a uniform refund policy in contrast to the present discretionary procedures allowed to the States. B. Why Significant: A GAO eudit in 1979 found many instances where Federal Matching funds for assistance payments had not been refunded to the Federal government after checks were uncashed or canceled. Retaining unused Federal funds is contrary to Treasury regulations. C. Regulatory Analysis: Not required. D. Need: The regulations ere needed to essure prompt refund of Federal funds. E. Legal Basis: 42 U.S.C. 403(a). F. Chronology: A Notice of Decision to Regulate was published on November 14, 1980 (45 FR 75243).	Jack Schanberger, (301) 594-6785, Legal Assistant, Office of Regulations, 6401 Security Boulevard, Baltimore, Md. 21235.
SSA 69—Old-Age, Survivors and Disability Insurance and Supplementel Security Income Program; Determinations of Disability, 20 CFR Part 404, Subpart Q and Part 416, Subpart J	A. Description: The proposed regulations specify the responsibilities of the Secretary and the State egencies in administering the disability program. They prescribe standards for accuracy of performance and processing time that State egencies are expected to meet in making disability determinations, end provide the administrative requirements and procedures SSA and the State egencies will follow in carrying out the disability determination function. B. Why Significant: These regulations ere intended to improve the quality of State agencies performance end improve the timeliness of disability determinations. These regulations will give the State agencies maximum practicable management flexibility in meeting objectives.	William Ziegler, Harry Short, (301) 594-7415, (301) 594-7337, Legal Assistent, Office of Regulations, 6401 Security Boulevard, Baltimore, Maryland 21235.

Social Security Administration—Continued

Title	Summary	Contact
	C. Regulatory Analysis: Not required. D. Need: The Social Security Disability amendments of 1980 require the Secretary to issue regulations to establish performance standards and other requirements for State agencies to insure effective and uniform administration of the SSA disability programs. E. Legal Basis: These regulations are issued under the authority contained in 42 U.S.C. 405, 421, 1302, 1382c and 1383. F. Chronology: A Notice of Decision to Regulate was published on September 26, 1980. (45 FR 63869).	
SSA 70—Old-Age, Survivors and Disability Insurance and Supplemental Security Income Programs; Experiments and Demonstration Projects Under Disability Insurance and SSI Programs, 20 CFR Parts 404, Subparts D and P and 416, Subparts B and I.	A. Description: Amendments of 1980 authorize the Secretary to conduct experiments and demonstration projects under the OASDI and SSI Programs. The proposed regulations will alter the requirements for disability benefits and the requirements for SSI benefits when a person has been selected to participate in an experiment or demonstration project under these amendments. B. Why Significant: Current regulations provide that in order to be eligible for title II and title XVI benefits, certain requirements must be met. The Social Security Disability Amendments of 1980 authorize the Secretary to waive compliance with benefit requirements for title II and title SVIII and waive any of the conditions, requirements, or limitations of title XVI. C. Regulatory Analysis: Not required. D. Need: While the statute does not mandata regulations, the provisions of the APA and the need to advise the public of potential impact of the demonstration projects and experiments seems to require regulations. E. Legal Basis: 42 U.S.C. 1310. F. Chronology:	Henry Lerner, (301) 594-7414, Legal Assistant, Office of Regulations, 6401 Security Boulevard, Baltimore, Md 21235.
SSA 71—Aid to Families With Dependent Children; Federal Financial Participation in the Cost of a Statewide Mechanized Claims Processing and Information Retrieval System, 45 CFR 205.	A. *Description:* These proposed regulations provide that 90 percent Federal matching funds will be available for the design, development, installation and implementation of computerized AFDC Statewide mechanized claims processing and information retrieval systems. This increased matching will also include the cost of purchasing or renting computer equipment and software used for the operation of the system. B. *Why Significant:* The regulation will reduce cost to both the State and Federal government in the operation of the AFDC program because of the systems implemented. C. *Regulatory Analysis:* Not required. D. *Need:* Thesa regulations implement section 406 of the Social Security Disability Amendment of 1980. E. *Legal Basis:* 94 Stat. 465, 466, 467 Pub. L. 96-265.	Pat O'Hare, (202) 245-0043, Policy Specialist, Office of Family Assistance, 2110 Switzer Building, 330 C Street, S.W., Washington, D.C. 20201.
SSA 72—Old Age, Survivors and Disability Insurance Programs; Time for Making of Social Security Contributions for Covered State and Local Employees, 20 CFR Part 404, Subpart M.	A. *Description.* These regulations change the rules governing the frequency with which States and interstate instrumentalities must deposit social security contributions on wages and salaries paid to covered employees. This new rule requires States and interstate instrumentalities to deposit contributions within 30 days after the end of each calendar month in which wages are paid. B. *Why Significant:* Regulations were scheduled to go into effect which would have required the States and interstate instrumentalities to deposit the social security contributions sooner than 30 days. Section 503 of the Social Security Disability Amendments of 1980 provided that 30 days would be the period within which these contributions must be deposited. These regulations reflect that amendment. C. *Regulatory Analysis:* Not required. D. *Need:* These regulations are required by the Social Security Disability Amendments of 1980. E. *Legal Basis.* Sections 205, 218, and 1102 of the Social Security Act. F. *Chronology:* Interim regulations were published on October 31, 1980 (45 FR 72110).	Armand Esposito, (301) 594-7455, Legal Assistant, Office of Regulations, 6401 Security Boulevard, Baltimore, MD 21235.

