prepared for a proposed highway project in the city of Beckley, Raleigh County, West Virginia.

FOR FURTHER INFORMATION CONTACT: Mr. David Price, Environmental and Highway Safety Engineer, Federal Highway Administration, 550 Eagan Street, Charleston, West Virginia 25301. Telephone (304) 348–2067, (FTS: 924–1207.

SUPPLEMENTARY INFORMATION: The FHWA, in cooperation with the WVDOH, will prepare an environmental impact statement (EIS) on a proposal to improve 1.4 miles of WVA 16 (North Valley Drive) in Beckley, West Virgina. The proposed improvement involves the reconstruction and widening of the existing WVA 16 from Raleigh County 6 (Ewart Avenue) to U.S. Route 19 (North Eisenhower Drive). WVA 16. serves as a major north-south route through the city as well as linking the downtown area with the shopping mall and residential developments north of the city. The section of highway under study can no longer accommodate current traffic volumes safely and efficiently.

Alternatives under consideration include: (1) taking no action; (2) widening the existing two-lane highway to five lanes by equal widening on each side; and (3) widening the existing two-lane highway to five lanes by alternating widening on each side (two alternatives). The action alternatives will have varying degrees of social, economic and environmental impacts. Potential impacts include relocation of businesses and residences, stream involvement and increase in noise levels.

A public involvement meeting has been held to solicit input on the proposed alignments. Letters describing the proposed action and soliciting comments will be sent to appropriate Federal, State, and local agencies. Copies of the draft EIS will be sent to appropriate Federal, State, and local agencies, and to private organizations and citizens who have previously expressed interest in the proposal. In addition, a public hearing will be held. Public notice will be given of the time and place of the hearing. No formal scoping meeting is planned at this time.

To ensure that the full range of issues related to this proposed action are addressed and all significant issues identified, comments and suggestions are invited from all interested parties. Comments or questions concerning this proposed action and the EIS should be directed to the FHWA at the address provided above.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Research, Planning and Construction. The provisions of OMB Circular No. A-95 regarding State and local clearinghouse review of Federal and federally assisted programs and projects apply to this program)

Issued on: April 21, 1981.

David Price,

Environmental and Highway Safety Engineer, Charleston, West Virginia.

[FR Doc. 81–12750 Filed 4–29–81; 8:45 am]

BILLING CODE 4910–22–M

Environmental Impact Statement: Quincy, Illinois and Marion County, Missouri

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of intent.

SUMMARY: The FHWA is issuing this notice to advise the public that an environmental impact statement will be prepared for a proposed replacement or rehabilitation of the existing two lane U.S. Route 24 Mississippi River Bridge at Quincy, Illinois, commonly none as the Quincy Memorial Bridge. The proposed project also includes associated roadway improvements in Illinois and Missouri. The FHWA and the Illinois Department of Transportation will act as lead agencies. The Missouri State Highway and Transportation Department will act as a cooperating agency.

FOR FURTHER INFORMATION CONTACT:

Mr. Lionel Wood, Staff Specialist for Environment, Federal Highway Administration, 320 W. Washington Street, 7th Floor, Springfield, Illinois 62701, phone (217) 492–4600

W. E. Burns, District Engineer, Illinois Department of Transportation, 126 East Ash Street, Springfield, Illinois 62706, Phone (217) 782–7301

SUPPLEMENTARY INFORMATION: The proposed action would consist of constucting 2- or 4-lane approaches to the Mississippi River Bridge from U.S. 24 (3rd & 4th Streets) in Quincy to the U.S. 61–24 interchange just east of Taylor, Missouri, a distance of approximately 5 miles. This proposed improvement will replace or rehabilitate a functionally and structurally deficient bridge, provide additional bridge traffic lanes for capacity, improve traffic conditions in Quincy, and improve the economic growth and development potential in the Quincy area.

Alternatives under consideration for this project include:

1. Widen only the traffic lanes on the existing bridge.

Construct a new 2-lane bridge three blocks north of the existing bridge (Broadway St. in Quincy) for one-way westbound traffic, and increase the lane widths of the existing 2-lane bridge for one-way eastbound traffic. Existing U.S. 24 would be improved to 4 lanes to the U.S. 61 and 24 interchange just east of Taylor, Missouri.

3. Construct a new 4-lane bridge from three blocks north of the existing bridge (Broadway St. in Quincy), to U.S. 24 just east of West Quincy, Missouri, and improve existing U.S. 24 to 4 lanes to the U.S. 61 & 24 interchange just east of Taylor, Missouri. The existing bridge would be removed with this alternative.

4. Construct a new 4-lane bridge and roadway from three blocks north of the existing bridge (Broadway St. in Quincy), to north of West Quincy, Missouri, and parallel to the Burlington Northern Railroad tracks to the U.S. 61 & 24 interchange just east of Taylor, Missouri. The existing bridge would be removed with this alternative.

5. Construct a 2- or 4-lane bridge from fifteen blocks north of the existing bridge (Locust St. in Quincy) parallel to and south of the Burlington Northern Railroad tracks to the U.S. 61 & 24 interchange just east of Taylor, Missouri; or connect into U.S. 24 just west of West Quincy and continue construction of 4 lanes to the U.S. 61 and 24 interchange just east of Taylor, Missouri. The existing bridge would remain in place with this alternative.

6. No build.

Possible environmental effects associated with this project include conversion of up to 30 acres of prime farmland and 18 acres of wetlands. Properties protected by Section 4(f) of the DOT Act may be affected and floodplain encroachments may occur. Endangered species habitat may also be affected. Displacements of 1 home, and up to 5 businesses may also result.

The scoping process will be achieved by review and comment on a scoping document that has been prepared by the Federal Highway Administration, Illinois Department of Transportation and Missouri Highway and Transportation Department. The scoping document will be sent to the Department of Interior, U.S. Fish and Wildlife Service, Department of Housing and Urban Development, Department of Agriculture, U.S. Environmental Protection Agency, National Park Service, U.S. Coast Guard and the U.S. Army Corps of Engineers. State and local agencies in Illinois and Missouri will also have an opportunity to review and comment on the scoping document. Other interested parties may obtain copies of the scoping document from the contact persons listed in this notice. A notice announcing the availability of the

scoping document will be published in local newspapers.

A formal scoping meeting will not be held for the proposed action.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Research, Planning and Construction. The provisions of OMB Circular No. A-19 regarding State and local clearinghouse review of Federal and federally assisted programs and projects apply to this program.)

Issued on: April 23, 1981.

Lionel H. Wood,

Staff Specialist for Environment, Federal Highway Administration.

[FR Doc. 81-12941 Filed 4-29-81; 8:45 am]

BILLING CODE 4910-22-M

Environmental Impact Statement; Clark County, Nev.

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of Intent.

SUMMARY: The FHWA is issuing this notice to advise the public that an environmental impact statement will be prepared for a proposed highway project in Clark County, Nevada.

FOR FURTHER INFORMATION CONTACT: A. J. Horner, Division Administrator, Federal Highway Administration, 1050 East William Street, Suite 300, Carson City, Nevada 89701, Telephone: (702) 885-5320, or J. J. King, Supervisor, Roadside Development and Environmental Services, Nevada Department of Transportation, 1263 South Stewart Street, Carson City, Nevada 89712, Telephone: (702) 885-5680.

SUPPLEMENTARY INFORMATION: The FHWA, in cooperation with the Nevada Department of Transportation (NDOT), will prepare an environmental impact statement (EIS) on a proposed improvement to U.S. 93 in Clark County, Nevada. The porposed improvement involves the reconstruction and widening of the existing U.S. 93 from the southern intersection of U.S. 3 with S.R. 500 (in Boulder City) northeasterly for a distance of approximately four miles. Also included in the proposed project is the reconstruction of both intersections of U.S. 93 with S.R. 500. Improvements to this highway are considered necessary to provide for the safe movement of the existing and projected traffic demand.

Alternatives under consideration include (1) taking no action, and (2) reconstruction and widening of the existing U.S. 93 to a two-lane highway with climbing lane and the reconstruction of both intersections of U.S. 93 with S.R. 500. There are several alternative designs for each intersection.

Letters describing the proposed project and soliciting comments will be sent to appropriate Federal, State, and local agencies as well as interested private organizations and individuals. In addition, a public informational meeting will be held May 19, 1981, in the Boulder City Council Chambers to provide general information about the project and solicit public reaction and comment. No formal scoping meeting is planned.

To ensure that the full range of issues related to this proposed action are addressed and all significant issues identified, comments and suggestions are invited from all interested parties. Comments, suggestions, or questions concerning this proposed action and the EIS should be directed to the FHWA or NDOT at the addresses provided above.

Dated: April 20, 1981.

A. J. Horner,

Division Administrator, Carson City, Nevada.

[FR Doc. 81-13071 Filed 4-29-81; 8:45 am]

BILLING CODE 4910-22-M

Federal Railroad Administration

[FRA Waiver Petition Docket HS-81-5]

Aroostook Valley Railroad Co.; Petition for Exemption From the Hours of Service Act

In accordance with 49 CFR 211.41 and § 211.9, notice is hereby given that the Aroostook Valley Railroad (AVR) has petitioned the Federal Railroad Administration (FRA) for an exemption from the Hours of Service Act (83 Stat. 464, Pub. L. 91-169, 45 U.S.C. 64a(e)). That petition requests that the AVR be granted authority to permit certain employees to continuously remain on duty for in excess of twelve hours.

The Hours of Service Act currently makes it unlawful for a railroad to require or permit specified employees to continuously remain on duty for a period in excess of twelve hours. However, the Hours of Service Act contains a provision that permits a railroad, which employs no more than fifteen employees who are subject to the statute, to seek an exemption from this twelve hour limitation.

The AVR seeks this exemption so that it can permit certain employees to remain continuously on duty for periods not to exceed sixteen hours. The petitioner indicates that granting this exemption is in the public interest and will not adversely affect safety. Additionally, the petitioner asserts that it employs no more than fifteen employees and has demonstrated good cause for granting this exemption.

Interested persons are invited to participate in this proceeding by submitting written views or comments. FRA has not scheduled an opportunity for oral comment since the facts do not appear to warrant it. Communications concerning this proceeding should identify the Docket Number, Docket Number HS-81-5, and must be submitted in triplicate to the Docket Clerk, Office of the Chief Counsel, Federal Railroad Administration, Nassif Building, 400 Seventh Street, SW, Washington, D.C. 20590. Communications received before May 25, 1981, will be considered by the FRA before final action is taken. Comments received after that date will be considered as far as practicable. All comments received will be available for examination both before and after the closing date for comments, during regular business hours in Room 8211, Nassif Building, 400 Seventh Street, SW, Washington, D.C. 20590.

(Sec. 5 of the Hours of Service Act of 1969 (45 U.S.C. 64a), 1.49(d)) of the regulations of the Office of the Secretary, 49 CFR 1.49(d)

Issued in Washington, D.C. on April 10, 1981.

Joseph W. Walsh,

Chairman, Railroad Safety Board.

[FR Doc. 81-12760 Filed 4-29-81; 8:45 am]

BILLING CODE 4910-06-M

DEPARTMENT OF THE TREASURY

Customs Service

[T.D. 81-94]

Tariff Classification; Region II Ruling Program; Manual Supplement 2300-09; Guidelines for Issuance of Selected Tariff Classification Rulings

Reproduced below is the text of Manual Supplement 2300-09, dated February 6, 1981, which relates to the issuance of selected tariff Classification rulings by the Regional Commissioner of Customs, Region II (New York).

Under T.D. 80-285 (45 FR 80100), which established the Region II Ruling Program, recipients of rulings from Region II are given the right to appeal those rulings to Customs Headquarters in Washington, D.C. Such appeals must be made promptly, following the procedures set forth in Section 5 of

Manual Supplement 2300–09, as set forth below.

John T. Roth,

Acting Director, Classification and Value Division.

April 15, 1981.

1. Purpose

This Manual Supplement sets forth the guidelines to be used in selecting the tariff classification ruling requests to be acted upon by Region II and in selecting those to be referred to Headquarters for action. These guidelines also cover the circumstances when Headquarters will refer tariff classification ruling requests to Region II for action. Information is also included in this Manual Supplement concerning appeals from Region II rulings, Headquarters' review of Region II rulings for which publication is proposed, and the monitoring of Region II rulings generally for consistency with the law, the regulations, and administrative and judicial precedents.

2. Background

On December 3, 1980, T.D. 80–285 was published in the **Federal Register** (45 FR 80100) amending Part 177 of the Customs Regulations (19 CFR Part 177) to authorize the Regional Commissioner, New York (Region II), to issue selected tariff classification rulings. These amendments became effective on January 2, 1981. As noted in the explanatory material contained in T.D. 80–285, the Director, Classification and Value Division, Headquarters, has the responsibility for issuing the guidelines to be used by the Regional Commissioner in determining the ruling requests to be acted upon by Region II and those which should be referred to Headquarters for action. The Director, Classification and Value Division, will monitor the rulings issued by Region II for compliance with the law, regulations, and applicable precedents. Region II rulings which are recommended by the Regional Commissioner for publication will be reviewed by Headquarters prior to publication.

3. Action

The following guidelines will be used in identifying the tariff classification ruling requests to be acted upon by Region II, whether received in New York or at Headquarters. The guidelines also provide for the handling of appeals of rulings issued by Region II, for the monitoring by Headquarters of Region II rulings, and for the review of rulings issued by Region II which are recommended for publication in the Customs Bulletin.

These guidelines will apply only with respect to requests for tariff classification rulings which are received on or after January 2, 1981. Requests for rulings received prior to that date will be processed by Headquarters.

4. Guidelines for the Issuance of Tariff Classification Rulings by Region II

The authority delegated to Region II by T.D. 80–285 extends only to rulings requested with respect to prospective transactions. The transactions for which rulings are requested involve many specialty areas, many types of ruling applicants and correspondents, and an infinite variety of fact patterns. Some of the requests received by Region II will be readily identifiable as items appropriately ruled upon or otherwise acted upon by Region II. Other requests will be more complex, often involving issues other than those specifically set forth in the request. Whether these requests should be selected for Region II action or referred to Headquarters will be determined by application of the guidelines set forth below and the exercise of good judgment.

It is likely that Region II will receive correspondence which does not require a ruling by either Region II or Headquarters, such as inquires involving pending transactions. These items should be referred by Region II directly to the port or district where the transaction is pending for reply (or processing in accordance with the internal advice procedures, if applicable). In such instances, the correspondent will be notified of the referral.

Headquarters' experience with the administrative rulings program indicates that tariff classification ruling requests are likely to fall into one of 14 categories, as described below in paragraphs A through N. Requests in certain of the categories will be handled exclusively by Region II, while requests which fall into other categories will be processed solely by Headquarters. In the remaining categories, however, a determination of the proper office to handle the request must be made using the guidelines provided.

A. *Inquires Answerable by Information Letters.* Any ruling request or inquiry which would be answered best by an information letter, as defined in section 177.1(d)(2) of the Customs Regulations (19 CFR 177.1(d)(2)), will be acted upon by Region II. Letters of this nature received by Headquarters will be referred to Region II for reply.

B. *Ruling Requests in Which No Issues Are Raised.* In this category of ruling requests, the correspondent will make no classification claims or claims for exemptions, or otherwise offer any specific suggestions as to how the request should be answered. The classifications in this category of requests will be arrived at by routine applications of the language of specific provisions or pertinent headnotes or of other fundamental rules of construction. This category of ruling requests will be acted upon by Region II unless action by Headquarters would be appropriate under one or more of the guidelines set forth below.

C. *Ruling Requests Involving Unsupported Classification Claims.* Requests in this category will be similar in complexity to those requests where no claims are made, except that the claims which are made will be frivolous or otherwise based on contentions patently lacking in merit. Correspondence of this nature will often be from businessmen, tourists, or other correspondence showing an obvious unfamiliarity with classification principles. An example of this type of inquirty could be one in which the correspondent seeks to avoid a specific higher-rate provision in favor of a free-rate or lower-rate basket provision in the interest of "national trade policy" or other reasons clearly frivolous and not pertinent to the classification of the merchandise. This category of ruling requests will be acted upon by Region II unless bona fide issues warranting Headquarters' attention are raised. In this regard, it should be noted that the fact that the ruling request is from a customhouse broker or other correspondent for whom customs expertise may be presumed would not in itself remove a case from this category or from handling by Region II. However, requests which raise real social or economic issues should be referred to Headquarters under paragraph L, below.

D. *Ruling Requests Involving a Uniform Classification Practice.* Any ruling request which alleges the existence of a uniform and established classification practice based on liquidations, or which will result in a classification based on uniform liquidations rather than on the normal application of the tariff schedules, the headnotes, or the usual rules of construction will be referred to Headquarters for action.

E. *Ruling Requests Involving Special Tariff Classification Provisions.* Ruling requests which involve the entitlement to a conditional exemption from duty under any special tariff classification provisions will be referred to Headquarters for action unless it merely involves technical details concerning a prospective exemption claim normally handled locally. For examply, if the requirements of a specific port

concerning the filing of documentation or other evidence of entitlement are at issue, the matter will be referred to that port for action. Among the ruling in this category warranting Headquarters' attention are those which present such issues as substantial transformation, advancement in condition, further fabrication, diplomatic courtesy, application of the Florence Agreement, or other substantive issues relating the entitlement to free-rate provisions in Schedule 8, TSUS, the Generalized System of Preferences, or any other conditional exemption or special provision.

F. *Ruling Requests Involving Inconsistent Precedents.* Any ruling request concerning a tariff classification to which two or more precedents are pertinent, whether administrative or judicial, *and the precedents are in any material respect inconsistent,* will be referred for Headquarters' action. This guideline applies even when one or more the precedents is a Region II ruling. For further instructions regarding requests involving the application of judicial precedents, see paragraph K, below.

G. *Ruling Requests Involving Reconsiderations.* Any ruling request in which a reconsideration of a ruling (whether issued by Headquarters or Region II) is requested, or any matter which involves a pertinent administrative precedent which Region II believes should be reconsidered, will be referred to Headquarters. However, correspondence in which a reconsideration of a Region II ruling is requested *from Region II,* as opposed to Headquarters (see Section 5, below), will not be referred to Headquarters unless (1) the submission of new material or information makes the referral to Headquarters appropriate under another guideline, or (2) Region II believes that favorable action on the request (*i.e.*, modification or reversal of the earlier Region II ruling) is appropriate. Whenever requests for reconsideration are not referred to Headquarters, the correspondent will be advised of the right to appeal or protest.

H. *Ruling Requests Involving Issues of Fact.* Ruling requests involving bona fide issues of fact will be referred to Headquarters for action. The "issues of fact" contemplated by this guideline are present in those ruling requests where there is a conflict in the evidence present in the materials in the case file, or where the evidence present may be in conflict with information available from reliable secondary sources. For example, a bona fide issue of fact exists (1) if a ruling request includes a private laboratory analysis which is at variance with an official Customs Laboratory report, or (2) if information furnished by the party requesting the ruling is contradicted by information found in pertinent trade media. An issue of fact does not exist because the record is incomplete or pertinent facts or information is not known (for whatever reason). Similarly, an issue of fact does not exist because of bare allegations as to the existence of such an issue and does not result from the presentation of nonauthoritative evidence regarding the facts.

I. *Ruling Requests Presenting Multiple Issues.* Ruling requests involving merchandise where the tariff classification is contingent upon a determination outside the tariff classification area, such as valuation or appraisement, will be referred to Headquarters. However, a peacemeal disposition of the ruling request would be appropriate when the multiple issues presented are clearly separable. In such a situation, Region II will respond to the classification aspect(s) and would advise the party making the request that the balance of the issues presented have been referred to Headquarters for separate reply.

Ruling requests which might be considered to be of a "multi-issue" type because different types of merchandise are involved will be handled by Region II if they otherwise qualify. In appropriate circumstances, parties requesting rulings will be informed that the Customs Service cannot classify all of the items in a catalog or a lengthy list of items; in such cases, an effort will be made to furnish those parties with as much useful information as it is practical to furnish.

J. *Ruling Requests Containing Legal Briefs.* Some requests for rulings, particularly those submitted on behalf of importers or other interested parties by attorneys, may contain sophisticated arguments, advocating the application of a particular tariff provision, precedent, or concept. Ruling requests of this type will generally be acted upon by Headquarters. Region II should refer such requests to Headquarters unless it concludes (1) that *both* the arguments contained in the request, and the tariff classification advocated, are correct, and (2) that such conclusions are supported by uniform precedents and would have been reached by Region II notwithstanding the arguments made in the request.

K. *Ruling Requests Involving the Application of Judicial Precedents.* While one of the purposes of the Region II ruling program is to utilize the National Import Specialists' knowledge of legal precedents pertinent to the classification of merchandise, this resource will only be used to apply judicial precedents which are pertinent because the merchandise which was the subject of the precedent litigation was the same or similar to the merchandise to be ruled upon. However, a ruling request which seeks the application of legal precedents to merchandise of a different class or kind than that involved in the precedents will be referred to Headquarters for a decision. Any classification requiring the application of rules of construction, whether found in headnotes, judicial precedents, or elsewhere, will be referred to Headquarters whenever the application of two or more of such rules produces results that are inconsistent or when, in determining relative specificity, the application of the rules appears to produce ambiguous, impractical, unreasonable, or illogical results.

L. *Ruling Requests Having the Potential for Unusual Social or Economic Impact.* Ruling requests having the potential for unusual social or economic impact, or the potential for national publicity, will be referred to Headquarters for action. This category of cases may include matters where there is special public attention or interest, matters involving international trade organizations or foreign governments, or matters where Customs' action may be of interest to other Government agencies having responsibilities in the area of national trade policy.

M. *Pending Issues.* Region II will issue no rulings on issues which, to Region II's knowledge, the ruling applicant has pending in the form of an appeal, protest, or request for internal advice, or before the U.S. Court of International Trade or any other court. Unless the referral of correspondence of this type to Headquarters would serve some useful purpose, Region II will prepare a brief response to the ruling applicant explaining that a ruling on the issue(s) raised cannot be furnished because of the pendency of the related matter(s). A copy of that response, together with the incoming correspondence, will be forwarded to each office holding the primary file(s) in the pending matter(s) in order that a complete record of the matter may be maintained in the event of litigation.

N. *Other Ruling Requests.* In general, those ruling requests which are not disposed of by application of the foregoing guidelines will be handled by Headquarters. However, in distinguishing between matters which can be effectively acted upon by Region

II and those which are more appropriately handled by Headquarters, it should be borne in mind that the Region II rulings program seeks to utilize the expertise of the National Import Specialists in responding to classification inquiries or ruling requests *which involve well-settled areas or issues easily resolved by reference to precedents.* Ideally, this will permit Headquarters to concentrate its efforts on those matters in which its expertise may best be utilized, including the more complex ruling requests, ruling requests involving novel issues, and other matters which Headquarters action is required by law or regulations.

However, Region II should not fail to consider acting on a ruling request simply because the issues raised are complex or new. Similarly, Region II will not be disqualified from responding to a matter because its consideration of the issue would have been precluded had it been raised in connection with an application for internal advice or in connection with a request for further review of a protest.

It is anticipated that most ruling requests raising issues of the degree of complexity warranting Headquarters attention will be submitted by professionals or experts in various aspects of importing or international trade who will be aware of the option of submitting their presentations to Headquarters, rather than to Region II, and will do so.

5. Appeals

Under T.D. 80–285, recipients of rulings from Region II are given the right to appeal those rulings to Headquarters. The regulations provide no time limit for the filing of that appeal. However, it is possible that between the time when a ruling has been issued and the time the appeal is filed the status of the transaction covered by the ruling may change. Those changes may affect the treatment of the appeal.

When the merchandise has been entered, the entry has been liquidated in accordance with a Region II ruling, and the time for filing a protest has not elapsed, Headquarters will only consider an appeal of that ruling as an adjunct to the protest procedures, as explained below. To provide a separate, direct appeal to the Headquarters in those circumstances could mislead the appellant as to the finality of the liquidation and the necessity to file a timely protest in order to preserve the required standing to sue the Government.

While the status of the transaction to which the Region II ruling relates remains prospective, the ruling may be appealed directly to Headquarters. If the status of the transaction changes from prospective to ongoing after such an appeal if filed, the appellant should provide the port having jurisdiction over the transaction with a copy of both the Region II ruling and the appeal, in order that liquidation can be suspended pending Headquarters action on the appeal.

When the appeal is filed after the status of the transaction has changed from prospective to either ongoing (*i.e.*, the merchandise covered by the ruling has arrived in the U.S., but the entry has not been liquidated) or completed (the entry has been liquidated), the following procedures will be observed:

A. *Appeals Before Liquidation.* When a recipient of a Region II ruling appeals that ruling to Headquarters prior to liquidation of the merchandise covered by that ruling, Headquarters will unconditionally grant the requested review of that ruling. A copy of the Region II ruling and the appeal should be filed by the appellant with the port having jurisdiction over the transaction in order that liquidation of the entry or entries involved can be suspended pending completion of Headquarters' review of the ruling. Although such an appeal may not be properly the subject to a request for internal advice under section 177.11(b)(ii) of the Customs Regulations (19 CFR 77.11(b)(ii)), Headquarters will accord such appeals the same priority status.

D. *Appeals After Liquidation, but Before Liquidation Is Final.* When the transaction to which the Region II ruling relates has been liquidated in accordance with that ruling, but the liquidation has not become final, the proper avenue of appeal of that ruling to Headquarters is through the protest procedures set forth in Part 174 of the Customs Regulations (19 CFR Part 174). When a port or district receives a protest of a Region II ruling, it shall forward the protest and its recommendations to Headquarters for review. Upon completion of the review by Headquarters, which shall be coordinated with Region II, the protest and other documents shall be returned to the port or district together with instructions for the disposition of the protest. The Region II ruling will be modified or reversed, if appropriate.

C. *Appeals After Liquidation Is Final.* When the transaction to which the Region II ruling relates has been liquidated in accordance with that ruling, and that liquidation has become final, an appeal of that ruling must be considered moot. The review of a Region II ruling in those circumstances would serve no purpose in view of the finality of the liquidation. However, if the appellant continues to qualify for a ruling because there will be further prospective transactions, the appeal will be handled in the same manner as an original request for a ruling. In the event that the claims made are sustained and a modification or reversal of the earlier ruling is obtained, the appellant will be advised that the new ruling will not be applicable to any liquidations which have become final, but will only apply to future importations.

6. Recordkeeping, Publication, and Monitoring

Region II will retain the files for all matters it handles. Complete records will be kept primarily to have the necessary records available for transfer to the U.S. Court of International Trade in the event a Region II ruling (or the failure of Region II to rule) becomes the subject of litigation. In this connection, procedures similar to those now in effect at Headquarters will be observed with respect to maintaining reports or memorandums of all telephone contacts or conferences preceding the issuance of a ruling (to the extent that such contacts or conferences provide *factual* information on which the ultimate ruling is based). In some instances, the complete Region II ruling file (including samples, exhibits, laboratory reports, and other pertinent materials) may be requested by Headquarters in connection with a formal or informal review of the ruling. See Section 5.A. and B., above.

Region II will assign to every inquiry it handles under Part 177 of the Customs Regulations and these guidelines a 6-digit control number beginning with 800000. Copies in triplicate of all Region II rulings will be forwarded to the Director, Classification and Value Division, at Headquarters, together with an "Office of Regulations and Rulings Publication Determination" form, within 30 days of issuance. Region II's recommendations as to publication will be set forth on the latter form and will be reviewed, together with the ruling, by Headquarters. A Keyword Precedent Report for each Region II ruling will be completed by Headquarters.

7. Effect on Other Procedures

The relationship between the Region II ruling program and the Headquarters appellate procedures, and the protest review and internal advice programs, is explained in Sections 4 and 5, above. See Sections 5 and 6 for further information concerning the relationship of the Region II ruling program to the litigation process.

Nothing in these guidelines should be construed as curtailing in any way the normal accessibility of Headquarters personnel for advice and counsel.

8. Expiration Date

This Manual Supplement will expire upon the incorporation of the guidelines contained herein in P&PM 2300.

[FR Doc. 81-12802 Filed 4-29-81; 8:45 am]
BILLING CODE 4810-22-M

VETERANS ADMINISTRATION

Calendar of Significant Information Collections

AGENCY: Veterans Administration.

ACTION: Notice.

SUMMARY: In order to inform the public of the most important upcoming infomation collections, the Veterans Administration (VA) is publishing a calendar list of significat information collections for the next 12 months. The calendar has been developed in conformance with a memorandum request from the Office of Management and Budget dated January 12, 1981, under the provisions of E.O. 12174, "Paperwork". The calendar contains all significant information collections proposed to be introduced, those subject to revision and those not previously approved by the Office of Management and Budget. The VA considers an information collection request significant if it has the following qualities: Subsatntail program or policy importance, cost to the government, and burden on the public (e.g., requires 250,000 or more persons to report or maintain specific records, has an annual estimated burden of more than 100,000 hours, has an estimated burden of more than two hours per respondent per year).

FOR FURTHER INFORMATION CONTACT: R. C. Whitt, Agency Clearance Officer, Management Services (62), 810 Vermont Avenue, N.W., Washington, D.C. 20420 (202) 389-2386. Requests for copies of proposed forms, supporting documents, and comments and questions about the items on the calendar should be directed to the above address.

SUPPLEMENTARY INFORMATION: Each entry to the calendar contains the following information:

The title of the form;

OMB approval number (if any);

Agency form number(s) (if any);

The purpose of the information collection;

Who will be required or asked to report;

The Standard Industrial Classification Codes (SIC) referring to specific respondent groups that are affected;

Whether small businesses or organizations are affected;

An estimate of the number of responses;

An estimate of the total number of burden hours (per FY for a 3 year period);

How often the form will be filled out;

Whether the collection is voluntary, mandatory, or required to obtain a benefit;

An estimate of the cost to the Federal Government; and

An abstract describing the need for ans uses of the information collection.

Approved: April 20, 1981.

Rufus H. Wilson,

Acting Administrator.

Calendar of Significant Information Collection Items

(1) *Request for Determination of Eligibility and Available Loan Guaranty*

OMB No. 2900-0086.

VA Form 26-1880.

Application for benefits.

Individuals.

SIC: Not applicable.

Not used for small businesses.

500,000 responses.

125,000 burden hours.

On occasion.

Required to obtain benefit.

$3,655,000 Federal cost.

Serves as veteran's application for certificate of eligibility for home loan benefits authorized by 38 U.S.C., chapter 37. Provides military service periods and previous guaranteed loan information, if any, to facilitate determination on entitlement required by 38 U.S.C. 1802(a), (b), and (c) and 1818.

(2) *Certification of Loan Disbursement:*

OMB No. 2900-0030.

VA Form 26-1876.

Application for benefits.

Individuals and businesses.

SIC: 602, 604, 612, and 616.

Small businesses.

312,000 responses.

156,000 burden hours.

On occasion.

Required to obtain benefit.

$1,301,000 Federal cost.

Lender's report of home loan closing required by 38 U.S.C. 1802(c). Provides data on terms and closing for loan examination determinations that 38 U.S.C. chapter 37 requirements have been met, terms of loan and conditions affecting the property are in compliance with VA regulations, and are substantially those on which VA based its prior approval.

(3) *50 Percent Employment Survey:*

OMB No. 2900-0235.

VA Forms 22-8722, 22-8723, 22-8724.

Regulatory or compliance.

Graduates of vocational courses, schools and state approving agencies.

SIC: 824.

Not used by small businesses.

300,000 responses.

514,650 burden hours.

Biennially.

Voluntary for student; required of schools; mandatory for state approving agencies.

$245,000 Federal cost.

Authorized by 38 U.S.C. 1673 and 1723, these reports obtain information from graduates, schools and state approving agencies. The information is used to determine effectiveness of the VA's educational benefits program.

(4) *Pension Verification—Interview Worksheet:*

OMB No. 2900-0271.

VA Forms 20-8848, 20-8849, 20-8849a, 20-8849b, 20-8849c.

Program evaluation.

VA pensioners.

SIC: Not applicable.

Not used by small businesses.

4,028 responses.

18,126 burden hours.

Recurring (annually).

Required to obtain or retain benefit.

$500,000 Federal cost.

To continuously verify benefit entitlement and payment under the Veterans Administration pension program. The program will monitor both the self-reporting system of the pensioners and the VA's income questionnaire processing. The findings will be used to identify and correct any defects in the system.

(5) *Solicitation of Identification Data:*

OMB No. (new—not assigned).

VA Form 21-8332a.

Regulatory or compliance.

Individuals.

SIC: Not applicable.

Not used by small businesses.

700,000 responses.

116,667 burden hours.

Nonrecurring.

Mandatory.

$210,000 Federal cost.

The identification data requested will include names, dates of birth and social security numbers for use in identifying veterans or persons claiming or receiving VA benefits and their records and may be used to verify Social Security benefit entitlement (including

amounts payable) with the Social Security Administration (38 CFR 1.575).

[FR Doc. 81-12970 Filed 4-29-81: 8:45 am]
BILLING CODE 8320-01-M

Members of the Performance Review Boards

AGENCY: Veterans Administration.

ACTION: Notice.

SUMMARY: Under the provisions of 5 U.S.C. 4314(c)(4), notice is hereby given of the names of the members of the Performance Review Boards in the Veterans Administration. This notice revises the entire list of members published in the **Federal Register**, 45 FR 35474, dated May 27, 1980.

EFFECTIVE DATE: April 24, 1981.

FOR FURTHER INFORMATION CONTACT: K. Joyce Edwards, Office of Personnel (05A), Veterans Administration, 810 Vermont Avenue, NW., Washington, D.C. 20420 (202-389-3423).

The Members of the VA's Performance Review Boards are:

VA Performance Review Board

Charles E. Clark, Assistant Administrator for Personnel
Donald L. Custis, M.D., Chief Medical Director
Dorothy L. Starbuck, Chief Benefits Director
William R. Martin, Assistant Administrator for Data Management and Telecommunications
Sydney J. Shuman, Chairman, Board of Veterans Appeals
Conrad Hoffman, Controller
Raymond S. Blunt, Assistant Administrator for Planning and Program Evaluation
H. David Burge, Director, Office of Manpower Programs
William A. Salmond, Assistant Administrator for Construction

Department of Medicine & Surgery, Performance Review Board

Turner Camp, M.D., Associate Deputy Chief Medical Director
Donald B. Thompson, Executive Assistant to Chief Medical Director
James A. Christian, Executive Assistant to Deputy Chief Medical Director
Murray Mitts, M.D., Deputy Associate Deputy Chief Medical Director for Operations
Philip T. White, M.D., Deputy Associate Deputy Chief Medical Director for Program Management
Charles V. Yarbrough, Director, Management Support Staff
Carlton M. Smith, Director, Northeastern Region
Charles R. Paulk, Director, Mid-Atlantic Region
Dan G. Kadrovach, Director, Southeastern Region
James H. Caldwell, Jr., Director, Great Lakes Region
Thomas P. Mullon, Director, Mid-Western Region
John J. Peters, Jr., Director, Western Region

Department of Veterans Benefits, Performance Review Board

John W. Hagan, Jr., Deputy Chief Benefits Director
John P. Travers, Field Director, Western Region
David M. Walls, Field Director, Eastern Region
James J. Cox, Director, Veterans Assistance Service
Albert W. Glass, Director, Loan Guaranty Service

Dated: April 20, 1981.

Rufus H. Wilson,
Acting Administrator.

[FR Doc. 81-12971 Filed 4-29-81: 8:45 am]
BILLING CODE 8320-01-M

Sunshine Act Meetings

Federal Register
Vol. 46, No. 83
Thursday, April 30, 1981

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

CONTENTS

1

COPYRIGHT ROYALTY TRIBUNAL.

[Docket No. CRT 80-5]

TIME AND DATE: 10 a.m., June 2, 3, 4, 5, 1981.

PLACE: Room 414, 2100 K Street, N.W., Washington, D.C. 20036.

STATUS: Open.

MATTERS TO BE CONSIDERED: Distribution of 1979 Jukebox Royalty Fees.

Clarence L. James, Jr.,

Chairman, Copyright Royalty Tribunal.

[S-682-81 Filed 4-28-81; 3:46 pm]

BILLING CODE 1410-07-M

2

FEDERAL ELECTION COMMISSION.

DATE AND TIME: Tuesday, May 5, 1981 at 10 a.m.

PLACE: 1325 K Street, N.W., Washington, D.C.

STATUS: This meeting will be closed to the public.

MATTERS TO BE CONSIDERED: Personnel. Compliance. Litigation. Audits.

* * * * *

DATE AND TIME: Thursday, May 7, 1981 at 10 a.m.

PLACE: 1325 K Street, N.W., Washington, D.C. (fifth floor).

STATUS: This meeting will be open to the public.

MATTERS TO BE CONSIDERED:

Setting of dates for future meetings
Correction and approval of minutes
Certifications
Advisory opinion 1981-18—Jerry W. Powell, Counsel, Central Bancshares of the South, Inc.
Pending legislation
Appropriations and budget
Classification actions
Routine administrative matters

PERSON TO CONTACT FOR INFORMATION: Mr. Fred Eiland, Public Information Officer; telephone: 202-523-4065.

Lena L. Stafford,

Administrative Assistant.

[S-680-81 Filed 4-28-81; 3:04 pm]

BILLING CODE 6715-01-M

3

FEDERAL ENERGY REGULATORY COMMISSION.

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: 46 FR 23649, April 28, 1981.

PREVIOUSLY ANNOUNCED TIME AND DATE OF MEETING: 10 a.m., April 29, 1981.

CHANGE IN THE MEETING: The following items are being added:

Item No., Docket No., and Company

CAG-20. RP72-6-031, RP72-6-032, CP77-289-025 and CP76-87, El Paso Natural Gas Co.
M-6. RM80-42, Tax normalization for certain items reflecting timing differences in the recognition of expenses or revenues for ratemaking and income tax purposes.
RP-6. TA81-2-48-000, Michigan Wisconsin Gas Pipe Line Co.
CP-5. (a) CP80-430 and CP81-144-000, Columbia Gas Transmission Corp.; (b) CP81-20-000, Columbia Gas Transmission Corp. and Transcontinental Gas Pipe Line Corp.; (c) CP79-2-6-001, Columbia Gas Transmission Corp.

Lois D. Cashell,

Acting Secretary.

[S-678-81 Filed 4-28-81; 11:54 am]

BILLING CODE 6450-85-M

4

FEDERAL HOME LOAN BANK BOARD.

TIME AND DATE: Wednesday, May 6, 1981.

PLACE: 1700 G Street, N.W., board room, six floor, Washington, D.C.

STATUS: Open meeting.

CONTACT PERSON FOR MORE INFORMATION: Mr. Marshall (202-377-6679).

MATTERS TO BE CONSIDERED:

Application for Bank Membership—The Binghamton Savings Bank, Binghamton, New York
Request for Extension of Time to Open a Branch Office—First Federal Savings & Loan Association of Sioux City, Sioux City, Iowa
Proposed Merger; Maintenance of Branch Office; Cancellation of Membership and Insurance and Transfer of Stock—Home Federal Savings & Loan Association, Bishopville, South Carolina into Security Federal Savings & Loan Association, Columbia, South Carolina
Designation of Supervisory Agents
Branch Office Application—First Federal Savings & Loan Association, of Brainerd, Brainerd, Minnesota
Application for Bank Membership—The Dime Savings Bank of New York, Brooklyn, New York
Service Corporation Activity—First Federal Savings & Loan Association of Willoughby, Willoughby, Ohio

No. 480, April 28, 1981.

[S-677-81 Filed 4-28-81; 9:42 am]

BILLING CODE 6720-01-M

5

FEDERAL HOME LOAN BANK BOARD.

PREVIOUSLY ANNOUNCED TIME AND DATE OF MEETING: 10 a.m., Wednesday, May 6, 1981.

PLACE: 1700 G Street N.W., board room, sixth floor, Washington, D.C.

STATUS: Open meeting.

CONTACT PERSON FOR MORE INFORMATION: Mr. Marshall (202-377-6679).

CHANGES IN THE MEETING: The following item has been withdrawn from the open portion of the Bank Board meeting of Wednesday, May 6, 1981.

Proposed Merger; Maintenance of Branch office; Cancellation of Membership and Insurance and Transfer of Stock—Home Federal Savings & Loan Association, Bishopville, South Carolina *into* Security Federal Savings & Loan Association, Columbia, South Carolina.

No. 481, April 28, 1981.

[S-679-81 Filed 4-28-81; 1:46 pm]

BILLING CODE 6720-01-M

6

FEDERAL RESERVE SYSTEM.

Board of Governors

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: 46 FR, 23040, Wednesday, April 22, 1981.

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING: 10 a.m. Monday, April 27, 1981.

CHANGES IN THE MEETING: One of the items announced for inclusion at this meeting was consideration of any agenda items carried forward from a previous meeting; the following such closed item(s) was added:

Proposals with respect to the Board's employment goals. (This matter was originally announced for a meeting on April 20, 1981)

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board (202) 452–3204.

Dated: April 27, 1981.

James McAfee,

Assistant Secretary of the Board.

[S-681-81 Filed 4-28-81; 3:53 pm]

BILLING CODE 6210-01-M

7

SECURITIES AND EXCHANGE COMMISSION.

Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Pub. L. 94–409, that the Securities and Exchange Commission will hold the following meetings during the week of May 4, 1981, in Room 825, 500 North Capitol Street, Washington, D.C.

An open meeting will be held on Wednesday, May 6, 1981, at 10 a.m., followed by a closed meeting.

The Commissioners, their legal assistants, the Secretary of the Commission, and recording secretaries will attend the closed meeting. Certain staff members who are responsible for the calendared matters may be present.

The General Counsel of the Commission, or his designee, has certified that, in his opinion, the items to be considered at the closed meeting may be considered pursuant to one or more of the exemptions set forth in 5 U.S.C. 552b(c)(4)(8)(9)(A) and (10) and 17 CFR 200.402(a)(4)(8)(9)(i) and (10).

Acting Chairman Loomis and Commissioners Evans, Friedman, and Thomas determined to hold the aforesaid meeting in closed session.