Office of Child Support Enforcement

OCSE-1—Office of Child Support Enforcement—Availability and Rate of Federal Financial Participation, 45 CFR Part 304.	A. *Description:* This final regulation will provide for Federal Financial Participation in the costs of child support enforcement services provided by State IV-D agencies to individuals who are not eligible for cash assistance under the Aid to Families with Dependent Children (AFDC) program between October 1, 1978 and March 31, 1980. B. *Why Significant:* This regulation will extend from September 30, 1978 to March 31, 1980. The Federal government's financial participation for State child support enforcement agencies expenses for services provided to non-AFDC families during the period October 1, 1978 through March 31, 1980. C. *Regulatory Analysis:* Not required. D. *Need:* P.L. 96-178, January 2, 1980 authorized a continuation of FFP for the non-AFDC program through March 31, 1980. E. *Legal Basis:* PL 96-178, 42 U.S.C. 652(a)	Mike Fitzgerald, (301) 443-5301, Program Analyst, Policy Branch, Office of Child Support Enforcement, 6110 Executive Blvd., Room 924, Rockville, MD 20852.
OCSE-2—Office of Child Support Enforcement—Strengthening of CSE, Audit and Penalty Regulations, 45 CFR Parts 301, 302, 304, and 305.	A. *Description:* These proposed regulations will revise, clarify, and strengthen the existing regulations which provide for an annual audit of the effectiveness of State Child Support Enforcement programs under Title IV-D of the Social Security Act. B. *Why Significant:* These regulations specify the Secretary's criteria for an effective program and are the basis for Federal audit and for reducing Federal funds for the Aid to Families with Dependent Children (AFDC) programs in States that fail to have an effective child support program. C. *Regulatory Analysis:* Not required. D. *Need:* These proposed regulations are the first step in OCSE's commitment to strengthen the Child Support Enforcement program audit and penalty regulations after obtaining additional program and audit experience. E. *Legal Basis:* 42 U.S.C. 1302 and 42 US.C 652(a). F. *Chronology:* A Notice of Decision to Develop Regulations was published on February 27, 1980 (45 FR 12857).	Maunce Huguley, (301) 443-5301, Legislation and Regulations Analyst, Policy Branch, Office of Child Support Enforcement, 6110 Executive Blvd. Room 924, Rockville, MD 20852.
OCSE-3—Office of Child Support Enforcement—Optional Procedures for Distribution of Child Support Collections (Immediate Distribution), 45 CFR Parts 302 and 304.	A. *Description:* These final regulations will permit State Child Support Enforcement agencies to distribute AFDC child support collections immediately upon receipt. In addition, they will provide these same agencies the option of using the current rate of FFP in their respective State's AFDC program to calculate the amount of each child support collection to be applied as reimbursement of the Federal government's share of AFDC payments. B. *Why Significant:* The revision of these regulations will provide significant administration benefits for the States that chocse to use them. C. *Regulatory Analysis:* Not required. D. *Need:* These regulations will permit more efficient State distribution procedures, will reduce an unwarranted administrative burden, and will make State IV-D programs more effective. E. *Legal Basis:* 42 U.S.C. 1302, 42 U.S.C. 652(a).	Frank Lindh, (301) 443-4276, Program Analyst, Policy Branch, Office of Child Support Enforcement, 6110 Executive Blvd., Room 924, Rockville, MD 20852.
OCSE-4—Office of Child Support Enforcement—OCSE Recodification, Phase I, 45 CFR Parts 302 and 304.	A. *Description:* These proposed regulations will reorganize and clarify several existing OCSE regulations including those on Distribution of Child Support Collections and the availability of Federal financial participation.	Steve Henigson (301) 443-4276, Chief, Policy Branch, Office of Child Support Enforcement, 6110 Executive Blvd., Room 924, Rockville, MD 20852.

Office of Child Support Enforcement—Continued

Title	Summary	Contact
	B. *Why Significant:* These proposed regulations will be written in simpler, clearer language as part of the Department's "Operation Common Sense" initiative. In addition, substantive policy changes will be proposed in the regulations regarding availability and restrictions on Federal Financial Participation and Internal Revenue Service collection. C. *Regulatory Analysis:* Not required. D. *Need:* These regulations are being rewritten to meet the Department's "Operation Common Sense" standards and to make substantive policy needed to improve the operation of the Child Support Enforcement program. E. *Legal Basis:* 42 U.S.C. 652(a). F. *Chronology:* A Notice of Intent to develop the proposed regulations was published on August 3, 1978 (43 FR 34164).	
OCSE-5—Office of Child Support Enforcement—OCSE Recodification, Phase II, 45 CFR Parts 302 and 303.	A. *Description:* These proposed regulations clarify and revise all existing OCSE regulations in Part 302 not included in the Phase I OCSE recodification. B. *Why Significant:* These proposed regulations will clarify existing regulations so as to make them more readily understandable. In addition, several substantive policy changes will be proposed in the regulations. C. *Regulatory Analysis:* Not required. D. *Need:* These regulations are being rewritten to meet the Department's "Operation Common Sense" standards and to make substantive policy needed to improve the operation of the Child Support Enforcement program. E. *Legal Basis:* 42 U.S.C. 652(a). F. *Chronology:* A Notice of Intent to develop the proposed regulations was published on August 3, 1978 (43 FR 34164).	Steve Henigson (301) 443-4276, Chief, Policy Branch, Office of Child Support Enforcement, 6110 Executive Blvd., Room 924, Rockville, MD 20852