The subject matter of the open meeting scheduled for Tuesday, May 5, 1981, at 9:00 a.m., will be:

1. Consideration of whether to grant the Freedom of Information Act (FOIA) Waiver of Fees Appeal of Jay Gary Finkelstein, in connection with the FOIA request for Commission files concerning Lifespring Corporation. For further information, please contact Gilles Attia at (202) 272–2448.

2. Consideration of whether to release to the public a study, entitled *A Monitoring Report on the Operation of the Cincinnati Stock Exchange National Securities Trading System.* For further information, please contact Terry M. Chuppe at (202) 523–5623.

The subject matter of the closed meeting scheduled for Tuesday, May 5, 1981, following the 9:00 a.m. open meeting, will be:

Opinions.
Freedom of Information Act appeals.
Institution of administrative proceeding of an enforcement nature.
Institution of injunctive action and administrative proceeding of an enforcement nature.

At times changes in Commission priorities require alterations in the scheduling of meeting items. For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact: Bruce Mendelsohn at (202) 272–2091.

April 27, 1981.

[S-676-81 Filed 4-27-81; 5:12 pm]

BILLING CODE 3010-01-M

federal register

Thursday
April 30, 1981

Part II

Department of Transportation

Federal Aviation Administration

Airplanes; Certification and Operations; Correction

Federal Register

Tuesday
May 30, 1995

Part II

Department of Transportation

Federal Aviation Administration

Airplane Certification and Operations
Standards

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 125

[Docket No. 19779; Amdt. No. 125-2]

Airplanes; Certification and Operations; Correction

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment corrects errors made when the final Part 125 regulation was printed in the Federal Register (45 FR 67214; October 9, 1980). This amendment is required to ensure that ambiguity resulting from those errors is eliminated.

EFFECTIVE DATE: April 30, 1981.

FOR FURTHER INFORMATION CONTACT: Jean Casciano, Regulatory Projects Branch (AVS-24), Safety Regulations Staff, Associate Administrator for Aviation Standards, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone (202) 755-8716.

SUPPLEMENTARY INFORMATION: When Notice of Proposed Rulemaking No. 79-19 was published (44 FR 66324; November 19, 1979), proposed § 125.247(e) read "No person may operate any airplane unless the installed engines have been maintained in accordance with the overhaul periods recommended by the manufacturer or *a program* approved by the Administrator . . ." (emphasis supplied). However, when the manuscript copy of the final rule was sent to the Federal Register for printing, the words "a program" were inadvertently omitted and § 125.247(d)(1) (the subparagraphs were restructured), as submitted and as published, read "The installed engines have been maintained in accordance with the overhaul periods recommended by the manufacturer or approved by the Administrator; and". The words "a program" are necessary to express the concept that a program approved by the Administrator is a satisfactory alternative to compliance with the overhaul periods recommended by the manufacturer.

In addition, when the final rule was sent to the Federal Register for printing, § 125.381(c)(2) stated "Is on final approach segment using a nonprecision approach procedure, or . . ." However, when the rule was printed, editorial marks were misread and the final rule was printed to read "Is on final approach using a segment/nonprecision approach procedure, or . . ." It is necessary to correct this ambiguity so the codification document provision is the same as the provision in the amendment signed by the Administrator.

Need for Immediate Adoption

Since this amendment corrects errors, eliminates ambiguity, and imposes no additional burden on any person, I find that notice and public procedure are unnecessary and contrary to the public interest and that good cause exists for making it effective in less than 30 days.

Adoption of the Amendment

Accordingly, Part 125 of the Federal Aviation Regulations (14 CFR Part 125) is amended as follows, effective April 30, 1981.

PART 125—CERTIFICATION AND OPERATIONS: AIRPLANES HAVING A SEATING CAPACITY OF 20 OR MORE PASSENGERS OR A MAXIMUM PAYLOAD CAPACITY OF 6,000 POUNDS OR MORE

1. By revising § 125.247(d)(1) to read as follows:

§ 125.247 Inspection programs and maintenance.

* * * * *

(d) * * *

(1) The installed engines have been maintained in accordance with the overhaul periods recommended by the manufacturer or a program approved by the Administrator; and

* * * * *

(2) By revising § 125.381(c)(2) to read as follows:

§ 125.381 Takeoff and landing weather minimums: IFR.

* * * * *

(c) * * *

(2) Is on final approach segment using a nonprecision approach procedure, or

* * * * *

(Secs. 313, 601 through 610, and 1102, Federal Aviation Act of 1958, as amended (49 U.S.C. 1354, 1421-1430, and 1502); sec. 6(c), Department of Transportation Act (49 U.S.C. 1655(c)))

Note.—The FAA has determined that this document involves a regulation which is not a major rule under Executive Order 12291 or a significant regulation under the DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979). Since this regulatory action involves an amendment that corrects an inadvertent omission and an editorial error and does not make a substantive change, the anticipated impact is so minimal that it does not warrant preparation of a regulatory evaluation.

Issued in Washington, D.C., on April 6, 1981.

Charles E. Weithoner,

Acting Administrator.

[FR Doc. 81-12625 Filed 4-29-81; 8:45 am]

BILLING CODE 4910-13-M

federal register

Thursday
April 30, 1981

Part III

Department of Education

Office of the Secretary

Semiannual Regulations Agenda and Review List

DEPARTMENT OF EDUCATION

Office of the Secretary

34 CFR Subtitle A and Chs. I–VII
41 CFR Ch. 34

Semiannual Regulations Agenda and Review List

AGENCY: Department of Education.

ACTION: Publication of the semiannual agenda of regulations.

SUMMARY: The Secretary of Education publishes a semiannual agenda of regulations under development as required by Executive Order 12291 entitled "Federal Regulations" and the Regulatory Flexibility Act. This agenda provides a brief description of regulations being developed by the Department of Education. The purpose of the agenda is to encourage more effective public participation in the regulatory process by giving the public early information about pending regulatory activities.

FOR FURTHER INFORMATION: Questions or comments related to specific regulations listed in this agenda should be directed to the contact person listed for that set of regulations. Questions or comments on the overall agenda should be directed to A. Neal Shedd, Director, Division of Regulations Management, Office of the General Counsel, Department of Education, Room 2129 FOB–6, 400 Maryland Avenue, S.W., Washington, D.C. 20202. Telephone (202) 245–7091.

SUPPLEMENTARY INFORMATION: Executive Order 12291, dated February 17, 1981, and the Regulatory Flexibility Act require the Department of Education to publish, in October and April of each year, an agenda of proposed regulations that the Department has issued or expects to issue. This is the first semiannual agenda published by the Department. It includes both proposed regulations currently being drafted and pending final regulations for which NPRMs have been published.

For each set of proposed or final regulations listed, the agenda provides a: (1) title; (2) summary; (3) contact person; and (4) decision date (expected month of publication of the final regulations (FR) or the notice of proposed rulemaking (NPRM)).

The summary of each set of regulations includes: (1) a brief description of the proposed or final regulations; (2) notice whether a regulatory impact analysis is required by Executive Order 12291; (3) notice whether a regulatory flexibility analysis is required by the Regulatory Flexibility Act; (4) a brief statement of the Department's objectives in issuing the regulations; (5) the legal basis for the regulations; and (6) the Code of Federal Regulations part number assigned to the regulations.

The Department is required by Executive Order 12291 to prepare a regulatory impact analysis for any set of regulations that is a "major rule" as defined by the Order, and that is not exempted from the requirements in the Order. This semiannual agenda specifies whether or not a regulatory impact analysis will be prepared for each set of regulations listed.

The Regulatory Flexibility Act, Pub. L. 96–354, enacted September 19, 1980, requires that Federal agencies take into account the impact of their regulations on "small entities," including small businesses, small governmental jurisdictions, and other small organizations. The Department must prepare an initial regulatory flexibility analysis for any proposed regulations for which a notice of proposed rulemaking is issued on or after January 1, 1981 if the proposed regulations will have a significant economic impact on a substantial number of small entities. A reference has therefore been included in this agenda to indicate whether a regulatory flexibility analysis is required.

This publication in the **Federal Register** does not impose any binding obligation on the Department with regard to any specific item on the agenda. Regulatory action in addition to the items listed is not precluded.

Dated: April 23, 1981.

T. H. Bell,

Secretary of Education.

Department of Education Semiannual Regulations Agenda and Review List

Title	Summary	Contact	Earliest expected decision date
Continuing Education Outreach-State-Administered Program.	A. *Description:* The regulations establish requirements for a program designed primarily to increase access to post-secondary education for underserved adults. B. *Regulatory impact analysis:* Not required. C. *Regulatory flexibility analysis:* Not required. D. *Objectives:* The regulations describe options available to the States, establish administrative requirements for the conduct of the program, particularly those pertaining to reports and waivers, and reflect recent statutory changes. E. *Legal basis:* Section 111–115 of Title I–B of the Higher Education Act of 1965, as amended by Pub. L. 96–374 (20 U.S.C. 1011–1015). F. *Citation:* 34 CFR Part 605.	J. E. Donahue, (202) 245–9868.	FR May 1981.
Continuing Education Outreach-Special Projects Program.	A. *Description:* The regulations establish requirements governing grants and contracts to institutions of higher education, public and private organizations, States, and businesses to meet postsecondary educational needs of adult learners. B. *Regulatory impact analysis:* Not required. C. *Regulatory flexibility analysis:* Not required. D. *Objectives:* The regulations provide comprehensive program information for potential applicants and establish procedures for receipt and evaluation of application. E. *Legal basis:* Section 116 of Title I–B of the Higher Education Act of 1965, as amended by Pub. L. 96–374 (20 U.S.C. 1016). F. *Citation:* 34 CFR Part 606.	J. E. Donahue (202) 245–9868.	FR May 1981.
Institutional Aid Programs	A. *Description:* The regulations contain the general fiscal and administrative requirements for three programs under Title III of the Higher Education Act. B. *Regulatory impact analysis:* Not required. C. *Regulatory flexibility analysis:* Not determined. D. *Objective:* The regulations establish general provisions common to the operation of the three programs. E. *Legal basis:* Title III of the Higher Education Act of 1965, as amended by Pub. L. 96–374 (20 U.S.C. 1051–1069). F. *Citation:* 34 CFR Part 624.	Alfreda Liebermann (202) 245–2384.	NPRM June 1981.
Strengthening Institutions Program	A. *Description:* The regulations implement a program of assistance to improve the academic quality, institutional management, and fiscal stability of eligible institutions. B. *Regulatory impact analysis:* Not required. C. *Regulatory flexibility analysis:* Not determined.	Alfreda Liebermann (202) 254–2384.	NPRM June 1981.

Department of Education Semiannual Regulations Agenda and Review List—Continued

Title	Summary	Contact	Earliest expected decision date
	D. *Objective:* The regulations establish requirements of a program designed to assist certain institutions of higher education in solving problems, stabilizing their management and fiscal operations, and improving the overall quality of their operations. E. *Legal basis:* Title III of the Higher Education Act of 1965, as amended by Pub. L. 96-374 (20 U.S.C. 1057-1059). F. *Citation:* 34 CFR Part 625.		
Aid to Institutions with Special Needs Program.	A. *Description:* The regulations implement a program that provides short-term Federal assistance to strengthen the planning, management, and fiscal capabilities of institutions with special needs. B. *Regulatory impact analysis:* Not determined. C. *Regulatory flexibility analysis:* Not required. D. *Objective:* The regulations establish the requirements of a program that provides a maximum of five years, assistance to resolve the special needs of certain institutions of higher education. E. *Legal basis:* Title III of the Higher Education Act of 1965, as amended by Pub. L. 96-374 (20 U.S.C. 1060-1063). F. *Citation:* 34 CFR Part 626.	Alfreda Liebermann (202) 245-2384.	NPRM June 1981.
Challenge Grant Program	A. *Description:* The regulations implement a program under which certain institutions of higher education are eligible for matching assistance as an incentive to develop new sources of financial support. B. *Regulatory impact analysis:* Not required. C. *Regulatory flexibility analysis:* Not determined. D. *Objective:* The regulations establish the requirements of a program designed to assist institutions to develop new sources of income to overcome conditions that may threaten their survival. E. *Legal basis:* Title III of the Higher Education Act of 1965, as amended by Pub. L. 96-374 (20 U.S.C. 1064-1065). F. *Citation:* 34 CFR Part 627.	Alfreda Liebermann, (202) 245-2384.	NPRM June 1981.
College Library Resources Program	A. *Description:* The regulations establish the requirements governing the award of grants to assist institutions of higher education and other eligible library institutions to improve the quality of their library holdings and networking capabilities. B. *Regulatory impact analysis:* Not required. C. *Regulatory flexibility analysis:* Not required. D. *Objectives:* The regulations implement statutory changes and changes resulting from program experience. E. *Legal basis:* Part A of Title II of the Higher Education Act of 1965, as amended by Pub. L. 96-374 (20 U.S.C. 1021). F. *Citation:* 34 CFR Part 773.	Frank Stevens, (202) 245-9530.	FR May 1981.
Library Research and Demonstration Program.	A. *Description:* The regulations establish the requirements governing the award of grants to assist in encouraging research and demonstration projects related to the improvement of libraries, training in librarianship, and improvement of information technology. B. *Regulatory impact analysis:* Not required. C. *Regulatory flexibility analysis:* Not required. D. *Objectives:* The regulations implement statutory changes, and changes resulting from the administrative experience of the program and incorporate the general selection criteria of EDGAR. E. *Legal basis:* Part B of title II of the Higher Education Act of 1965, as amended by Pub. L. 96-374 (20 U.S.C. 1021 *et seq*). F. *Citation:* 34 CFR Part 777.	Frank Stevens, (202) 245-9530.	FR May 1981.
Library Career Training Program	A. *Description:* The regulations to institutions of higher education and other eligible library institutions for training in librarianship and for the improvement of library and information science. B. *Regulatory impact analysis:* Not required. C. *Regulatory flexibility analysis:* Not determined. D. *Objectives:* The amended regulations clarify requirements governing applications for grants and simplify previous regulatory language. E. *Legal basis:* Part B of Title II of the Higher Education Act of 1965, as amended by Pub. L. 96-374 (20 U.S.C. 1021). F. *Citation:* 34 CFR Part 776	Frank Stevens, (202) 245-9530.	NPRM August 1981.
Strengthening Research Library Resources.	A. *Description:* The regulations amend existing regulations for a program that assist the Nation's major research libraries to maintain and strengthen their holdings and offer services to researchers and scholars. B. *Regulatory impact analysis:* Not required. C. *Regulatory flexibility analysis:* Not determined. D. *Objectives:* The amended regulations clarify requirements governing applications for grants and incorporate changes resulting from program experience. E. *Legal basis:* Part C of Title II of the Higher Education Act of 1965, as amended by Pub. L. 96-374 (20 U.S.C. 1021). F. *Citation:* 34 CFR Part 778.	Frank Stevens, (202) 245-9530.	NPRM August 1981.
Teacher Corps Programs—General	A. *Description:* The regulations establish common provisions governing the three types of Teacher Corps Projects: Teacher Corps Training Projects, Youth Advocacy Projects and Mathematics and Science Development Projects. The program is designed to improve teacher preparation, increase opportunities for children of low-income families, juvenile delinquents, and youth offenders; and develop curriculum offerings or instructional materials that improve instruction in mathematics and science. B. *Regulatory impact analysis:* Not required. C. *Regulatory flexibility analysis:* Not required. D. *Objectives:* The regulations reflect recent statutory changes in the program and clarify the differences among the three types of projects. E. *Legal basis:* Title V-A of the Higher Education Act of 1965, as amended by Pub. L. 96-374 (20 U.S.C. 1101 *et seq.*). F. *Citation:* 34 CFR Part 791.	Preston Royster, (202) 653-8320.	FR May 1981.
Teacher Corps—Training Projects	A. *Description:* The regulations establish the requirements for a program of assistance to projects designed to develop methods and procedures for increasing learning opportunities for children from low-income families, develop and demonstrate new and improved approaches to train educational personnel, and install and disseminate improved practices of teacher education. B. *Regulatory impact analysis:* Not required. C. *Regulatory flexibility analysis:* Not required.	Preston Royster, (202) 653-8320.	FR May 1981.

Department of Education Semiannual Regulations Agenda and Review List—Continued

Title	Summary	Contact	Earliest expected decision date
	D. *Objectives:* The regulations implement and clarify requirements governing applications for grants, the selection of grantees, and the conducting of activities authorized under this program. E. *Legal basis:* Title V-A of the Higher Education Act of 1965, as amended by Pub. L. 96-374 (20 U.S.C. 1101 *et seq.*). F. *Citation:* 34 CFR Part 792.		
Teacher Corps—Youth Advocacy Projects.	A. *Description:* The regulations establish the requirements for a program of assistance to projects designed to provide remedial, basic, and secondary education to juvenile delinquents and youth offenders. B. *Regulatory impact analysis:* Not required. C. *Regulatory flexibility analysis:* Not required. D. *Objectives:* The regulations implement and clarify requirements governing applications for grants, the selection of grantees, and the conducting of projects under this program. E. *Legal basis:* Title V-A of the Higher Education Act of 1965, as amended by Pub. L. 96-374 (20 U.S.C. 1101, *et seq.*). F. *Citation:* 34 CFR Part 793.	Preston Royster, (202) 653-8320.	FR May 1981.
Teacher Corps—Mathematics and Science Development Projects.	A. *Description:* The regulations establish the requirements for a program of assistance to projects designed to (1) develop, improve, or test curriculum offerings or instructional materials for training teachers in mathematics and science; and (2) provide training for teachers to increase their effectiveness in developing instructional materials and in teaching mathematics and science in schools that have a high concentration of children from low-income families. B. *Regulatory impact analysis:* Not required. C. *Regulatory flexibility analysis:* Not required. D. *Objective:* The regulations implement statutory changes authorizing activities interpreted as being consistent with the types of projects funded under the Teacher Corps Program. E. *Legal basis:* Title V-A of the Higher Education Act of 1965, as amended by Pub. L. 96-374, (20 U.S.C. 1101 *et seq.*). F. *Citation:* 34 CFR Part 794.	Preston Royster, (202) 653-8320.	FR May 1981.
Museum Services Program	A. *Description:* The regulations govern a grant program that assists museums carrying out institutional assessments to measure their programs and operations by generally accepted professional standards. B. *Regulatory impact analysis:* Not required. C. *Regulatory flexibility analysis:* Not required. D. *Objectives:* The regulations expand the types of assistance offered under the program. E. *Legal basis:* Section 201-210 of the Museum Services Act of Title II of the Arts, Humanities, and Cultural Affairs Act of 1976 (20 U.S.C. 961-968); (5 U.S.C. 552b). F. *Citation:* 34 CFR Part 64.	Tom Litkowski, (202) 426-6577.	FR May 1981.
Experimental Program for Opportunities in Advanced Study and Research in Education.	A. *Description:* The regulations contain requirements governing the award of grants to experimental activities that demonstrate effective ways of increasing the participation of members of underrepresented groups in the field of educational research and development. B. *Regulatory impact analysis:* Not required. C. *Regulatory flexibility analysis:* Not required. D. *Objective:* The regulations implement administrative requirements that revise the language and format of current provisions and improve their quality. E. *Legal basis:* Section 405 of the General Education Provisions Act, as amended (20 U.S.C. 1221e) F. *Citation:* 34 CFR Part 703.	Frank Alejandro, (202) 245-8827.	FR May 1981.
Women's Educational Equity Act Program.	A. *Description:* The regulations—which add a subpart to existing regulations—govern a program of financial assistance (Tier II) that helps educational agencies and institutions implement projects of local significance to meet the requirements of Title IX of the Education Amendment of 1972. B. *Regulatory impact analysis:* Not determined. C. *Regulatory flexibility analysis.* Not determined. D. *Objective:* The regulations implement requirements of the grant program for funding Tier II projects. E. *Legal basis:* Part C of Title IX of the Elementary and Secondary Education Act of 1965, as amended (20 U.S.C. 3341-48), and Section 408 of the General Education Provisions Act (20 U.S.C. 1221e-3). F. *Citation:* 34 CFR Part 745.	Leslie Wolfe, (202) 245-2181.	NPRM May 1981.
Fund for the Improvement of Postsecondary Education.	A. *Description:* The regulations contains requirements for a program of grants to help postsecondary institutions and agencies improve postsecondary education. B. *Regulatory impact analysis:* Not determined. C. *Regulatory flexibility analysis:* Not determined. D. *Objectives:* The regulations alter the format and language of the current regulations to conform with the Education Department General Administrative Regulations, and implement changes with respect to annual priorities, selection criteria, and categories of competition. E. *Legal basis:* Title X of the Higher Education Act of 1965, as amended by Pub. L. 96-374 (20 U.S.C. 1135). F. *Citation:* 34 CFR Part 730.	Russell Y. Garth, (202) 245-8091.	NPRM May 1981.
Restrictions on the Use of Former Federal Employees.	A. *Description:* The regulations establish constraints on the services of certain former employees of the Department of Education in conjunction with contractual proposals, negotiations, and awards. B. *Regulatory impact analysis:* Not required. C. *Regulatory flexibility analysis:* Not required. D. *Objective:* The regulations implement the provisions in the Ethics of Government Act of 1978 concerning the use of former employees by adding a new section to the General Policies subpart of the Department's procurement regulations. E. *Legal basis:* The Department of Education Organization Act, Pub. L. 96-88 (20 U.S.C. 3474). F. *Citation:* 41 CFR, Chapter 34, Subpart 34-1.351	Frederick H. Hundemer, (202) 245-7166.	NPRM July 1961.
Cost of Attendance	A. *Description:* The regulations—which amends existing regulations—establish provisions used by the Pell Grant Program in determining a student's cost of attendance at an institution of postsecondary education. B. *Regulatory impact analysis:* Not required. C. *Regulatory flexibility analysis:* Not required.	William L. Moran, (202) 472-4300.	FR May 1981.