Office of the Secretary

OS-1—HEW's Age Discrimination Regulations.	A. *Description:* These regulations prohibit age discrimination in programs and activities receiving financial assistance from HEW. B. *Why Significant:* Protects individuals from age discrimination in HEW-assisted programs and activities. C. *Regulatory Analysis:* Not required. D. *Need:* To implement requirements of the Age Discrimination Act and government-wide age discrimination regulations (45 CFR Part 90) which require agency specific age discrimination regulations. E. *Legal Basis:* Pub. L. 94-135; 42 U.S.C. 6101 *et seq.* 45 CFR Part 90 F. *Chronology:* Government-wide age discrimination regulations published by HEW on June 12, 1979 (45 CFR 33768); HEW's agency specific NPRM published September 24, 1979 (44 FR 55107). Comment period ended November 23, 1979 G. *Citation:* 45 CFR Part 91.	Bayla White, Director, Age Discrimination Task Force, (202) 245-6284, Room 716E 200 Independence Ave SW., Washington, D.C. 20201
OS-3—Privacy Act Regulation.....	A. *Description:* These regulations implement the Privacy Act of 1974 in HEW by establishing agency policies and procedures for the maintenance of systems of individually identifiable personal records. B. *Why Significant:* The revised regulation will improve HEW's service to the public by making it easier for citizens to understand the procedures for exercising their rights under the Privacy Act. C. *Need:* The proposed revision is necessary to comply with the Department's Operation Common Sense and the President's Executive Order No. 12044. Both of these initiatives require the Department to revise its regulations to be easier for the public to read and understand. E. *Legal Basis:* 5 U.S.C. 552a; 5 U.S.C. 301. F. *Chronology:* The Department published its original regulation in the FEDERAL REGISTER on October 8, 1975. G. *Citation:* 45 CFR Part 5b	Hugh V. O'Neill, (202) 245-7588, HEW Privacy Act Coordinator, Department of Health, Education, and Welfare, Room 526F, 200 Independence Ave. SW., Washington, D.C. 20201
OS-4—Department Staff Manual—Information Security Program; General Requirements: Handling, marking, transmitting, storing, and safeguarding of national security information.	A. *Description:* This manual would implement Executive Order 12065, National Security Information, by requiring each agency of the Department to comply with the provisions of the Order relating to the classification, downgrading, declassification and safeguarding of national security information. B. *Why Significant:* The manual would outline general responsibilities for Department officials and employees who would be concerned with national security information, and it further outlines procedures whereby a member of the public, a government employee or agency can request the declassification and release of information originally classified by the Department. C. *Regulatory Analysis:* "Yes, being conducted." D. *Need:* To implement the provisions of Executive Order 12065 by providing general policies and procedures for the protection of national security information that is under the control of the Department. E. *Legal Basis:* Executive Order 12065, published on July 3, 1978 (43 FR 28949) F. *Chronology:* Notice was published June 4, 1979, (44 FR 31981) Deletion of obsolete regulation; notice on availability of interim Department Security Manual. "Final Rule" currently under review	Kenneth E. Lopez, Director, Division of Security and Protection, Office of Investigations, Office of the Inspector General, Department of Health, Education, and Welfare, Room 5455, North Building, 330 Independence Avenue SW., Washington, D.C. 20201, telephone 202-245-6566
OS-5—Availability of Information to the Public	A. *Description:* This proposal would revise our rules for handling requests for information under the Freedom of Information Act. It tells how to make a Freedom of Information request, who can release information and who can decide not to release it; how much time it should take, how much we charge, and what can be done if we do not release information. B. *Why Significant:* Substantial interest is anticipated because the proposal amplifies and clarifies procedures for responding to public requests for information. C. *Regulatory Analysis:* Not required. D. *Need:* Recent court decisions and our experience since the last revision in 1974 require modifying our rules to implement the Freedom of Information Act. E. *Legal Basis:* 5 U.S.C. 552, U.S.C. 301, 42 U.S.C. 1306, and 31 U.S.C. 483a F. *Chronology:* Notice of intent to revise this regulation was published on November 18, 1978 (41 FR 50846). The comment period closed on January 17, 1977. The NPRM will have a comment period.	Russell M. Roberts, Freedom of Information Officer, Office of Public Affairs, HEW, Room 1181F, Humphrey Building, 200 Independence Avenue SW., Washington, D.C. 20201 472-7453
OS-6—Nondiscrimination on the Basis of Race, Color or National Origin Under Programs Receiving Federal Assistance Through the Department of Health and Human Services 45 CFR Part 80.	A. *Description:* These revised regulations carry out the provisions of Title VI of the Civil Rights Act of 1964 which prohibits discrimination on the basis of race, color or national origin in programs receiving federal financial assistance from the Department of Health and Human Services. B. *Why Significant:* The proposed regulations revise the Department's existing Title VI regulations to (1) delete references to programs now funded by the Department of Education, (2) add examples and provisions specific to programs funded by the Department of Health and Human Services, (3) incorporate suggestions from the Department of Justice under their Title VI coordination responsibilities, and (4) improve readability. C. *Regulatory Analysis:* Decision pending on completion of preliminary study	Brenda Kohn, Staff Attorney Office of the General Counsel, Civil Rights, Washington, D.C. 20201, 202-245-7420