Department of Education Semiannual Regulations Agenda and Review List—Continued

Title	Summary	Contact	Earliest expected decision date
	D. *Objective:* The regulations implement new provisions of the Higher Education Act of 1965 (Section 482(d)), as amended by the Education Amendments of 1980. E. *Legal basis:* Title IV, Part E, of the Higher Education Act of 1965, as amended by Pub. L. 96-374 (20 U.S.C. 1070a). F. *Citation:* 34 CFR Part 690.		
State Student Incentive Grant Program	A. *Description:* The regulations amend and simplify a program that provides grants to stimulate States to develop and expand grant assistance to eligible students at institutions of postsecondary education. B. *Regulatory impact analysis:* Not required. C. *Regulatory flexibility analysis:* Not required. D. *Objectives:* The regulations implement changes contained in the Education Amendments of 1980 and simplify previous requirements. E. *Legal basis:* Sections 415A-415D of the Higher Education Act of 1965, as amended by Pub. L. 96-374 (20 U.S.C. 1070c-1070c-3). F. *Citation:* 34 CFR Part 692.	Lanora Smith, (202) 472-4265.	FR May 1981.
Upward Bound Program	A. *Description:* The regulations implement a grant program designed to help develop the skills and motivation of students who need academic support to complete successfully a program of education beyond high school. The program is intended for individuals who are of low income or who are potential, first-generation college students. B. *Regulatory impact analysis:* Not required. C. *Regulatory flexibility analysis:* Not required. D. *Objective:* The regulations state the requirements for conducting projects that assist academically promising students to discover their ability and to pursue preparation for postsecondary education. E. *Legal basis:* Sections 417A and 417C of Title IV of the Higher Education Act of 1965, as amended by Pub. L. 96-374 (20 U.S.C. 1070d; 1070d-1a). F. *Citation 34CFR Part 645.*	Mary K. Smith, (202) 245-2511.	FR May 1981.
Special Services for Disadvantaged Students.	A.*Description:* The regulations implement a grant program that assists institutions of higher education in providing a range of supportive services to help students to complete postsecondary education. The program is intended for individuals who are physically handicapped or are first-generation college students of low income. B. *Regulatory impact analysis:* Not required. C. *Regulatory flexibility analysis:* Not required. D. *Objective:* The regulations state the requirements for conducting projects designed to help certain students complete programs of postsecondary education. E. *Legal basis:* Section 417A and D of Title IV of the Higher Education Act of 1965, as amended by Pub. L. 96-374 (20 U.S.C. 1070d; 1070d-1b). F. *Citation:* 34 CFR Part 646.	Mary K. Smith, (202) 245-2511.	FR May 1981.
Talent Search Program	A. *Description:* The regulations implement a grant program that identifies and assists qualified youths to complete secondary education and to enter programs of postsecondary education. Projects also assist individuals who have not completed programs of secondary and postsecondary education to reenter educational programs. B. *Regulatory impact analysis:* Not required. C. *Regulatory flexibility analysis:* Not required. D. *Objective:* The regulations state the requirements for conducting projects that help low-income and potential, first generation college students to complete secondary school and enter or reenter postsecondary educational programs. E. *Legal basis:* Section 417A and 417B of Title IV of the Higher Education Act of 1965, as amended by Pub. L. 96-374 (20 U.S.C. 1070d, 1070d-1). F. *Citation:* 34 CFR Part 643.	Mary K. Smith, (202) 245-2511.	FR May 1981.
Educational Opportunity Centers Program	A. *Description:* The regulations implement a grant program that assist the development and operation of centers providing a range of educational information and services to individuals interested in pursuing postsecondary education. The program is intended to serve mainly persons of low-income who are first generation college students or potential, first-generation college students. B. *Regulatory impact analysis:* Not required. C. *Regulatory flexibility analysis:* Not required. D. *Objective:* The regulations state the requirements for establishing and operating a center designed to assist certain persons interested in pursuing programs of postsecondary education. E. *Legal basis:* Sections 417A and 417E, of the Higher Education Act of 1965, as amended by Pub. L. 96-374 (20 U.S.C. 1070d; 1070d-1c). F. *Citation:* 34 CFR Part 644.	Mary K Smith, (202) 245-2511.	FR May 1981.
Training Program for Special Programs Staff and Leadership Personnel.	A. *Description:* The regulations implement a grant program that assists institutions and organizations in providing training for staff and leadership personnel involved in projects under the Special Programs for Students from Disadvantaged Backgrounds. The training is designed, also, to improve the operation of projects. B. *Regulatory impact analysis:* Not needed. C. *Regulatory flexibility analysis:* Not required. D. *Objective:* The regulations state the requirements for conducting a project to train staff and leadership personnel. E. *Legal basis:* Sections 417A and 417F of Title IV of the Higher Education Act of 1965, as amended by Sec. 405, Pub. L. 96-374 (20 U.S.C. 1070d; 1070-1d). F. *Citation:* 34 CFR Part 642.	Mary K. Smith, (202) 245-2511.	FR May 1981.
Performance Standards for Special Programs for Students from Disadvantaged Backgrounds.	A. *Description:* The regulations, which amend the regulations governing five programs, state additional criteria for evaluating certain applications. The amendment affects the following programs: Special Services for Disadvantaged Students, Staff Development, Talent Search, Upward Bound, and Educational Opportunity Centers. B. *Regulatory impact analysis:* Not required. C. *Regulatory flexibility analysis:* Not determined. D. *Objectives:* The regulations implement criteria the Secretary uses to evaluate past performance by applicants that have conducted special programs profits within the previous three years. E. *Legal basis:* Section 417A of Title IV of the Higher Education Act of 1965, as amended by Pub. L. 96-374 (20 U.S.C. 1070d). F. *Citation:* 34 CFR Parts 642, 643, 644, 645, and 646.	Mary K. Smith, (202) 245-5211.	NPRM June 1981.

Department of Education Semiannual Regulations Agenda and Review List—Continued

Title	Summary	Contact	Earliest expected decision date
Veterans Cost of Instruction Payment Program.	A. *Description:* The regulations establish requirements for a program that assists eligible institutions in meeting the educational needs of enrolled Vietnam-era veterans through a full-time Office of Veterans Affairs. B. *Regulatory impact analysis:* Not required. C. *Regulatory flexibility analysis:* Not required. D. *Objectives:* The regulations implement policy decisions, changes in the eligibility criteria, and the payment process of the program. E. *Legal basis:* Section 420 of Title IV, Higher Education Act of 1965, as amended by Pub. L. 96-374 (20 U.S.C. 1070e-1). F. *Citation:* 34 CFR Part 629.	Stanley Patterson, (202) 245-2806.	FR May 1981.
Parent Loans for Undergraduate Students Program.	A. *Description:* The regulations implement a new program of low-interest loans to parents of dependent students in undergraduate study at institutions of postsecondary education. B. *Regulatory impact analysis:* Not required. C. *Regulatory flexibility analysis:* Not required. D. *Objective:* The regulations state the requirements for participation in this new program authorized by the Education Amendments of 1980. E. *Legal basis:* Title IV, Part B, of the Higher Education Act of 1965, as amended by Pub. L. 96-374 (20 U.S.C. 1070e-1). F. *Citation:* 34 CFR Part 683.	Jane Bryson, (202) 245-2475.	FR May 1981.
College Housing Program	A. *Description:* The regulations implement a program that provides long-term, low-interest loans to colleges and universities. B. *Regulatory impact analysis:* Not required. C. *Regulatory flexibility analysis:* Not required. D. *Objective:* The regulations establish the criteria and other requirements for loans to institutions of higher education for construction, acquisition, or modification of dormitories, faculty housing, and related facilities. E. *Legal basis:* Section 401 et seq. of the Housing Act of 1950, as amended (12 U.S.C. 1749); Section 306 of the Department of Education Organization Act (20 U.S.C. 3446). F. *Citation:* 34 CFR Part 614.	Thomas Carr, (202) 245-9514.	FR with invitation to comment, May 1981.
Financial Assistance for Construction, Reconstruction, and Renovation of Academic Facilities—General.	A. *Description:* The regulations contains the general provisions common to four grant and loans programs that provide financial assistance for the improvement of higher education academic facilities. B. *Regulatory impact analysis:* Not required. C. *Regulatory flexibility analysis:* Not required. D. *Objective:* The regulations establish the general requirements governing these programs of grants and loans to institutions of higher education. E. *Legal basis:* Sections 701-742 of Title VII of the Higher Education Act of 1965, as amended by Pub. L. 96-374 (20 U.S.C. 11322-1132e-1). F. *Citation:* 34 CFR Part 617.	Lou Anderson, (202) 245-3253.	FR June 1981.
Financial Assistance for the Construction, Reconstruction, and Renovation of Undergraduate Academic Facilities.	A. *Description:* The regulations establish the selection criteria and other provisions governing grants to institutions of higher education for the construction, reconstruction, or renovation of undergraduate academic facilities. B. *Regulatory impact analysis:* Not required. C. *Regulatory flexibility analysis:* Not required. D. *Objectives:* The regulations implement provisions of the program related to the awarding of grants and reflect recent statutory changes. E. *Legal basis:* Sections 701-742 of Title VII of the Higher Education Act of 1965, as amended by Pub. L. 96-374 (20 U.S.C. 1132a-1132e-1). F. *Citation:* 34 CFR Part 618.	Lou Anderson, (202) 245-3253.	FR June 1981.
Financial Assistance for the Construction, Reconstruction, and Renovation of Graduate Academic Facilities..	A. *Description:* The regulations establish the criteria and requirements for grants to institutions of the higher education for construction, reconstruction, or renovation of graduate academic facilities. B. *Regulatory impact analysis:* Not required. C. *Regulatory flexibility analysis:* Not required. D. *Objectives:* The regulations implement provisions of the program related to the awarding of grants and reflect recent statutory changes. E. *Legal basis:* Sections 701-742 of Title VII of the Higher Education Act of 1965, as amended by Pub. L. 96-374 (20 U.S.C. 1132a-1132e-1). F. *Citation:* 34 CFR Part 619.	Lou Anderson, (202) 245-3253.	FR June 1981.
Loans for the Construction, Reconstruction, and Renovation of Academic Facilities.	A. *Description:* The regulations establish the selection criteria and other provisions governing loans to institutions of higher education for the construction, reconstruction, or renovation of academic facilities. B. *Regulatory impact analysis:* Not required. C. *Regulatory flexibility analysis:* Not required. D. *Objectives:* The regulations implement provisions of the program related to the awarding of loans and reflect recent statutory changes. E. *Legal basis:* Sections 701-742 of Title VII of the Higher Education Act of 1965, as amended by Pub. L. 96-374 (20 U.S.C. 1132a-1132e). F. *Citation:* 34 CFR Part 620.	Lou Anderson, (202) 245-3253.	FR June 1981.
Annual Interest Grants for the Construction, Reconstruction, and Renovation of Academic Facilities.	A. *Description:* The regulations establish the selection criteria and other provisions governing annual interest grants to institutions of higher education to reduce the cost of borrowing funds for the construction, reconstruction, or renovation of academic facilities. B. *Regulatory impact analysis:* Not required. C. *Regulatory flexibility analysis:* Not required. D. *Objectives:* The regulations implement the provisions of the program and reflect recent statutory changes E. *Legal basis:* Sections 701-742 of Title VII of the Higher Education Act of 1965, as amended by Pub. L. 96-374 (20 U.S.C. 1132a-1132e-1) F. *Citation:* 34 CFR Part 621	Lou Anderson, (202) 245-3253.	FR June 1981.
Cooperative Education Program—General Provisions.	A. *Description:* The regulations establish the general provisions governing four components of a program designed to assist institutions of higher education in providing students the opportunity to gain career exposure in work experiences B. *Regulatory Impact analysis:* Not required C. *Regulatory flexibility analysis:* Not required D. *Objective:* The regulations implement general requirements common to the several components of the program E. *Legal basis:* Title VIII of the Higher Education Act of 1965, as amended by Pub. L. 96-374 (20 U.S.C. 1133-1133b) F. *Citation:* 34 CFR Part 631	Barbara Freeman, (202) 245-2146.	FR June 1981.

Department of Education Semiannual Regulations Agenda and Review List—Continued

Title	Summary	Contact	Earliest expected decision date
Cooperative Education Program—Administration.	A. *Description:* The regulations establish requirements governing grants to institutions of higher education for projects designed to provide students with educationally related work experiences B. *Regulatory impact analysis:* Not required C. *Regulatory flexibility analysis:* Not required D. *Objectives:* The regulations implement legislative changes, provide necessary information to potential applicants, and establish the selection criteria by which applications are evaluated E. *Legal basis:* Title VIII of the Higher Education Act of 1965, as amended by Pub. L. 94-374 (20 U.S.C. 1133-1133a) F. *Citation:* 34 CFR Part 632	Barbara Freeman, (202) 245-2146.	FR June 1981.
Cooperative Education Program—Demonstration.	A. *Description:* The regulations establish requirements governing the award of demonstration grants to institutions of higher education to institutionalize cooperative education on a comprehensive, institution-wide basis for a diverse student population B. *Regulatory impact analysis:* Not required C. *Regulatory flexibility analysis:* Not required D. *Objectives:* The regulations implement legislative changes, provide necessary information to potential applicants, and establish criteria by which applications are evaluated E. *Legal basis:* Title VIII of the Higher Education Act of 1965, as amended by Pub. L. 96-374 (20 U.S.C. 1133-1133b) F. *Citation:* 34 CFR Part 633	Barbara Freeman, (202) 245-2146.	FR June 1981.
Cooperative Education Program—Research.	A. *Description:* The regulations establish requirements governing grants to institutions of higher education to conduct research in methods of improving cooperative education programs, promoting the use of cooperative education as an alternative approach, and developing cooperation between secondary schools and institutions of higher education B. *Regulatory impact analysis:* Not required C. *Regulatory flexibility analysis:* Not required D. *Objectives:* The regulations implement legislative changes, provide information to potential applicants, and establish requirements for the program E. *Legal basis:* Title VIII of the Higher Education Act of 1965, as amended by Pub. L. 96-374 (20 U.S.C. 1133-1133b) F. *Citation:* 34 CFR Part 634	Barbara Freeman, (202) 245-2146.	FR June 1981.
Cooperative Education Program—Training.	A. *Description:* The regulations establish the criteria and requirements governing training grants to develop and expand the capacity of institutions to carry out cooperative education programs. B. *Regulatory impact analysis:* Not required. C. *Regulatory flexibility analysis:* Not required. D. *Objectives:* The regulations implement legislative changes, provide information to potential applicants, and establish requirements for evaluating applications. E. *Legal basis:* Title VIII of the Higher Education Act of 1965, as amended by Pub. L. 96-374 (20 U.S.C. 1133, 1133b). F. *Citation:* 34 CFR Part 635.	Barbara Freeman, (202) 245-2146.	FR June 1981.
Law School Clinical Experience Program	A. *Description:* The regulations establish requirements for a program that provides assistance to accredited law schools to establish or expand programs of clinical experience for students in the practice of law. B. *Regulatory impact analysis:* Not required. C. *Regulatory flexibility analysis:* Not required. D. *Objective:* The regulations implement the provisions of the program. E. *Legal basis:* Part E of Title IX of the Higher Education Act of 1965, as amended by Pub. L. 96-374 (20 U.S.C. 1134n-1134p). F. *Citation:* 34 CFR Part 639.	Alan Schiff, (202) 245-2347.	FR May 1981.
Assistance for Training in the Legal Profession.	A. *Description:* The regulations establish the criteria and requirements governing assistance to individuals from disadvantaged backgrounds to undertake training for the legal profession. B. *Regulatory impact analysis:* Not required. C. *Regulatory flexibility analysis:* Not required. D. *Objectives:* The regulations implement provisions covering eligible activities and costs under the program. E. *Legal basis:* Part D of Title IX of the Higher Education Act of 1965, as amended by Pub. L. 96-374 (20 U.S.C. 1134). F. *Citation:* 34 CFR Part 651.	Heather Dillinger, (202) 245-2347.	FR May 1981.
National Graduate Fellows Program	A. *Description:* The regulations establish eligibility and indicate how individuals apply for followships for doctoral studies in the arts, the humanities, and the social sicences. B. *Regulatory impact analysis:* Not required. C. *Regulatory flexibility analysis:* Not required. D. *Objectives:* The regulations implement new provisions required by the Education Amendments of 1980. E. *Legal basis:* Part C of Title IX of the Higher Education Act, as amended by Pub. L. 96-374 (20 U.S.C. 1134h-1134k). F. *Citation:* 34 CFR Part 650.	Heather Dillinger, (202) 245-2347.	FR May 1981.
Institutional Grants for Graduate and Professional Study.	A. *Description:* The regulations establish the criteria and requirements for a program providing financial assistance to institutions of higher education to maintain and strengthen the quality of programs of graduate and professional study and to strengthen undergraduate programs. B. *Regulatory impact analysis:* Not required. C. *Regulatory flexibility analysis:* Not required. D. *Objectives:* The regulations implement new provisions required by the Education Amendments of 1980. E. *Legal basis:* Part A of Title IX of the Higher Education Act of 1965, as amended by Pub. L. 96-374 (20 U.S.C. 1134-113b). F. *Citation:* 34 CFR Part 648.		
Secretary's State-Administered and Discretionary Programs of Vocational Education.	A. *Description:* The regulations amend matching requirements of a program that provides assistance to States for national priority programs for handicapped and disadvantaged persons. The regulations also make minor, technical amendments to the discretionary portions of the program. B. *Regulatory impact analysis:* Not required. C. *Regulatory flexibility analysis:* Not required.	Lee Cornelsen, (202) 472-3440.	FR May 1981.

Department of Education Semiannual Regulations Agenda and Review List—Continued

Title	Summary	Contact	Earliest expected decision date
	D. *Objective:* The regulations provide guidance in preparing State plans, amend the criteria for and make other regulatory changes in one of the discretionary programs, and provide for the awarding of grants—in addition to contracts—under another discretionary program. E. *Legal basis:* Vocational Act of 1963, as amended by Pub. L. 94-482, Pub. L. 95-40, and Pub. L. 96-46 (20 U.S.C. 2301-2461). F. *Citation:* 34 CFR Parts 400 and 406.		
Bilingual Education Amendments—Training Projects.	A. *Description:* The regulations clarify statutory requirements concerning the formation of an advisory council to assist in the development of an application under this program and statutory requirements concerning the priority for assisting applications that propose to serve areas having the greatest need for training projects. B. *Regulatory impact analysis:* Not required. C. *Regulatory flexibility analysis:* Not required. D. *Objective:* The regulations clarify statutory requirements concerning advisory councils for applicants and explain how the Secretary will implement the statutory requirement giving priority to applicants that will serve areas having the greatest need. E. *Legal basis:* Title VII of the Elementary and Secondary Education Act of 1965, as amended by Pub. L. 95-561 (20 U.S.C. 3203, 3231, and 3233). F. *Citation:* 34 CFR Part 510.		
Bilingual Education—Desegregation Support Program.	A. *Description:* The regulations implement a program of Federal financial assistance to local education agencies implementing desegregation plans to meet the special educational needs of minority group children who are from an environment in which the dominant language is other than English and who, as a result of language barriers and cultural differences, do not have equal educational opportunity. B. *Regulatory impact analysis:* Not required. C. *Regulatory flexibility analysis:* Not required. D. *Objective:* The regulations implement application and grant requirements related to the provision of Federal financial assistance to desegregating local educational agencies for special educational programs for eligible minority groups children. E. *Legal basis:* Part D of Title VII of the Elementary and Secondary Education Act of 1965, as amended by Pub. L. 95-561 (20 U.S.C. 3261). F. *Citation:* 34 CFR Part 520.	Regina Robbins, (202)472-3520.	FR May 1981.
School Assistance in Federally Affected Areas (SAFA) (School Construction).	A. *Description:* The regulation implement statutory amendments concerning basis of eligibility, hearings, and payment; establish an order of funding priority, describe criteria for waivers, and describe special rules for federally operated schools. B. *Regulatory impact analysis:* Not required. C. *Regulatory flexibility analysis:* Not required. D. *Objectives:* The regulations implement amendments to the law and clarify existing requirements. E. *Legal basis:* Pub. L. 81-815 (20 U.S.C. 631-647), as amended by Pub. L. 95-561. F. *Citation:* 34 CFR Part 221.	Alan Balkma, (202) 245-8412.	FR September 1981.
School Assistance in Federally Affected Areas—Disasters.	A. *Description:* The regulations establish requirements governing the provision of financial assistance to local educational agencies that have incurred disaster damage. B. *Regulatory impact analysis:* Not required. C. *Regulatory flexibility analysis:* Not required. D. *Objectives:* The regulations reflect changes in the operation of the program as a result of a management review. E. *Legal basis:* Section 7 of Pub. L. 81-874 (20 U.S.C. 241-1) and Sec. 16 of Pub. L. 81-815, as amended by Pub. L. 95-561 (20 U.S.C. 646). F. *Citation:* 34 CFR Part 219.	Robert Schneider, (202) 245-8412.	FR May 1981.
Migrant Education—High School Equivalency Program (HEP) and College Assistance Migrant Program (CAMP).	A. *Description:* The regulations implement programs of assistance to institutions of higher education for projects providing educational and supportive services to students whose families are engaged in migrant and seasonal farmwork. B. *Regulatory impact analysis:* Not required. C. *Regulatory flexibility analysis:* Not required. D. *Objective:* The regulations establish requirements for projects designed to assist eligible students in obtaining the equivalent of a high school diploma and in successfully adjusting to postsecondary school. E. *Legal basis:* Subpart 5, Part A, Section 418A of Title IV of the Higher Education Act of 1965, as amended by Pub. L. 96-374 (20 U.S.C. 1070d-2). F. *Citation:* 34 CFR Part 206.	John Ridgway, (202) 245-2222.	FR May 1981.
School Assistance in Federally Affected Areas—Special Impact Aid Program for Refugees.	A. *Description:* The regulations implement a program of Federal financial assistance to local educational agencies that experience in any school year an enrollment increase of at least 20 students who have fled from Cambodia, Vietnam, Laos, or Haiti. B. *Regulatory impact analysis:* Not required. C. *Regulatory flexibility analysis:* Not required. D. *Objectives:* The regulations establish requirements for receiving and using Federal financial assistance. E. *Legal basis:* Pub. L. 81-874, as amended by Pub. L. 96-374 (20 U.S.C. 239a). F. *Citation:* 34 CFR Part 222.	Carroll Dexter, (202) 472-4014.	FR May 1981.
Migrant Education—Interstate and Intrastate Coordination Program.	A. *Description:* The regulations implement a program of Federal financial assistance to improve interstate and intrastate coordination of migrant education activities among State education agencies (SEAs) and local educational agencies. B. *Regulatory impact analysis:* Not required. C. *Regulatory flexibility analysis:* Not required. D. *Objectives:* The regulations establish requirements for interstate and intrastate coordination activities in mingrant education. They also enable the Secretary to establish, in consultation with SEAs, priority areas for program funding and to establish appropriate criteria that will ensure the selection of Quality proposals in areas of national need. E. *Legal basis:* Subpart 1, Part B, Section 143 of Title I of the Elementary and Secondary Education Act of 1965, as amended by Pub. L. 95-561 (20 U.S.C. 2763). F. Citation: *34 CFR Part 205.*	John Ridgway, (202) 245-2222.	NPRM June 1981.

Department of Education Semiannual Regulations Agenda and Review List—Continued

Title	Summary	Contact	Earliest expected decision date
Titles I and IV, ESEA—By-Pass Procedures.	A. *Description:* The regulations establish procedures for the submission of written objections and for show-cause hearings when the Secretary proposes to implement a by-pass to provide equitable services for children enrolled in private schools. B. *Regulatory impact analysis:* Not required. C. Regulatory flexibility analysis: Not required. D. *Objective:* The regulations provide specific timelines and procedures to ensure that an expeditious and fair decision is made on whether the Secretary should implement a by-pass. E. *Legal basis:* Sec. 130 of Title I of the Elementary and Secondary Education Act of 1965, as amended by Pub. L. 95-561 (20 U.S.C. 2740); and Sec. 406 of Title IV of the Elementary and Secondary Education Act of 1965, as amended by Pub. L. 95-561 (20 U.S.C. 3086). F. *Citation:* 34 CFR Parts 201 and 774.	Stephen Freid, (202) 426-6300.	FR May 1981.
Education Department General Administrative Regulations (EDGAR)—Amendments—Parts 75 and 76.	A. *Description:* The regulations consolidate fiscal and administrative requirements for direct grant and State-administered programs of the Department of Education (ED) by incorporating 34 CFR Part 74 (regulations for the Administration of Grants). B. *Regulatory impact analysis:* Not determined. C. Regulatory flexibility analysis: Not required. D. *Objectives:* The regulations assist eligible parties in applying for grants and in conducting or administering federally assisted projects by having all ED fiscal and administrative requirements incorporated into one document. E. *Legal basis:* Sec. 408(a)(1) of Pub. L. 90-247, as amended (20 U.S.C. 1221e-3(a)(1)). F. *Citation:* 34 CFR Parts 75 and 76.	Fred Hundemer, (202) 245-1766.	FR August 1981.
EGDAR Amendments— Parts 75 and 76...	A. *Description:* The regulations incorporate into the Education Department General Administrative Regulations the "Cost Principles" currently found in the appendices of 34 CFR Part 74. B. *Regulatory impact analysis:* Not determined. C. *Regulatory flexibility analysis: Not required.* D. *Objective:* The regulations assist affected parties by incorporating into one document all fiscal and administrative requirements. E. *Legal basis:* Section 408(a)(1) of Pub. L. 90-247, as amended (20 U.S.C. 1221e-3(a)(1)). F. *Citation:* 34 CFR Parts 75 and 76.	Joseph Connor, (202) 245-1766.	FR August 1981.
EDGAR Amendments—Part 76.....	A. *Description:* The regulations amend the Education Department General Administrative Regulations by adding requirements for participation in State-administered programs by children enrolled in private schools. B. *Regulatory impact analysis:* Not required. C. *Regulatory flexibility analysis:* Not required. D. *Objective:* The amendment states requirements for participation by eligible children enrolled in private schools. E. *Legal basis:* Section 408(9)(1) of Pub. L. 90-247, as amended (20 U.S.C. 1221e-3(a)(1)). F. *Citation:* 34 CFR Part 76.	Phil Rosenfelt, (202) 427-6300.	FR August 1981.
International Education Programs—General.	A. *Description:* The regulations contain general regulatory requirements common to four programs. B. *Regulatory impact analysis:* Not required. C. *Regulatory flexibility analysis:* Not required. D. *Objectives:* The regulations reflect statutory changes and implement new requirements for grants. E. *Legal basis:* Title VI of the Higher Education Act of 1965, as amended by Pub. L. 96-374 (20 U.S.C. 1121-1127); the Elementary and Secondary Education Act of 1965, Pub. L. 89-10 (20 U.S.C., 3063-3065). F. *Citation:* 34 CFR Part 655.	Joseph Belmonte, (202) 245-2356.	FR June 1981.
National Resource Centers and Fellowships Program for Language and Area or Language and International Studies.	A. *Description:* The regulations specify requirements governing the establishment and operation of National Resource Centers for the teaching of any modern foreign language. B. *Regulatory impact analysis:* Not required. C. *Regulatory flexibility analysis:* Not required. D. *Objectives:* The regulations reflect statutory changes and implement new requirements for grants. E. *Legal basis:* Title VI of the Higher Education Act of 1965, as amended by Pub. L. 96-374 (20 U.S.C. 1122). F. *Citation:* 34 CFR Part 656.	Joseph Belmonte, (202) 245-2356.	FR June 1981.
Undergraduate International Studies and Foreign Language Program.	A. *Description:* The regulations establish requirements governing financial assistance to strengthen and improve undergraduate instruction in international studies and foreign languages in the U.S. B. *Regulatory impact analysis:* Not required. C. *Regulatory flexibility analysis:* Not required. D. *Objectives:* The regulations reflect statutory changes and implement new requirements for grants. E. *Legal basis:* Title VI of the Higher Education Act of 1965, as amended by Pub. L. 96-374 (20 U.S.C. 1124). F. *Citation:* 34 CFR Part 658.	Joseph Belmonte, (202) 245-2356.	FR June 1981.
International Studies and Research Program.	A. *Description:* The regulations establish requirements governing financial assistance for research, studies, surveys, and the development of specialized materials. B. *Regulatory impact analysis:* Not required. C. *Regulatory flexibility analysis:* Not required. D. *Objectives:* The regulations reflect statutory changes and implement new requirements for awards. E. *Legal basis:* Title VI of the Higher Education Act of 1965, as amended by Pub. L. 96-374 (20 U.S.C. 1125). F. *Citation:* 34 CFR Part 660.	Joseph Belmonte, (202) 245-2356.	FR June 1981.
International Understanding Program.....	A. *Description:* The regulations establish requirements governing a new program of grants to stimulate in education at all levels understanding about cultures, actions, and interconnections of nations and people. B. *Regulatory impact analysis:* Not required. C. *Regulatory flexibility analysis:* Not required.	Joseph Belmonte, (202) 245-9758.	FR June 1981.

Department of Education Semiannual Regulations Agenda and Review List—Continued

Title	Summary	Contact	Earliest expected decision date
	D. *Objectives:* The regulations reflect new statutory provisions and implement requirements for grants. E. *Legal basis:* Part N of Title III of the Elementary and Secondary Education Act of 1965, as amended Pub. L. 96-374 (20 U.S.C. 3063-3065). F. *Citation:* 34 CFR Part 667.		
Teacher Centers	A. *Description:* The regulations govern awards of grants to local educational agencies and institutions of higher education to plan, establish, and operate teacher centers. B. *Regulatory impact analysis:* Not determined. C. *Regulatory flexibility analysis:* Not required. D. *Objective:* The regulations propose changes in the original interpretation and implementation of the statute with respect to administration of the program. E. *Legal basis:* Title V-B of the Higher Education Act of 1965, as amended Pub. L. 96-374 (20 U.S.C. 1119a). F. *Citation:* 34 CFR Part 240.	Bruce Gaarder, (202) 472-5502.	NPRM June 1981.
National Institute of Handicapped Research.	A. *Description:* The regulations establish general administrative requirements for programs under the National Institute of Handicapped Research B. *Regulatory impact analysis:* Not required. C. *Regulatory flexibility analysis:* Not required. D. *Objectives:* The regulations provide selection criteria and operating procedures common to the programs. E. *Legal basis:* Title II of the Rehabilitation Act of 1973, as amended by Pub. L. 95-602 (29 U.S.C. 760-762). F. *Citation:* 34 CFR Part 350.	Nathan Ed Acree, (202) 472-5248.	FR May 1981.
Handicapped Research: Research and Demonstration projects.	A. *Description:* The regulations govern a program of assistance to projects designed to improve vocational and other rehabilitation services to handicapped individuals through the planning and conducting of research, demonstration activities, and specialized research. B. *Regulatory impact analysis:* Not required. C. *Regulatory flexibility analysis:* Not required. D. *Objectives:* The regulations described the types of projects authorized under the program and establish selection criteria and operating procedures of the program. E. *Legal basis:* Title II of the Rehabilitation Act of 1973, as amended by Pub. L. 95-602 (29 U.S.C. 760-762). F. *Citation:* 34 CFR Part 351.	Nathan Ed Acree, (202) 472-5248.	FR May 1981.
Handicapped Research: Rehabilitation Research and Training Centers.	A. *Description:* The regulations govern a program of assistance to centers that conduct coordinated and advanced programs of research in rehabilitation, disseminate research findings, and provide training for rehabilitation personnel. B. *Regulatory impact analysis:* Not required. C. *Regulatory flexibility analysis:* Not required. D. *Objectives:* The regulations describe the types of activities supported by the Secretary and establish selection criteria and operating procedures for the program. E. *Legal basis:* Title II of the Rehabilitation Act of 1973, as amended by Pub. L. 95-602 (29 U.S.C. 760-762). F. *Citation:* 34 CFR Part 352.	Nathan Ed Acree, (202) 472-5248.	
Handicapped Research: Rehabilitation Engineering Program.	A. *Description:* The regulations govern a program of assistance for the application of technology as a means of solving problems in rehabilitation. B. *Regulatory impact analysis:* Not required. C. *Regulatory flexibilty analysis:* Not required. D. *Objectives:* The regulations establish selection criteria and operating procedures for the program. E. *Legal basis:* Title II of the Rehabilitation Act of 1973, as amended by Pub. L. 95-602 (29 U.S.C. 760-762). F. *Citation:* 34 CFR Part 353.	Nathan Ed Acree, (202) 472-5248.	FR May 1981.
Handicapped Research: Model Research and Training Program.	A. *Description:* The regulations govern a program of assistance for the establishment and operation of centers that conduct research and training related to evaluating and developing the employment potential of the handicapped. B. *Regulatory impact analysis:* Not required. C. *Regulatory flexibility analysis:* Not required. D. *Objectives:* The regulations describe the types of activities eligible for assistance and establish selection criteria and operating procedures for the program. E. *Legal basis:* Title II of the Rehabilitation Act of 1973, as amended by Pub. L. 95-602 (29 U.S.C. 760-762). F. *Citation:* 34 CFR Part 354.	Nathan Ed Acree, (202) 472-5248.	FR May 1981.
Handicapped Research: Knowledge Dissemination and Utilization.	A. *Description:* The regulations govern a program of assistance to promote the dissemination and use of knowledge and research generated by projects funded by the National Institute of Handicapped Research and other sources. B. *Regulatory impact analysis:* Not required. C. *Regulatory flexibility analysis:* Not required. D. *Objectives:* The regulations describe the types of activities eligible for assistance and establish selection criteria and operating procedures for the program. E. *Legal basis:* Title II of the Rehabilitation Act of 1973, as amended by Pub. L. 95-602 (29 U.S.C. 760-762). F. *Citation:* 34 CFR Part 355.	Nathan Ed Acree, (202) 472-5248.	FR May 1981.
Handicapped Research: Research Fellowships.	A. *Description:* The regulations govern a program of assistance to highly qualified individuals to conduct research related to rehabilitation problems of the handicapped. B. *Regulatory impact analysis:* Not required. C. *Regulatory flexibility analysis:* Not required. D. *Objectives:* The regulations describe eligibility requirements for fellows, the types of problems that may be researched, and the criteria used to select fellows. E. *Legal basis:* Title II of the Rehabilitation Act of 1973, as amended by Pub. L. 95-602 (29 U.S.C. 760-762). F. *Citation:* 34 CFR Part 356.	Nathan Ed Acree, (202) 472-5248.	FR May 1981.
Rehabilitation Technical Assistance Program.	A. *Description:* the regulations govern a program of technical assistance in matters related to the management of rehabilitation facilities or in matters related to the removal of architectural, transportation, or communication barriers to the handicapped. B. *Regulatory impact analysis:* Not required. C. *Regulatory flexibility analysis:* Not required.		

Department of Education Semiannual Regulations Agenda and Review List—Continued

Title	Summary	Contact	Earliest expected decision date
	D. *Objective:* The regulations implement requirements for conducting projects under the program. E. *Legal basis:* Sections 12(a) and 506 of the Rehabilitation Act of 1973, as amended by Pub. L. 95-602 (29 U.S.C. 711(a) and 794(b)). F. *Citation:* 34 CFR Part 393.		
The Helen Keller National Center for Deaf-Blind Youths and Adults.	A. *Description:* The regulations govern a program of assistance to a center designed for the vocational rehabilitation of deaf-blind individuals. B. *Regulatory impact analysis:* Not required. C. *Regulatory flexibility analysis:* Not required. D. *Objective:* The regulations implement the revised statutory authority for the center program. E. *Legal basis:* Section 313 of the Rehabilitation Act of 1973, as amended by Pub. L. 95-602 (29 U.S.C. 777c). F. *Citation:* 34 CFR Part 394.	Harold F. Shay, (202) 245-0079.	FR May 1981.
Research in Education of the Handicapped.	A. *Description:* The regulations amend current regulations for a program providing grants and contracts for research in the education of the handicapped, including model projects. B. *Regulatory impact analysis:* Not required. C. *Regulatory flexibility analysis:* Not required. D. *Objectives:* The regulations establish priority areas for the funding of model projects and research projects and a method for the annual selection of priorities. They also revise current regulations to provide for contractual awards to for-profit organizations. E. *Legal basis:* Section 641-644 of the Education of the Handicapped Act, as amended by Pub. L. 95-49 (20 U.S.C. 1441-1444). F. *Citation:* 34 CFR Part 324.	Jane Case Williams, (202) 245-3387.	FR May 1981.
Needs Analysis: Common Form—1982-1983.	A. *Description:* The regulations provide a common needs analysis for the need-based student aid programs under Title IV of the Higher Education Act. The programs affected are: Pell Grant, National Direct Student Loans, Supplemental Educational Opportunity Grants, College Work-Study, and Guaranteed Student Loan. B. *Regulatory impact analysis:* Not required. C. *Regulatory flexibility analysis:* Not determined. D. *Objectives:* The regulations establish needs analysis provisions common to the operation of the affected student aid programs. E. *Legal basis:* Section 417A of Title IV of the Higher Education Act of 1965, as amended by Pub. L. 96-374 (20 U.S.C. 1069). F. *Citation:* 34 CFR Part 690.	William Moran, (202) 472-4300.	NPRM June 1981.
Innovative Regulatory Techniques.....	A. *Description:* The regulations amend the Education Department General Administrative Regulations (EDGAR) and some program regulations to provide administrative relief for certain applicants for grants and certain recipients of grants under programs of the Department of Education. B. *Regulatory impact analysis:* Not required. C. *Regulatory flexibility analysis:* Not determined. D. *Objectives:* The regulations implement provisions that permit certain entities to establish apply and their own compliance and administrative procedures to meet regulatory goals. They also exempt certain small entities from some administrative requirements. E. *Legal basis:* Department of Education Organization Act, Pub. L. 96-88 (20 U.S.C. 3474). F. *Citation:* 34 CFR Parts 75, 76, 77, 106, and 674.	Ruth Feldman, (202) 472-1058.	NPRM July 1981.

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federal register

Thursday
April 30, 1981

Part IV

Department of Health and Human Services

Office of the Secretary

Semi-Annual Agenda of Regulations

DEPARTMENT OF HEALTH AND HUMAN SERVICES

20 CFR Ch. III

21 CFR Ch. I

42 CFR Chs. I–IV

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

Semi-Annual Agenda of Regulations

AGENCY: Department of Health and Human Services.

ACTION: Publication of semi-annual agenda of regulations (Executive Order 12291 and the Regulatory Flexibility Act of 1980).

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

This Agenda contains only those regulations that are: (1) specifically required by statute or court order; (2) implementing decisions made after January 20, 1981; or (3) the result of ongoing review of existing regulations initiated prior to January 20, 1981.

The Department is in the process of establishing new procedures intended to reduce significantly the number and scope of new regulations issued in the future. In addition, the Department is undertaking a systematic review of significant regulations already "on the books" to eliminate unnecessary and overly burdensome requirements.

Many regulations listed in the Department's last semi-annual agenda (published on December 19, 1980) are not included in this April list. The Secretary is reviewing all regulatory actions initiated but not completed prior to January 20, 1981, and decisions to proceed will be made on a case-by-case basis. Therefore, exclusions from this agenda only signifies that decisions have not been made on particular regulatory actions in the December 1980 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, SW., Washington, D.C. 20201, Telephone: (202) 245–3160.

Dated: April 23, 1981.

Richard S. Schweiker,

Secretary of Health and Human Services.

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

Office of the Secretary

Title	Summary	Contact
OIG–1—Grants to States for State Medicaid Fraud Control Units.	A. *Description:* The OIG is reconsidering policy decisions made in existing regulations that governor State Medicaid Fraud Control Units and their relationship to State Medicaid agencies. These rules set forth eligibility for funding, mandatory and optional functions, staffing requirements, application and reporting procedures, and funding limitations. B. *Why Significant:* The proposed amendments would eliminate some unnecessary limitations on unit funding, but would increase minimum requirements for participation to strengthen unit performance. Some of these changes are in response to a GAO report, congressional enactment of permanent funding for these units and expressions of concern on unit activities, and OIG experience with the units. C. *Regulatory Analysis:* Not required D. *Need:* To interpret P.L. 96–499 and to improve the productivity of the units E. *Legal Authority:* P.L. 96–499; P.L. 95–142; Sections 1903(a)(6) and 1102 of the Social Security Act. F. *Chronology:* The regulations proposal is the first step in the development of the proposed amendments. G. *Covered by the Regulatory Flexibility Act:* No	Joseph J. Piazza, Director, Division of State Fraud Control, Office of Inspector General, 330 Independence Ave. SW., Washington, D.C. 20201 202/472–3222.
OS–1—Requirements and Procedures Applicable to Appeals Before the Departmental Grant Appeals Board.	A. *Description:* This final rule would set out the requirements and procedures for appeals to Departmental Grant Appeals Board for certain disputes (listed therein) arising for HHS programs. B. *Why Significant:* This rule will revise earlier editions and is designed to provide a fair and impartial process as well as substantial revision to provide for a quick and flexible process. C. *Regulatory Analysis:* Not needed D. *Need:* To keep impartiality of Board while at the same time providing a quicker more flexible process for grantees and agencies. To aid in shortening the time for final closeout or audit reports that are in dispute. E. *Legal Basis:* 5 USC 301; Reorganization Plan of 1953 (Sec. 1, 5, 6 and 7) F. *Chronology:* Revision of previous edition proposed rule published on January 6, 1981; Public Hearing held February 17; comment period ended March 9, 1981.	Norval D. (John) Settle, Chair, Departmental Grant Appeals Board, Room 2004, Switzer Building, 330 C Street SW., Washington, D.C. 20201.
OCR–1—Nondiscrimination on the Basis of Age in Federally Assisted Programs.	A. *Description:* The regulation will prohibit age discrimination in programs and activities that receive financial assistance from the Department. B. *Why Significant:* The regulation will set forth the specific responsibilities of recipients and will protect individuals from age discrimination in HHS-assisted programs and activities. C. *Regulatory Analysis:* Not required D. *Need:* Pursuant to the Act the Secretary is required to promulgate agency-specific regulations setting forth the responsibilities of its recipients. E. *Legal Basis:* 42 U.S.C. 6101 *et seq* F. *Chronology:* Government-wide final regulations to implement the Act were published by the Department in the FEDERAL REGISTER on June 12, 1979 (44 FR 33768). The Department's agency-specific NPRM was published September 24, 1979 (44 FR 55108). Comment period ended November 23, 1979. G. *Covered by Regulatory Flexibility Act:* No	George Lyon, Office of the General Counsel, Civil Rights Division, (202) 245–6246, 330 Independence Ave. SW., Washington, D.C. 20201.
Cost Principles for Nonprofit Organizations	A. *Description:* Amendment to HHS General grants administration regulation to implement OMB Circular A–122, Cost Principles for Nonprofit 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	Gary Talesnik, Office of Grants and Contract Financial Management, Room 533–H, Humphrey Bldg., 200 Independence Avenue SW., Washington, D.C. 20201, 202–245–8771.