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	D. *Need:* The Department is no longer responsible for programs transferred to the Department of Education. Examples and references to those programs are deleted in the revision, and more emphasis is put on health and human services issues and programs. In addition, the Department of Justice in a letter on March 3, 1980 proposed that specific changes be made in the regulations pursuant to 28 CFR 42.401–.415. Some of these proposals are included in the proposed revision. E. *Legal Basis:* Title VI of the Civil Rights Act of 1964, 42 U.S.C. 2000d *et seq.* F. *Chronology:* None	
OS-7—Publicizing "Adverse" Information.....	A. *Description:* This regulation has been rewritten and simplified to make it easier for people to understand how they can obtain a retraction or correction when HEW has issued an incorrect statement about them that adversely affects them. B. *Why Significant:* This regulation would clarify and simplify our policy and implement a recommendation of the Administrative Conference of the United States. C. *Regulatory Analysis:* Not required. D. *Need:* The regulation would implement a recommendation of the Administrative Conference of the United States and set out the rights of persons asking HHS to correct erroneous information and the limits on HHS employees in releasing "adverse" information. E. *Legal Basis:* 5 U.S.C. 301. F. *Chronology:* A proposed rule was published on February 19, 1980 (45 F.R. 10820). The comment period closed on April 21, 1980.	Russell M. Roberts, Office of Public Affairs, Room 118F, Humphrey Building, 200 Independence Avenue S.W., Washington, D.C. 20201, (202) 472-7453.
OS-8—Joint Recodification Project—AFDC, Adult Financial Assistance, Medicaid, Social Service Programs (SSA, HCFA, OHDS).	A. *Description:* These regulations will revise the requirements for State administration of the applications, eligibilty determinations and fair hearings procedures in the concerned programs. B. *Why Significant:* These regulations govern critical aspects of State procedures that directly affect individuals and families seeking and receiving assistance in all the States and territories. C. *Regulatory Analysis:* A threshold study is being prepared. D. *Need:* To clarify requirements, and to establish coordinated procedures in order to simplify administration in the States and territories. E. *Legal Basis:* Sections 2(a)(8), 402(a)(10), 1002(a)(11), 1102, 1402(a)(10), 1602(a)(8), (AABD) and 1902(a)(8) of the Social Security Act. F. *Chronology:* A Notice of Decision to Develop Regulations was published March 19, 1979 at 44 F.R. 16449.	Terry Bancroft Dowd, Deputy General Counsel for Regulatory Review, Coordinator-Joint Recodification Task Force, (202) 245-6733, Office of the General Counsel, HHS, Room 706.E, 200 Independence Avenue, S.W., Washington, D.C. 20201
OS-9—Department of Health and Human Services Standards of Conduct.	A. *Description:* These regulations are a revision of the Department of Health and Human Services (HHS) standards of conduct. They are issued to tell HHS employees and special Government employees what standards of conduct are expected of them in performing their duties and what activities are permitted or prohibited both while they are employed and after their employment with HHS ends. B. *Why Significant:* This is the first major revision of the Standards since 1966. C. *Regulatory Analysis:* Not required. D. *Need:* Revisions ae needed to include new requirements of law and/or policy, to clarify existing provisions and to give exampls to help officials who must apply the regulations. E. *Legal Basis:* 5 CFR Part 735. F. *Chronolgy:* None.	Ms. Florence Perman, Director, Division of Personnel Policy, Office of the Assistant Secetary for Personnel Administration, Department of Health and Human Services, Room 2314, Switzer Building, 330 Independence Avenue, S.W., Washinglon, D.C. 20201.
OS-10—Cost Principles for Nonprofit Organizations	A. *Description:* Amendment to HHS general grants administration regulation to implement OMB Circular A-122, Cost Principles for Non-profit organizations. B. *Why significant:* Amendment would implement Government-wide cost principles and further the objective of having consistent rules for Federal grantees. C. *Regulatory Analysis.* Not required. D. *Need:* Required to comply with OMB directive. E. *Legal Besis:* 5 USC 301. F. *Chronology:* None	Gary Talesnik, Office of Grant and Contract Financial Management, Room 533-H, Humphrey Bldg., 200 Independanoe Avenue, S.W., Washington, D.C. 20201, 202-245-8771.