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

Office of the Secretary

Title	Summary	Contact
	D. *Need:* Required to comply with OMB directive E. *Legal Basis:* 5 U.S.C. 301 F. *Chronology:* None G. *Covered by the Regulatory Flexibility Act:* No	
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 administrative 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 G. *Covered by the Regulatory Flexibility Act:* No	Edward Tracy, Office of Grant and Contract Financial Management, Room 533-H, Humphrey Bldg., 200 Independence Avenue SW., Washington, D.C. 20201, 202-755-7633.
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, 45 U.S.C. 1302 F. *Chronology:* None G. *Covered by the Regulatory Flexibility Act:* No	Edward Tracy, Office of Grant and Contract Financial Management, Room 533-H, Humphrey Bldg., 200 Independence Avenue SW., Washington, D.C. 20201, 202-755-7633.
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 regulations 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 G. *Covered by the Regulatory Flexibility Act:* No	Matthias Lasker, Director, Division of Grants Policy and Regulations Development, OGP, Room 513D, Humphrey Bldg., 200 Independence Avenue SW. Washington, D.C. 20201, 202-245-7565.
HHS Procurement Regulation	A. *Description:* Periodic amendments to HHS Procurement Regulation to implement OMB and GSA procurement policy directives and Federal Procurement Regulations. B. *Why Significant:* Amendments will implement government-wide policies and procedures which govern Federal contracts. C. *Regulatory Analysis:* Not required D. *Need:* Required to comply with OMB and GSA policy directives and regulations. E. *Legal Basis:* Chapter 3, Title 41 U.S.C. F. *Chronology:* None G. *Covered by the Regulatory Flexibility Act:* No	Fred Lewis, Office of Procurement Policy, Room 539H, Humphrey Bldg., 200 Independence Avenue SW., Washington, D.C. 20201, 202-245-8740.
Payments With Checks-Paid Letters of Credit and Delay-of-Drawdown Letters of Credit.	A. *Description:* The regulations will require that certain recipient organizations adopt the checks-paid letter of credit technique or the alternative delay-of-drawdown technique. B. *Why Significant:* Provides as a regulatory base that a uniform funding method be used in making funds available to DHHS recipient organizations. The funding method will insure that any recipient organization which draws an advance of Federal funds, using a letter of credit, will have their funds as they need them, but not far in advance of their need. C. *Regulatory Analysis:* Not required D. *Need:* While the statute does not mandate regulations, the magnitude of advance payments to recipient organizations requires that more sophisticated funding mechanisms be utilized. E. *Legal Basis:* 42 U.S.C. 4213 F. *Chronology:* None G. *Covered by the Regulatory Flexibility Act:* No	David Dukes, Deputy Assistant Secretary for Finance, Room 705D Hubert Humphrey Building, 200 Independence Ave. SW., Washington, D.C. 20201, (202) 254-7084.
Due Process Principles	A. *Description:* The regulation will prescribe the actions that will be taken by DHHS in resolving or attempting to resolve cash management deficiencies or abuses demonstrated by any recipient organization. B. *Why Significant:* Provides a regulation to ensure that DHHS recipient organizations know what will happen when they do not operate within the cash management requirements. In addition to knowing what will happen the recipient organizations will know the time frame in which the various actions will be taken. C. *Regulatory Analysis:* Not required D. *Need:* While the statute does not mandate regulations they are necessary in order to permit DHHS to carry out its cash management responsibilities under the letter of credit and non-letter of credit payment systems. E. *Legal Basis:* *State of New York* v. *Patricia Harris,* Civil Action No. 80-1265 (U.S.D.C. D.C. July 11, 1980). F. *Chronology:* None G. *Covered by the Regulatory Flexibility Act:* No	David Dukes, Deputy Assistant Secretary for Finance, Room 705D Hubert Humphrey Building, 200 Independence Ave. SW., Washington, D.C. 20201, (202) 245-7084.

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

Public Health Service

Title	Summary	Contact
PHS—Confidentiality of Alchohol and Drug Abuse Patient Records, minimium requirements for protecting.	A. *Description:* These regulations apply to the records of the indentity, 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 406(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 Department's experience with the regulation over the past five 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 and a decision made to recodify. Notice of Decision to develop Regulations published January 2, 1980 (45 FR 53) with a 60-day comment period. G. *Covered by the Regulatory Flexibility Act:* Yes	Judith T. Galloway, Legal Assistant, Alcohol, Drug Abuse, and Mental Health Administration, Room 13C06, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857. Telephone (301) 443-3200.
PHS—Foreign Quarantine Regulations: Requirements and Inspections.	A. *Description:* This NPRM would provide procedures on preventing the introduction, transmission, or spread of communicable diseases from foreign countries into the United States. B. *Why Significant:* The procedures affect 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. G. *Covered by Regulatory Flexibility Act:* Yes	Mr. Anthony M. Scardaci, Associate Director, Center for Prevention Services, Centers for Disease Control, 1600 Clifton Road NE., Atlanta, Georgia 30333, (404) 329-3773, FTS: 236-3773.
PHS—Medical Examination of Aliens	A. *Description:* This NPRM would provide 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. G. *Covered by Regulatory Flexibility Act:* Yes	Mr. Anthony M. Scardaci, Associate Director, Center for Prevention Services, Centers for Disease Control, 1600 Clifton Road NE., Atlanta, Georgia 30333, 404-329-3773, FTS: 236-3773.
PHS-NIOSH—Research and Demonstration Grants (42 CFR Part 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 and to delete provisions that duplicate or conflict with 45 CFR Part 74: (1) Grants for research and demonstrations relating to occupational safety and health (42 CFR Part 87); and (2) grants for advancement of health in coal mining (42 CFR Part 55). B. *Why Significant:* These regulations provide the regulatory base for these grant 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 1977. E. *Legal Basis:* (1) Occupational Safety and Health Act of 1970 (29 U.S.C. 669(a)(1)); and (2) 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 (45 FR 16209). G. *Covered by Regulatory Flexibility Act:* No	Ms. Mary L. Flint, Regulations Specialist, National Institute for Occupational Safety and Health, 5600 Fishers Lane, Room 8-11, Rockville, Maryland 20857, (301) 443-4493, FTS: 443-4493.

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

Public Health Service

Title	Summary	Contact
PHS—Fees for Direct Training, Centers for Disease Control.	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 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:* Notice of Decision to Develop Regulations published December 19, 1980 (45 FR 83579). G. *Covered by Regulatory Flexibility Act:* No.	Dr. Seth N. Leibler, Acting Director, Center for Professional Development and Training, Centers for Disease Control, 1600 Clifton Road NE., Atlanta, Georgia 30333, (404) 262-6671, FTS: 236-6671.
PHS—Indian Health Care Improvement Act Programs.	A. *Description:* This NPRM would amend 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 regulations which establish 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 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 P.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. *Covered by the Regulatory Flexibility Act:* No.	Richard J. McCloskey, Indian Health Service, Room 5A-39, 5600 Fishers Lane, Rockville, Maryland 20857, (301-443-1116).
PHS—Grants for Development, Construction, and Operations of Facilities and Services.	A. *Description:* This NPRM would amend 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 system. B. *Why Significant:* The regulation will conform existing IHS grant administration regulations to the Department's regulations which established 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. A0-102, Revised (published September 12, 1977, 42 FR 45828), to conform with the Department's regulations on grant administration (45 CFR Part 74). E. *Legal Basis:* 5 U.S.C. 301; 42 FR 45828; 25 U.S.C. 450. F. *Chronology:* Changes governed by procedures out-lined in Section 107(c) of Pub. L. 93-638 requiring proposed 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, the current regulation 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. *Covered by the Regulatory Flexibility Act:* No.	Richard J. McCloskey, Indian Health Service, Room 5A-39, 5600 Fishers Lane, Rockville, Maryland 20857, (301-443-1116).
PHS—Indian Health.	A. *Description:* This final rule amends Subpart A, Scope and Definition, and Subpart B, Availability of Services, are revised as parat of the Department's "Operation Common Sense" to make them clearer. Subpart D, Contagious and Infectious Diseases, is being rescinded 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:* Part of the Department's continuing Review of existing Regulations. 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; NPRM published November 19, 1980; comment period ended January 5, 1981. G. *Covered by the Regulatory Flexibility Act:* No.	Richard J. McCloskey, Indian Health Service, Room 5A-39, 5600 Fishers Lane, Rockville, Maryland 20857, (301-443-1116).
PHS—Redesignation of Contract Health Service Delivery Area (CHSDA) for the Penobscot Reservation.	A. *Description:* This final rule amends 42 CFR 36.22(a) 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 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).	Richard J. McCloskey, Indian Health Service, Room 5A-39, 5600 Fishers Lane, Rockville, Maryland 20857, (301-443-1116).

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

Public Health Service

Title	Summary	Contact
	F. *Chronology:* Since it is a technical amendment, a NOI was not required. An NPRM was published on January 6, 1981; the comment period closed February 5, 1981. G. *Covered by the Regulatory Flexibility Act:* No	
PHS—Redesignation of Contract Health Service Delivery Area (CHSDA) for the Passamaquoddy Reservation.	A. *Description:* This NPRM would amend 42 CFR 36.22(a) to change the CHSDA for the Passamaquoddy Reservation. B. *Why Significant:* This is a technical amendment affecting only the Passamaquoddy Indian Tribe. C. *Regulatory Analysis:* Not required D. *Need:* The CHSDA for the Passamaquoddy Reservation needs to be amended to reflect the service area funded by Congress which is greater than that derived by a technical application of the current regulation. 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 NOI is not required G. *Covered by the Regulatory Flexibility Act:* No	Richard J. McCloskey, Indian Health Service, Room 5A-39, 5600 Fishers Lane, Rockville, Maryland 20857, (301-443-1116).
PHS—Redesignation of Contract Health Service Delivery Area (CHSDA) for the Reservation of the Mississippi Band of Choctaw Indians.	A. *Description:* This NPRM would amend 42 CFR 36.22(a) to change the CHSDA for the Mississippi Choctaw Reservation. B. *Why Significant:* This is a technical amendment affecting only the Mississippi Bank of Choctaw Indians. C. *Regulatory Analysis:* Not required D. *Need:* The CHSDA for the Mississippi Choctaw Reservation needs to be amended to add two counties which were inadvertently omitted when the regulations 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 NOI is not required G. *Covered by the Regulatory Flexibility Act:* No	Richard J. McCloskey, Indian Health Service, Room 5A-39, 5600 Fishers Lane, Rockville, Maryland 20857 (301-443-1116).
PHS—Redesignation of Contract Health Service Delivery Area (CHSDA) to conform with Congressional Intent.	A. *Description:* This NPRM would amend 42 CFR 36.22(a) to include in regulation the CHSDA for the Siletz Tribe of Oregon and the Pascua Yaqui Indians of Arizona. B. *Why Significant:* This is a technical amendment affecting only the Siletz and Pascua Yaqui. C. *Regulatory Analysis:* Not required D. *Need:* Both tribes have recently been recognized by Acts of Congress in which Congress indicated the tribes' service area. E. *Legal Basis:* 25 U.S.C. 13 (Snyder Act) and 42 U.S.C. 2001 (Transfer Act); P.L. 95-125 (Siletz Restoration Act); and P.L. 95-375 (Extension of Federal Benefits to Pasqua Yaqui Indians). F. *Chronology:* None. Since it is a technical amendment, a NOI is not required G. *Covered by the Regulatory Flexibility Act:* No	Richard J. McCloskey, Indian Health Service, Room 5A-39, 5600 Fishers Lane, Rockville, Maryland 20857, (301-443-1116).
PHS—Abortion	A. *Description:* This NPRM proposes to add Subpart F, Abortions and Related Medical Services in Indian Health Services Facilities and Health Service Programs, to 42 CFR 36, to make the Indian Health Service policy on provision of abortion services consistent with that of other Department of Health and Human Services programs. B. *Why Significant:* This regulation would apply the "Hyde Amendment" restrictions to IHS. C. *Regulatory Analysis:* Not required D. *Need:* The Secretary has determined that the Department should adopt a consistent policy. E. *Legal Basis:* 25 U.S.C. 13 (Snyder Act) and U.S.C. 2001 and 2003 (Transfer Act). F. *Chronology:* None G. *Covered by the Regulatory Flexibility Act:* No	Richard J. McCloskey, Indian Health Service, Room 5A-39, 5600 Fishers Lane, Rockville, Maryland 20857, (301-443-1116).
PHS—Indian Self-Determination Contracts	A. *Description:* This NPRM would amend 42 CFR 36, Subpart I, and 41 CFR 3-4, Subpart 3-4.60 both titled Contracts Under the Indian Self-Determination Act. B. *Why Significant:* The current regulations are over five years old. Experience has indicated the need for a number of clarifications and changes. C. *Regulatory Analysis:* Not required D. *Need:* Program experience shows a need for a thorough review E. *Legal Basis:* 25 U.S.C. 450 F. *Chronology:* Changes governed by procedures outlined in Section 107(c), Pub. L. 93-638 requiring proposed 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, the current regulation requires that IHS consult with the tribes and that the final rule not go into effect until 60 days after publication in the FEDERAL REGISTER. G. *Covered by the Regulatory Flexibility Act:* No	Richard J. McCloskey, Indian Health Service, Room 5A-39, 5600 Fishers Lane, Rockville, Maryland 20857, (301-443-1116).
PHS—National Institutes of Health Center Grants.	A. *Description:* These regulations would cover grants by the National Institutes of Health for the support of research and demonstration centers. These regulations would replace existing regulations covering just centers supported by the National Heart, Lung and Blood Institute. These regulations would be available for other center programs which may be created in the future or operated under the general research authorities of NIH. B. *Why Significant:* Legislation has authorized research and demonstration centers for other diseases such arthritis and diabetes. C. *Regulatory Analysis:* Not required D. *Need:* To develop consistent regulations for research and demonstration centers funded by the National Institutes of Health. 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). G. *Covered by the Regulatory Flexibility Act:* No	Lowell D. Peart, NIH Regulations Officer, Division of Management Policy, National Institutes of Health, Bethesda, Md. 20205, (301) 496-4606.

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

Public Health Service

Title	Summary	Contact
PHS—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 59a deal with the NLM extramural programs. These rules provide guidance for applying for grants 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 regulations by (1) improving readability and (2) allowing for inclusion of updated nondiscrimination language. Part 59a is changed to remove the requirements that photocopies of biomedical materials be provided without charge to users. Part 63 is proposed to be deleted because NIH no longer has general traineeship authority and the sole remaining NLM program with authority is unfunded with no expectation of being refunded. Part 64 would be expanded to formally cover programs in ADAMHA. 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 U.S.C. 216, 42 U.S.C. 280b-2 F. *Chronology:* Notice of Decision to Regulate was published November 21, 1979 (44 FR 66852). G. *Covered by the Regulatory Flexibility Act:* No	Kenneth Carney, Acting Executive Officer, National Library of Medicine, Bethesda, Md. 20209, (301) 496-6491.
PHS—Protections for Employees Adversely Affected by State Actions to Emphasize Outpatient Mental Health Care.	A. *Description:* This final rule imposes new requirements on States to protect the existing rights and benefits of State employees adversely affected by deinstitutionalization of mental patients and provides certain training and job placement benefits for those employees. B. *Why Significant:* A significant number of employees in the mental health field are adversely affected by deinstitutionalization of mental patients. C. Regulatory Analysis: Not required D. *Need:* The Secretary of Health and Human Services is required by statute to publish regulations with which the Secretary of Labor concurs. E. *Legal Authority:* Section 901, Mental Health Systems Act F. *Chronology:* NPRM published January 22, 1981 (46 FR 7176). The comment period closed March 9, 1981. G. *Covered by the Regulatory Flexibility Act:* No	Anne B. Driscel, Assistant to the Director for Program Policy and Planning, Division of Mental Health Service Programs, National Institute of Mental Health, Parklawn Building, Room 11C-22, 5600 Fishers Lane, Rockville, Md. 20857, (301) 443-4676.

Office of Child Support Enforcement

Title	Summary	Contact
OCSE-1—Office of Child Support Enforcement—Federal Financial Participation in the Costs of Cooperative Agreements with Courts, 45 CFR Part 304.	A. *Description:* These proposed regulations will expand the availability of Federal funding of the costs of courts under cooperative agreements with child support agencies to include costs associated with judicial determinations. The expanded funding will be available in costs that exceed calendar year 1978 costs. Federal funding of costs of the judicial decisionmaker, however, will continue to be prohibited. B. *Why Significant:* The expanded Federal funding should encourage more courts to enter into cooperative agreements with child support enforcement agencies. C. *Regulatory Analysis:* Not required D. *Need:* To implement requirements of Section 404 of P.L. 96-265, the Social Security Disability Amendments of 1980, which apply to court costs incurred on or after July 1, 1980. E. Legal Basis: P.L. 96-265, 42 U.S.C. 655(c) F. *Chronology:* None G. *Covered by the Regulatory Flexibility Act:* No	Frank Lindh, (301) 443-5350, Program Analyst, Policy Branch, Office of Child Support Enforcement, 6110 Executive Blvd., Room 1010, Rockville, Maryland 20852.
OCSE-2—Office of Child Support Enforcement—Withholding of Advance Funds for Not Reporting, 45 CFR Part 301.	A. *Description:* These proposed regulations would prohibit advance payment of the Federal share of State child support enforcement expenses for a calendar quarter unless the State submits expenditure and child support collection reports for all prior quarters except the two most recent quarters. B. *Why Significant:* These proposed regulations could result in the withholding of quarterly advances of Federal child support funds from a State which failed to meet certain Federal reporting requirements. C. *Regulatory Analysis:* Not required D *Need:* To implement the requirements of Section 407 of P.L. 96-265, the Social Security Disability Amendments of 1980, which took effect in the quarter beginning January 1, 1981. E *Legal Basis:* P.L. 96-265, 42 U.S.C. 655(d) F *Chronology:* A Notice of Proposed Rulemaking was published on January 6, 1981 (46 FR 1319). The comment period closed on March 9, 1981. G. *Covered by Regulatory Flexibility Act:* No	Eileen Brooks, (301) 443-5350, Program Analyst, Policy Branch, Office of Child Support Enforcement, 6110 Executive Blvd., Room 1010, Rockville, Maryland 20852.
OCSE-3—Office of Child Support Enforcement—Requests for Collection by the Secretary of the Treasury, 45 CFR Parts 302 and 303.	A. *Description:* These proposed regulations would extend the availability of child support collection services by the Internal Revenue Service (IRS) to families not receiving Aid to Families with Dependent Children (AFDC). In addition, the proposed amendments remove the State plan requirement for IRS collections, and instead place this regulation under 45 CFR Part 303, Standards for Program Operations. Several additional minor changes are proposed to streamline the process of IRS collection. B. *Why Significant:* These regulations could be of significant benefit to non-AFDC families in the collection of child support because they permit the IRS to make collections on behalf of these families. C. *Regulatory Analysis:* Not required D. *Need:* To implement the requirements of Section 402 of P.L. 96-265, the Social Security Disability Amendments of 1980, which took effect on July 1, 1980. E. *Legal Basis:* P.L. 96-265, 42 U.S.C. 652(b)	Eileen Brooks, (301) 443-5350, Program Analyst, Policy Branch, Office of Child Support Enforcement, 6110 Executive Blvd., Room 1010, Rockville, Maryland 20852.

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

Office of Child Support Enforcement

Title	Summary	Contact
	F. *Chronology:* A Notice of Proposed Rulemaking was published on January 6, 1981 (46 FR 1321). The comment period closed on March 9, 1981. G. *Covered by Regulatory Flexibility Act:* No	
OCSE-4—Office of Child Support Enforcement—Computerized Child Support Enforcement Systems, 45 CFR Parts 302, 303, and 304.	A. *Description:* These regulations will specify conditions States must meet in order to receive 90 percent Federal matching in the costs of developing Child Support Enforcement computer systems. B. *Why Significant:* The higher rate of Federal matching provided for in these regulations will encourage States to develop better automatic data processing capability in their Child Support Enforcement programs. C. *Regulatory Analysis:* Not required D. *Need:* To implement the requirements of Section 405 of P.L. 96-265, the Social Security Disability Amendments of 1980, which take effect on July 1, 1981. E. *Legal Basis:* P.L. 96-265, 42 U.S.C. 655(a), 42 U.S.C. 654(16), 42 U.S.C. 652 (d) and (e). F. *Chronology:* None G. *Covered by Regulatory Flexibility Act:* No	Eileen Brooks, (301) 443-5350, Program Analyst, Policy Branch, Office of Child Support Enforcement, 6110 Executive Blvd., Room 1010, Rockville, Maryland 20852.
OCSE-5—Office of Child Support Enforcement—Availability of Incentive Payments to States Which Enforce and Collect on Their Own Behalf, 45 CFR Part 302.	A. *Description:* These regulations will extend the availability of incentive payments on assigned child support collections to any State which makes these collections on its own behalf. B. *Why Significant:* The expanded availability of incentives to States will encourage States to improve their Child Support Enforcement programs. C. *Regulatory Analysis:* Not required D. *Need:* To implement the requirements of Section 307 of P.L. 96-272, the Adoption Assistance and Child Welfare Act of 1980, which took effect on June 17, 1980. E. *Legal Basis:* P.L. 96-272, 42 U.S.C. 658 F. *Chronology:* None G. *Covered by Regulatory Flexibility Act:* No	Pierre Mooney, Program Analyst, (301) 443-5350, Office of Child Support Enforcement, 6110 Executive Blvd., Room 1010, Rockville, Maryland 20852.
OCSE-6—Office of Child Support Enforcement—Use of Federal Parent Locator Service (FPLS) in Child Custody and Parental Kidnapping Cases, 45 CFR Parts 302, 304.	A. *Description:* These proposed regulations would permit the use of the FPLS to locate parents in cases involving child custody and parental kidnapping. B. *Why Significant:* These regulations would extend the use of FPLS services for the first time to cases other than child support cases. C. *Regulatory Analysis:* Not required D. *Need:* To implement Section 9 of P.L. 96-611, the parental Kidnapping Prevention Act of 1980, which takes effect on July 1, 1981. E. *Legal Basis:* P.L. 96-611, 42 U.S.C. 663 F. *Chronology:* None G. *Covered by Regulatory Flexibility Act:* No	Pierre Mooney, (301) 443-5350, Program Analyst, Policy Branch, Office of Child Support Enforcement, 6110 Executive Blvd., Room 1010, Rockville, Maryland 20852.
OCSE-7—Office of Child Support Enforcement—Recovery of Assigned Child Support Payments Received Directly and Retained by AFDC Recipients, 45 CFR Parts 302 and 303.	A. *Description:* These proposed regulations will establish procedures for the recovery by IV-D agencies of assigned support payments which are received directly and retained by AFDC recipients. B. *Why Significant:* These proposed regulations will establish Federal policy in the area of recovery of direct payments, and will permit States the flexibility to handle these situations through either their IV-A or IV-D agencies. C. *Regulatory Analysis:* Not required D. *Need:* To clarify Federal policy in this matter in which the respective responsibilities of IV-A and IV-D agencies have been a source of some confusion among the States. E. *Legal Basis:* 42 U.S.C. 652(a), 42 U.S.C. 1302 F. *Chronology:* Interim instructions were provided by a joint action transmittal issued by OCSE and the Office of Family Assistance (SSA-AT-81-7 (OFA) and OCSE-AT-81-7, dated March 27, 1981). G. *Covered by the Regulatory Flexibility Act:* No	Frank Lindh, (301) 443-5350, Program Analyst, Policy Branch, Office of Child Support Enforcement, 6110 Executive Blvd., Room 1010, Rockville, Maryland 20852.

Social Security Administration

Title	Summary	Contact
Old-Age, Survivors and Disability Insurance and Supplemental Security Income Program; Determinations of Disability; 20 CFR Part 404, Subpart Q, and Part 416, Subpart J.	A. *Description:* The regulations will specify the responsibilities of the Secretary and the State agencies in administering the disability program. They prescribe standards for accuracy of performance and processing time that State agencies are expected to meet in making disability determinations, and provide the administrative requirements and procedures SSA and the State agencies will follow in carrying out the disability determination function. B. *Why Significant:* These regulations are intended to improve the quality of State agencies performance and improve the timeliness of disability determinations. These regulations will give the State agencies maximum practicable management flexibility in meeting objectives. C. *Regulatory Impact Analysis:* Not required D. *Need:* The Social Security Disability amendments of 1980 (section 304) 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) A Notice of Proposed Rulemaking was published on January 16, 1981 (46 FR 4584). G. *Covered by the Regulatory Flexibility Act:* No	William Ziegler, Harry Short, (301) 594-7415, (301) 594-7337, Legal Assistant, Office of Regulations, 6401 Security Boulevard, Baltimore, Maryland 21235.

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

Social Security Administration

Title	Summary	Contact
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 are also described. B. *Why Significant:* This regulation provides regulatory assurance to claimants that appeals will be heard promptly and decisions issued promptly. C. *Regulatory Impact Analysis:* Not required D. *Need:* These regulations are needed because, over the last several years, Congress, the Courts, representatives of individuals in social security matters, and the general public have expressed concern 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 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(ll) F. *Chronology:* A Notice of Proposed Rulemaking was published on March 12, 1980 (45 FR 12837). G. *Covered by the Regulatory Flexibility Act:* No	Phil Berge, (301) 594-7452, Legal Assistant, 6401 Security Boulevard, Baltimore, Maryland 21235.
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:* These regulations will recodify 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 guidelines for the use of representative payees are important for members of the public to know. C. *Regulatory Impact Analysis:* Not required D. *Need:* These regulations are being reviewed to consider the possible need for policy revisions, additions, or deletions. They are being rewritten to make them clearer and easier to understand. E. *Legal Basis:* 42 U.S.C. 304, 1302, 1383 F. *Chronology:* A Notice of Decision to Develop Regulations was published on June 19, 1979 (44 FR 35241). A Notice of Proposed Rulemaking was published on December 1, 1980 (45 FR 79501). G. *Covered by the Regulatory Flexibility Act:* No	Phil Berge, (301) 594-7452, Legal Assistant, Office of Regulations, 6401 Security Boulevard, Baltimore, Maryland 21235.
Supplemental Security Income Program; Eligibility; 20 CFR Part 416, Subpart B.	A. *Description:* These regulations will recodify the requirements for individuals to be eligible for SSI benefits. B. *Why Significant:* The basic rules on eligibility under the SSI program will be described in clear language. C. *Regulatory Impact Analysis:* Not required D. *Need:* These regulations are being reviewed to consider the possible need for policy revisions, additions, or deletions. They are being rewritten to make them clearer and easier to understand. E. *Legal Basis:* 42 U.S.C. 1302, 1381a, 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 September 4, 1980 (45 FR 58503). G. *Covered by the Regulatory Flexibility Act:* No	Rita Hauth, (301) 594-7112, Legal Assistant, Office of Regulations, 6401 Security Boulevard, Baltimore, Maryland 21235.
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:* What is counted as resources in the SSI program is an essential ingredient in determining eligibility. The complex rules will be stated as simply as possible. C. *Regulatory Impact Analysis:* Not required D. *Need:* These regulations are being reviewed to consider the possible need for policy revisions, additions, or deletions. They are being rewritten to make them clearer and easier to understand. E. *Legal Basis:* 42 U.S.C. 1302, 1382, 1382b, 1382c, and 1383 F. *Chronology:* A Notice of Decision to Develop Regulations was published on March 27, 1979 (44 FR 12837). G. *Covered by the Regulatory Flexibility Act:* No	Henry Lerner, (301) 594-7414, Legal Assistant, Office of Regulations, 6401 Security Boulevard, Baltimore, Maryland 21235.
Supplemental Security Income Program; Reductions, Suspensions, and Terminations; 20 CFR Part 416, Subpart M.	A. *Description:* These proposed regulations will recodify the rules for reducing, suspending and terminating an SSI recipient's benefits. B. *Why Significant:* The proposed rules will describe situations when a person may not receive all or part of his or her SSI benefits. C. *Regulatory Impact Analysis:* Not required D. *Need:* These regulations are being reviewed to consider the possible need for policy revisions, additions, or deletions. They are being rewritten to make them clearer and easier to understand. E. *Legal Basis:* 42 U.S.C. 1302, 1382, 1382c, 1382d, and 1383 F. *Chronology:* A Notice of Decision to Develop Regulations was published on June 19, 1979 (44 FR 35241). G. *Covered by the Regulatory Flexibility Act:* No	Charles Campbell, (301) 594-7453, Legal Assistant, Office of Regulations, 6401 Security Boulevard, Baltimore, Maryland 21235.
Supplemental Security Income Program; Interim Assistance Provisions; 20 CFR Part 416, Subpart S.	A. *Description:* These recodified regulations will revise and reorganize rules on interim assistance provisions under the Supplemental Security Income program. The rules permit the Social Security Administration to enter into an agreement with a State to repay the State for interim assistance it gives an individual while an application for SSI is pending. B. *Why Significant:* The rules permit SSA to withhold an individual's SSI benefit payment and send it to the State as repayment for interim assistance, upon the individual's written authorization. C. *Regulatory Impact Analysis:* Not required D. *Need:* These regulations are being reviewed to consider the possible need for policy revisions, additions, or deletions. They are being rewritten to make them clearer and easier to understand. 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 Develop Regulations was published on July 11, 1979 (44 FR 40531). A notice of proposed rulemaking was published on April 21, 1980 (45 FR 26719). G. *Covered by the Regulatory Flexibility Act:* No	Clara Powell, (301) 594-7459, Legal Assistant, Office of Regulations, 6401 Security Boulevard, Baltimore, Maryland 21235.

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Social Security Administration

Title	Summary	Contact
Supplemental Security Income Program; Medicaid Eligibility Determinations; 20 CFR Part 416, Subpart U.	A. *Description:* The proposed regulations will recodify the rules under which Social Security Administration agrees to make determinations of Medicaid eligibility for SSI beneficiaries on behalf of States and to give States other assistance in Medicaid program administration. B. *Why Significant:* The agreements avoid duplication of effort between State and Federal governments and simplify the Medicaid application process for applicants. C. *Regulatory Impact Analysis:* Not required. D. *Need:* These regulations are being reviewed to consider the possible need for policy revisions, additions, or deletions. They are being rewritten to make them clearer and easier to understand. E. *Legal Basis:* 42 U.S.C. 1302, 1383, 1383c, and 4222. F. *Chronology:* A Notice of Decision to Develop Regulations was published on June 19, 1979 (44 FR 35241). G. *Covered by the Regulatory Flexibility Act:* No.	Cliff Terry, (301) 594-7519, Legal Assistant, Office of Regulations, 6401 Security Boulevard, Baltimore, Maryland 21235.
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 the Freedom of Information Act to make them consistent with HHS'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 the availability of information together in one part. B. *Why Significant:* These are basically technical revisions to make SSA's rules consistent with those in 45 CFR Part 5. C. *Regulatory Impact Analysis:* Not required. D. *Need:* There is a need to review SSA's rules on the availability of information for consistency with HHS's, revise our rules to reflect creation of Health Care Financing Administration, and to transfer certain Medicare information which no longer applies to SSA activities to 42 CFR Part 5. E. *Legal Basis:* 42 U.S.C. 405 and 1302. F. *Chronology:* A Notice of Decision to Regulate was published on May 18, 1979 (44 FR 29102). G. *Covered by the Regulatory Flexibility Act:* No.	Armand Esposito, (301) 594-7455, Legal Assistant, Office of Regulations, 6401 Security Boulevard, Baltimore, Maryland 21235
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 Impact 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 Develop Regulations was published on September 15, 1980 (45 FR 60922) and a Notice of Proposed Rulemaking was published on December 22, 1980 (45 FR 84086). G. *Covered by the Regulatory Flexibility Act:* No.	Jack Schanberger, (301) 594-6785, Legal Assistant, Office of Regulations, 6401 Security Boulevard, Baltimore, Maryland 21235.
Old-Age, Survivors, Disability Insurance Program—Basic Computation of Benefits and Lump sums; 20 CFR Part 404, Subpart C.	A. *Description:* These regulations will contain the rules on computations of primary insurance amounts (PIA) in the old-age, survivors, and disability insurance programs. They will also include, for the first time, the new rules on excluding years of low earnings when computing disability benefits, as provided by the Social Security Disability Amendments of 1980. B. *Why Significant:* These regulations will simplify the complex rules on computing benefits, and will introduce the new rules on computing disability benefits. C. *Regulatory Impact Analysis:* Not required. D. *Need:* These regulations are needed so we can give the public clear rules and so we can add the provisions needed to implement section 102 of the Social Security Disability Amendments of 1980. E. *Legal Basis:* Sec. 215 of the Social Security Act; 42 U.S.C. 415; Pub. L. 96-265, Sec. 102. F. *Chronology:* A Notice of Decision to Develop Regulations was published on March 6, 1979 (44 FR 12205). A Notice of Proposed Rulemaking was published on June 25, 1980 (45 FR 42647) to simplify existing rules. A Notice of Proposed Rulemaking was published on December 22, 1980 (45 FR 84086) for the new disability computations, and a Notice of Decision to Develop Regulations was published on January 8, 1981 (46 FR 2093) to modify the new disability computation. G. *Covered by the Regulatory Flexibility Act:* No.	Jack Schanberger, (301) 594-6785, Legal Assistant, Office of Regulations, 6401 Security Boulevard, Baltimore, Maryland 21235.
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 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 Impact Analysis:* Not Required. D. *Need:* Required by the section 201 of the Social Security Amendments of 1980. E. *Legal Basis:* Section 201(a) and (b) of Pub. L. 96-265. F. *Chronology:* Interim regulations were published on January 22, 1981 (46 FR 6903). G. *Covered by the Regulatory Flexibility Act:* No.	Fred Miranda, (301) 594-7341, Legal Assistant, Office of Regulations, 6401 Security Boulevard, Baltimore, Maryland 21235.

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

Social Security Administration

Title	Summary	Contact
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 10/1/80; (2) Earned income tax credits are earned income as of January 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 affect benefit prior to 1980. These credits would have been unearned income as of 1980 and would have resulted in lower benefits, if this law would not have been enacted. C. *Regulatory Impact Analysis:* Not required. D. *Need:* The regulations will provide the criteria to carry out section 202 of Social Security Disability Amendments of 1980 and the Technical Corrections Act of 1979. E. *Legal Basis:* (1) 42 U.S.C. 1382a; (2) 42 U.S.C. 1382a. F. *Chronology:* A Notice of Proposed Rulemaking was published on January 19, 1981 (46 FR 4949). G. *Covered by the Regulatory Flexibility Act:* No.	Rita Hauth, (301) 594-7112, Legal Assistant, Office of Regulations, 6401 Security Boulevard, Baltimore, Maryland 21235.
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; (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 Impact 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. 1382a; (2) 42 U.S.C. 1382c and 1382j. F. *Chronology:* A Notice of Decision to Develop Regulations was published on November 14, 1980 (45 FR 75225). G. *Covered by the Regulatory Flexibility Act:* No.	Rita Hauth, (301) 594-7112, Legal Assistant, Office of Regulations, 6401 Security Boulevard, Baltimore, Maryland 21235.
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 affect 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 Impact 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:* A Notice of Decision To Develop Regulations was published on November 26, 1980 (45 FR 78726). G. *Covered by the Regulatory Flexibility Act:* No.	Harry Short, (301) 594-7337, Legal Assistant, Office of Regulations, 6401 Security Boulevard, Baltimore, Maryland 21235.
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 Impact Analysis:* Not required. D. *Need:* The proposed regulations are needed to implement Section 302 of the Social Security Disability Amendments of 1980. E. *Legal Basis:* 42 U.S.C. 405, 423, 1302, 1382c, and 1383. F. *Chronology:* G. *Covered by the Regulatory Flexibility Act:* No.	David Smith, (301) 594-7396, Legal Assistant, Office of Regulations, 6401 Security Boulevard, Baltimore, Maryland 21235.
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 to 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 Impact 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 Develop Regulations was published on November 14, 1980. G. *Covered by the Regulatory Flexibility Act:* No.	Harry Short, (301) 594-7337, Legal Assistant, Office of Regulations, 6401 Security Boulevard, Baltimore, Maryland 21235.
Old-Age, Survivors and Disability Insurance and Supplemental Security Income Program; Personalized Notices to Be Provided Certain SSA Claimants; 20 CFR Parts 404, Subpart J, and 416, Subpart N.	A. *Description:* Any decision made by the Secretary which involves a determination of disability under title II or title XVI, unfavorable in whole or part to the disabled individual, shall contain a statement of the cause in understandable language setting forth a discussion of the evidence and stating the Secretary's determination and the reason or reasons upon which it is based. Where a 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.	Phil Berge, (301) 594-7452, Legal Assistant, Office of Regulations, 6401 Security Boulevard, Baltimore, Maryland 21235.

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

Social Security Administration

Title	Summary	Contact
	C. *Regulatory Impact Analysis:* Not required D. *Need:* The proposed regulations implement Section 305 of the Social Security Disability Amendments of 1980. E. *Legal Basis:* 42 U.S.C. 405 and 1302 F. *Chronology:* A Notice of Decision To Develop Regulations was published on September 10, 1980 (45 FR 59589). G. *Covered by the Regulatory Flexibility Act:* No	
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 Impact 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 sect. 306 of Pub. L. 96-265. F. *Chronology:* A Notice of Decision to Develop Regulations was published on September 16, 1980 (45 FR 61315). G. *Covered by the Regulatory Flexibility Act:* No	Cliff Terry, (301) 594-7519, Legal Assistant, Office of Regulations, 6401 Security Boulevard, Baltimore, Maryland 21235.
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. 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 Impact Analysis:* Not required D. *Need:* These regulations are needed to implement section 309 of 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). G. *Covered by the Regulatory Flexibility Act:* No	William Ziegler, (301) 594-7415, Legal Assistant, Office of Regulations, 6401 Security Boulevard, Baltimore, Maryland 21235.
Old Age, Survivors and Disability Insurance and Supplemental Security Income Programs; Payment of Certain Travel 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, and to claimants their representatives, and witnesses who attend reconsideration interviews and proceedings before administrative law judges. B. *Why Significant:* The proposed regulations are significant because they will explain when SSA will pay certain travel expenses. C. *Regulatory Impact Analysis:* Not required D. *Need:* These regulations are needed to implement Section 310 of the Social Security Disability Amendments of 1980. E. *Legal Basis:* 94 Stat. 459 and 460 Pub. L. 96-265 F. *Chronology:* A Notice of Decision to Develop Regulations was published on January 15, 1981 (46 FR 3547). G. *Covered by the Regulatory Flexibility Act:* No	Clara Barrett Powell, (301) 594-7459, Legal Assistant, Office of Regulations, 6401 Security Boulevard, Baltimore, Maryland 21235.
Aid to Families With Dependent Children; Disclosure of Information for Audits; 45 CFR 205.50.	A. *Description:* This interim regulation will permit HHS to disclose information concerning applicants and recipients under title IV-A of the Social Security Act. Disclosure is permitted for purposes of program audits conducted by any governmental entity authorized by law to conduct such audits. B. *Why Significant:* Clarifies existing guidelines on disclosure, so that all States and the Federal Government are consistent. C. *Regulatory Impact Analysis:* Not required D. *Need:* To implement section 403 of the Social Security Disability Amendments of 1980. E. *Legal Basis:* 94 Stat. 462, Pub. L. 96-265 F. *Chronology:* G. *Covered by the Regulatory Flexibility Act:* No	Jack Schanberger, (301) 594-6785, Legal Assistant, Office of Regulations, 6401 Security Boulevard, Baltimore, Maryland 21235.
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 interim regulations will 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 regulations will reduce cost to both the State and Federal governments in the operation of the AFDC program because of the systems implemented. C. *Regulatory Impact Analysis:* Not required D. *Need:* These regulations will implement section 406 of the Social Security Disability Amendment of 1980. E. *Legal Basis:* 94 Stat. 465, 466, 467 Pub. L. 96-265 F. *Chronology:* G. *Covered by the Regulatory Flexibility Act:* No	Pat O'Hare, (202) 245-0043, Policy Specialist, Office of Family Assistance, 2110 Switzer Building, 330 C Street, S.W., Washington, D.C. 20201.