OS-11—Cost Allocation Plans for Public Assistance Programs.	A. *Description:* Revision and consolidation of current program regulations on submission and approval of cost allocation plans used by State agencies to claim aministrative costs on public assistance programs (e.g., Medicaid, AFDC, etc.). B. *Why significant:* Regulation would provide comprehensive guidance on the submission and approval of cost allocation plans required to claim administrative costs on all HHS financed public assistance programs. C. *Regulatory Analysis.* Not required. D. *Need:* To clarify requirements, eliminate duplicative coverage in individual program regulations, provide more definitive guidance, and simplify appeals procedures related to "cross-cutting" cost disallowances. E. *Legal Basis:* Sec. 1102, 49 Stat. 647, 42 U.S.C. 1302. F. *Chronology:* None.	Edward Tracy, Office of Grant and Contract Financial Management, Room 533-H, Humphrey Bldg., 200 Independance Avenue, S.W., Washington, D.C. 20201, 202-755-7633.
OS-12—Equipment Acquired Under Public Assistance Programs.	A. *Description:* Revision and consolidation of current program regulations on the allowability of equipment costs under public assistance programs (e.g., Medicaid, AFDC, etc.) and on the management and disposition of equipment under the programs. B. *Why significant:* Regulation would substantially liberalize and simplify current regulations on this subject. C. *Regulatory Analysis.* Not required. D. *Need:* To establish a more realistic threshold for determining whether equipment costs can be claimed at the time of purchase or must be depreciated. Also needed to eliminate duplicative coverage in individual program regulations, and to simplify and clarify regulations. E. *Legal Basis:* Sec. 1102, 49 Stat. 647, 42 U.S.C. 1302. F. *Chronology:* None.	Edward Tracy, Office of Grant and Contract Financial Management, Room 533-H, Humphrey Bldg., 200 Independance Avenue, S.W., Washington, D.C. 20201. 202-755-7633.
OS-13—Administration of Grants, 45 CFR Part 74	A. *Description:* These amendments will transfer certain policies contained in the Department's Grants Administration Manual to the HHS grants administration regulation. Miscellaneous clarifications and refinements of current provisions of the regulation will also be made. B. *Why Significant.* This action will secure public participation in the making of grant administration rules which have previously been adopted without public comment. The change will also simplify administrative burdens on grantees who deal with more than one HHS granting agency. C. *Regulation Analysis:* Not required. D. *Need:* The regulation will reduce burdens on grantees, and eliminate the need for HHS granting agencies to publish implementation of many policies in the Grants Administration Manual. E. *Legal Basis:* Sec. U.S.C. 301. F. *Chronology:* None.	Matthias Lasker, Director, Division of Grants Policy and Regulations Development, OGP, Room 513D, Humphrey Bldg. 200 Independence Avenue, S.W., Washington, D.C. 20201, 202-245-7565.

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OS–14—Personnel Administration Requirements of Grants to State and Local Governments.	A. *Description:* This regulation would require that all State and local government recipients of HHS mandatory (formula) grants adopt a merit system of personnel administration for the employees who administer or carry out the grant program. B. *Why Significant:* Similar requirements now exist in a number of HHS mandatory (formula) grant program. This regulation would extend the requirement to all such programs. C. *Regulatory Analysis:* Not required. D. *Need:* Carries out the intent of Congress as set forth in the Intergovernmental Personnel Act of 1970 and the Civil Service Reform Act of 1978. E. *Legal Basis:* Above-cited legislation. F. *Chronology:* None.	Matthias Lasker, Director, Division of Grants Policy and Regulations Development, OGP, Room 513D, Humphrey Bldg 200 Independence Avenue, S.W., Washington, D.C. 20201, 202–245–7565.

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