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

Social Security Administration

Title	Summary	Contact
Old Age, Survivors, and Disability Insurance and Supplemental Security Income Programs; Deductions, Reductions and Nonpayment of Benefits; 20 CFR Part 404, Subpart E, and 416, Subpart K.	A. *Description:* These proposed 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 proposed 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 Impact 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 Develop Regulations was published on October 20, 1980 (45 FR 69248). G. *Covered by the Regulatory Flexibility Act:* No	Larry Dudar, (301) 594-6629, Legal Assistant, Office of Regulations, 6401 Security Boulevard, Baltimore, Maryland 21235.
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 Impact Analysis:* Not required D. *Need:* These regulations are required to implement section 503 of 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). G. *Covered by the Regulatory Flexibility Act:* No	Armand Esposito, (301) 594-7455, Legal Assistant, Office of Regulations, 6401 Security Boulevard, Baltimore, Maryland 21235.
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 XVIII and waive any of the conditions, requirements, or limitations of title XVI. C. *Regulatory Impact Analysis:* Not required D. *Need:* These regulations are needed to implement section 505 of the Social Security Disability Amendments of 1980. E. *Legal Basis:* 42 U.S.C. 1310 F. *Chronology:* A Notice of Decision to Develop Regulations was published on January 8, 1981 (46 FR 2093). G. *Covered by the Regulatory Flexibility Act:* No	Henry Lerner, (301) 594-7414, Legal Assistant, Office of Regulations, 6401 Security Boulevard, Baltimore, Maryland 21235.
Aid to Families With Dependent Children Program; Incentive for AFDC Recipients to Report Earned Income; 45 CFR 206 and 233.	A. *Description:* The proposed 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 proposed 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 Impact Analysis:* Not required D. *Need:* New rulemaking is necessary to implement section 302 of the Adoption Assistance Child Welfare Act of 1980 in order to assure uniform interpretation by States. E. *Legal Basis:* 94 Stat. 528, Pub. L. 96-272 F. *Chronology:* A Notice of Decision to Develop Regulations was published on December 16, 1980 (45 FR 82681). G. *Covered by the Regulatory Flexibility Act:* No	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.
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:* These 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 States 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 Impact Analysis:* Not required D. *Need:* To implement section 303 of the Adoption Assistance and Child Welfare Act of 1980. 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 F. *Chronology:* A Notice of Decision to Develop Regulations was published on December 16, 1980 (45 FR 82681). G. *Covered by the Regulatory Flexibility Act:* No	Connie Katz, (202) 245-2021, Policy Specialist, Office of Family Assistance, Room B416, Transpoint Building, 2100 Second St. SW., Washington, D.C. 20024.

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

Social Security Administration

Title	Summary	Contact
Supplemental Security Income Program; Disposing of Resources for Less Than Fair Market Value; 20 CFR Part 416, Subpart L.	A. *Description:* These proposed regulations provide that an individual (or eligible spouse) who gives away or sells any nonexcludable resource for less than fair market value for the purpose of establishing SSI eligibility will have those disposed of resources counted toward the resource limit for 24 months from the date of disposal. The disposal of a resource at less than fair market value is presumed to be for the purpose of establishing SSI eligibility unless the individual can present convincing evidence that the disposal was exclusively for some other purpose. B. *Why Significant:* These proposed regulations will affect an individual's eligibility for SSI benefits when the individual disposes of a resource for less than fair market value. C. *Regulatory Impact Analysis:* None required. D. *Need:* To implement section 0005 of Pub. L. 96-611. E. *Legal Basis:* 42 U.S.C. 1382b, 94 Stat. 3567. F. *Chronology:* G. *Covered by the Regulatory Flexibility Act:* No.	Henry Lerner, (301) 594-7414, Legal Assistant, Office of Regulations, 6401 Security Boulevard, Baltimore, Maryland 21235.
Old-Age, Survivors, and Disability Insurance Program; Benefits for Certain Prisoners; 20 CFR Part 404.	A. *Description:* The proposed regulations place certain restrictions on the payment of disability benefits to persons who have been convicted of a felony and are imprisoned. B. *Why Significant:* The proposed regulations are significant because they specify the conditions under which disability benefits will not be paid to an imprisoned felon and how a finding of disability may be affected. C. *Regulatory Impact Analysis:* Not required. D. *Need:* Required by Section 5 of the Amendments to the Social Security Program (P.L. 96-473). E. *Legal Basis:* Pub. L. 96-473. F. *Chronology:* G. *Covered by the Regulatory Flexibility Act:* No.	William Ziegler, (301) 594-7415, Legal Assistant, Office of Regulations, 6401 Security Boulevard, Baltimore, Maryland 21235.
Aid to Families With Dependent Children; Child Support Reporting and Matching Procedures; 45 CFR Chapter II.	A. *Description:* This proposed regulation will require the Department to reduce a State's quarterly grant under title IV-A when the State has child support collections which are unreported or not reported in accordance with Federal regulations. B. *Why Significant:* Why Significant: Makes explicit the reduction of Federal Financial Participation by the amount of the Federal share of child support collections made by a State under title IV-D of the Social Security Act. C. *Regulatory Impact Analysis:* Not required. D. *Need:* To implement section 407(c) of Pub. L. 96-265, the Social Security Disability Amendments of 1980. E. *Legal Basis:* Pub. L. 96-265, section 407(c). F. *Chronology:* G. *Covered by the Regulatory Flexibility Act:* No.	John McDonald, (202-245-2056, Financial Management Specialist, Office of Family Assistance, 2100 2nd Street, S.W., Washington, D.C. 20024.
Old-Age, Survivors and Disability Insurance Programs; Changes to the Retirement Test; 20 CFR Part 404, Subpart E.	A. *Description:* These regulations will contain the rules that will eliminate some of the harsh and unintended effects of the Social Security Amendments of 1977. They are retroactively effective as of January 1978. B. *Why Significant:* The provisions of the regulations (1) permit the use of the monthly earnings test to certain beneficiaries in the year that entitlement terminates for a reason other than death, (2) exclude for the purposes of the annual earnings test, self-employment income received in a year after the inital year of entitlement not attributable to services performed after the month of entitlement; and (3) provide all beneficiaries the use of the monthly earnings test in at least 1 year after 1977. C. *Regulatory Impact Analysis:* Not required. D. *Need:* These regulations are needed so we can give the public clear rules and make them aware of the changes that are required by sections 1, 3, and 4 of the 1981 Amendments to the Social Security Program. E. *Legal Basis:* Secs. 1, 3, and 4 of Public Law 96-473, 94 Stat. 2263. F. *Chronology:* G. *Covered by the Regulatory Flexibility Act:* No.	Clara Barrett Powell, (301) 594-7459, Legal Assistant, Office of Regulations, 6401 Security Boulevard, Baltimore, Maryland 21235.
Old-Age, Survivors, and Disability Insurance Program; Decreased Retroactivity of Benefit Applications; 20 CFR Part 404, Subpart G.	A. *Description:* This proposed regulation would reduce from 12 months to 6 months the maximum retroactivity of all social security insurance benefits that are not based on the worker's disability or the disability of a widow or widower. B. *Why Significant:* This change would mean that people who wait until some time after they become eligible for these benefits to apply for them will receive them for no more than 6 months before the month they apply, even if they have been eligible for more than 6 months. C. *Regulatory Impact Analysis:* Not required. D. *Need:* Required by Section 1011 of the Omnibus Reconciliation Act. E. *Legal Basis:* Sec. 202(j)(1) of the Social Security Act as amended by section 1011 Pub. L. 96-499 (the Omnibus Reconciliation Act of 1980). F. *Chronology:* Pub. L. 96-499 enacted 12/5/80. G. *Covered by the Regulatory Flexibility Act:* No.	Cliff Terry, (301) 594-7519, Legal Assistant, Office of Regulations, 6401 Security Boulevard, Baltimore, Maryland 21235.

Health Care Financing Administration

Title	Description	Contact
Health Care Institution Certifications and Surveys.	A. *Description:* Hospitals, nursing homes and other institutional health care providers are subject to frequent surveys and reviews. Many of these reviews are a result of the Federal Government's role in insuring the health and safety of patients. Given an expanding role and improved performance of some State and local governments and voluntary organizations in this area, a reassessment of the appropriate Federal role is warranted. B. *Why Significant:* Survey and certification requirements affect thousands of health care providers and are critical to ensuring health and safty of patients. Effective monitoring may be accomplished with greater flexibility to States without loss of quality of health services. C. *Regulatory Impact Analysis:* Yes.	Paul Willging, M.D., Deputy Administration, Health Care Financing Admin., 200 Independence Ave., S.W., Washington, D.C. 20201, (202) 245-6726.

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

Health Care Financing Administration

Title	Description	Contact
	D. *Need:* To promote State flexibility, reduce costs, and maintain quality standards. E. *Legal Basis:* Titles XVIII and XIX of the Social Security Act F. *Chronology:* Review announced by Vice President on March 25, 1981. One of three HHS regulations slated for review by the President's Task Force on Regulatory Relief. F. *Covered by the Regulatory Flexibility Act:* Yes	
Medicaid Regulations Affecting States	A. *Description:* At present a variety of regulations impose significant administrative requirements on States. States contend that these regulations hamper their ability to provide services to needy people at reasonable funding levels. In addtion, the President has promised States that regulatory relief will accompany his proposal to limit Federal Medicaid expenditures. For these reasons, a thorough review is needed. B. *Why Significant:* The regulations would provide greater flexibility to States in meeting the medical needs of Medicaid patients at reduced cost. C. *Regulatory Impact Analysis:* Yes D. *Need:* To reduce regulatory burdens on States and promote program efficiency. E. *Legal Basis:* Title XIX of the Social Security Act F. *Chronology:* Review announced by Vice President on March 25, 1981. One of three HHS regulations slated for review by the President's Task Force on Regulatory Relief. G. *Covered by Regulatory Flexibility Act:* No	Paul Willging, Deputy Administrator, Health Care Financing Admin., 200 Independence Ave., S.W., Washington, D.C. 20201, (202) 245-6726.
HCFA—Medicare/Medicaid Program: Differential Reimbursement/Swing Beds.	A. *Description:* This regulation will authorize reimbursement at the State Medicaid intermediate care facility or skilled nursing facility rate where the patient requires a lower level of care, but is inappropriately placed in a hospital; and will provide reimbursement for small, rural hospitals which have been granted a certificate-of-need for provision of long-term care services. This regulation will also set forth conditions of participation for discharge planning and social services for hospitals that provide "swing bed" services. B. *Why Significant:* This regulation will refine institutional reimbursement policies to assure more efficient delivery of needed health care. C. *Regulatory Analysis:* Not required D. *Need:* To implement Sec. 902 (a) and (b), and 904 (a) and (b) of P.L. 96-499, "Omnibus Reconciliation Act of 1980". E. *Legal Basis:* Secs. 1158, 1161, 1861(v)(1)(G), 1883, 1902 and 1918 of the Social Security Act. Secs. 902 and 904 of P.L. 96-499. F. *Chronology:* The final rule with comment period is currently under review. When the review is completed, it will be submitted to the Department for approval. G. *Covered by the Regulatory Flexibility Act:* Yes	Bill Goeller, ORP, DISR, RPB, Branch Chief, Room 1-D-1 ELR 6401 Security Blvd., Baltimore, MD 21207, 301-597-1802.
HCFA—Medicaid Program: Withholding of Federal Share of Payments to Medicaid Providers to Recover Medicare Overpayments.	A. *Description:* This regulation would allow HCFA to withhold the Federal share of Medicaid payments from providers and physicians in order to recover Medicare overpayments that cannot be recovered through the Medicare program either because the provider is participating in Medicare at a minimum level or the physician no longer accepts assignment for Medicare claims. B. *Why Significant:* This regulation would improve financial management, efficiency and accountability for certain Medicare provider overpayment. C. *Regulatory Analysis:* Not required D. *Need:* To implemented Sec. 905 of P.L. 96-499, "Omnibus Reconciliation Act of 1980". E. *Legal Basis:* Sec. 1914 of the Social Security Act. F. *Chronology:* The proposed rule is currently under review. When the review is completed, it will be submitted to the Department for approval. G. *Covered by the Regulatory Flexibility Act:* Yes	Samuel Guida, Director, DRIRE, OSPE, BPO, Room 1445, Meadows East Bldg., 6300 Security Boulevard, Baltimore, MD 21207, 301-594-8500.
HCFA—Reporting Financial Interest	A. *Description:* This regulation would require an entity to report only individual interests in mortgages, deeds of trust, notes, or other obligations if the interest equals the lesser of $25,000 or 5 percent of the value of the total property and assets. B. *Why Significant:* This regulation would improve the financial management, efficiency and accountability for certain Medicare providers. C. *Regulatory Analysis:* Not required D. *Need:* To implement Sec. 912 (a) and (b) of P.L. 96-499, "Omnibus Reconciliation Act of 1980". E. *Legal Basis:* Secs. 1124(a)(3)(A)(ii) and 1902(a)(35) of the Social Security Act; P.L. 95-142 and P.L. 96-499. F. *Chronology:* The final rule with comment period is currently under review. When the review is completed, it will be submitted to the Department for approval. G. *Covered by the Regulatory Flexibility Act:* No	James F. Patton, Director, DVPS, OPV, BQC, Rm. 2-E-5 ELR, 6401 Security Blvd., Baltimore, MD 21207, 301-594-8213.
HCFA—Medicare/Medicaid Programs: Exclusion of Health Care Professionals.	A. *Description:* This regulation will amend the current rule that excludes physicians and practitioners convicted of crimes from participation in the Medicare and Medicaid programs. This regulation will broaden this rule so that the provisions would also apply to other categories of health professionals, such as administrators of health care institutions. B. *Why Significant:* This regulation will clarify HCFA's authority to bar certain professionals from participation in the Medicare and Medicaid programs. C. *Regulatory Analysis:* Not required D. *Need:* To implement Sec. 913 of P.L. 96-499, "Omnibus Reconciliation Act of 1980". E. *Legal Basis:* Secs. 1128, 1862(e), 1902(a)(39), and 2003(d)(1) of the Social Security Act; P.L. 95-142 and P.L. 96-499. F. *Chronology:* The final rule with comment period is currently under review. When the review is completed, it will be submitted to the Department for approval. G. *Covered by the Regulatory Flexibility Act:* No	James F. Patton, Director, DVPS, OPV, BQC, Rm. 2-E-5 ELR, 6401 Security Blvd., Baltimore, MD 21207, 301-594-8213.

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

Health Care Financing Administration

Title	Description	Contact
HCFA—Medicaid Program Common Audit Requirements for Medicare, Medicaid and Maternal Child Health Providers.	A. *Description:* This regulation would require coordinated audits under the Medicare, Medicaid, and Maternal and Child Health programs. These audits must be coordinated through common procedures with audits performed for Medicare program purposes. If a State declines to participate, payment would be reduce to an amount estimated to be due the State if it had participated in a common audit. B. *Why Significant:* This regulation would eliminate duplicate audits of the same provider under Medicare, Medicaid and the Maternal and Child Health programs. C. *Regulatory Analysis:* Not required D. *Need:* To implement Sec. 914 (a), (b) and (c) of P.L. 96-499, "Omnibus Reconciliation Act of 1980". E. *Legal Basis:* Secs. 505(a)(16), 1128, 1129 and 1902(a)(42) of the Social Security Act. F. *Chronology:* The proposed rule is currently under review. When the review is completed, it will be submitted to the Department for approval. G. *Covered by the Regulatory Flexibility Act:* No	Dave Landis, Director, DPE, OSPE, BPO, Rm. 1445, Meadows East Bldg., 6300 Security Blvd., Baltimore, MD 21207, 301-594-8770.
HCFA—Medicare/Medicaid Program: Life Safety Code (Technical Amendment).	A. *Description:* This regulation will delete reference to the 1967 and 1973 editions of the Life Safety Code and require participating health facilities, hospitals, skilled nursing facilities and intermediate care facilities to comply with the edition of the Life Safety Code designated by the Secretary. A "grandfather" provision will be included to permit facilities which are in compliance with the 1967 or 1973 editions to be certified under these editions so long as they remain in compliance. B. *Why Significant:* This regulation will minimize regulatory burdens on facilities consistent with the protection of health and safety of patients and assure orderly adjustments to changing technology. C. *Regulatory Analysis:* Not required D. *Need:* To implement Sec. 915 of P.L. 96-499, "Omnibus Reconciliation Act of 1980". E. *Legal Basis:* Sec. 1861(j)(13) of the Social Security Act F. *Chronology:* The final rule with comment period is currently under review. When the review is completed, it will be submitted to the Department for approval. G. *Covered by the Regulatory Flexibility Act:* No	Mayer Zimmerman, Program Analyst, HSQB, 2nd Floor, Dogwood East Bldg., 1849 Gwynn Oak Ave., Baltimore, MD 20207, 301-594-3318.
HCFA—Medicaid/Medicare Program: Alternatives to Decertification of Long Term Care Facilities.	A. *Description:* This regulation will set forth provisions under Medicare and Medicaid for alternatives to the decertification of long term care facilities (skilled nursing facilities and intermediate care facilities) that are out of compliance with the conditions of participation. The regulation will also authorize HCFA to "look behind" State agency surveys on compliance where the adequacy of the State's determination is questionable. B. *Why Significant:* This regulation will make penalties for non-compliance more reasonable. C. *Regulatory Analysis:* Not required D. *Need:* To implement Sec. 916 (a), (b) and (c) of P.L. 96-499, "Omnibus Reconciliation Act of 1980". E. *Legal Basis:* Secs. 1866, 1902, and 1910 of the Social Security Act F. *Chronology:* The final rule with comment period is currently under review. When the review is completed, it will be submitted to the Department for approval. G. *Covered by the Regulatory Flexibility Act:* Yes	Robert Javec, Program Analyst, HSQB, 2nd Floor, Dogwood East Bldg., 1849 Gwynn Oak Ave., Baltimore, MD 21207, 301-594-3314

Significant Regulations—New Initiatives

Title	Summary	Contact
HCFA—Medicare/Medicaid Programs: Clinical Laboratory Reimbursement.	A. *Description:* This regulation will limit recognition of mark-up of Clinical Laboratory Reimbursement bills from a physician, for services performed by an independent laboratory, to the lesser of the reasonable charge of the laboratory or the amount charged by the physician, plus a nominal handling fee. B. *Why Significant:* This regulation will eliminate unnecessary expenditures for independent laboratory services ordered by a physician. C. *Regulatory Analysis:* Not required D. *Need:* To implement Sec. 918 of P.L. 96-499, "Omnibus Reconciliation Act of 1980". E. *Legal Basis:* Secs. 1833, 1842, and 1902 of the Social Security Act and Sec. 918 of P.L. 96-499. F. *Chronology:* The final rule with comment period is currently under review. When the review is completed, it will be submitted to the Department for approval. G. *Covered by the Regulatory Flexibility Act:* Yes	Paul Riesel, Branch Chief, PPRB, BPP, Rm. 1-A-3 ELR, 6401 Security Blvd., Baltimore, MD 21207, 301-597-1843.
HCFA—Medicare/Medicaid Programs: Professional Standards Review Organizations (PSRO) Membership Requirements; Advisory Groups to PSROs; and Statewide Professional Standards Review Council Advisory Group Membership.	A. *Description:* This regulation will revise PSRO membership requirements, delete requirements for formal advisory groups to PSROs and revise requirements for membership to the advisory groups of each Statewide PSRO council. B. *Why Significant:* This regulation will provide more effective PSRO performance. C. *Regulatory Analysis:* Not required D. *Need:* To implement Secs. 921, 922(a), 923 and 927 of P.L. 96-499, "Omnibus Reconciliation Act of 1980". E. *Legal Basis:* Secs. 1152, 1155, and 1162 of the Social Security Act F. *Chronology:* The final rule with comment period is currently under review. When the review is completed, it will be submitted to the Department for approval. G. *Covered by the Regulatory Flexibility Act:* No	Donna Federman, Program Analyst, HSQB, 1st Floor, Dogwood East Bldg., 1849 Gwynn Oak Ave., Baltimore, MD 21207, 301-594-4272.

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

Significant Regulations—New Initiatives

Title	Summary	Contact
HCFA—Medicare/Medicaid Program: Professional Standards Review Organizations (PSRO) Hospital Review—Routine Services; Preadmission Review; Preoperative Stays.	A. *Description:* This regulation would require PSROs that are able to do so to give priority to preadmission reviews of areas of relatively frequent over-utilization to assure that payment made under Medicare and Medicaid are medically appropriate. These areas include routine tests, unusually long preoperative stays and weekend admissions. B. *Why Significant:* This regulation would improve cost effectiveness by enabling PSROs to determine the appropriate setting for surgical procedures. C. *Regulatory Analysis:* Not required D. *Need:* To implement Secs. 924 and 926 of P.L. 96-499, "Omnibus Reconciliation Act of 1980". E. *Legal Basis:* Secs. 1154 and 1155 of the Social Security Act F. *Chronology:* The proposed rule is currently under review. When the review is completed, it will be submitted to the Department for approval. G. *Covered by the Regulatory Flexibility Act:* No	Sharman Stephens, Program Analyst, HSQB, 1st Floor, Dogwood East Bldg., 1849 Gwynn Oak Ave., Baltimore, MD 21207, 301-594-3103.
HCFA—Medicare Program: Home Health Agency Bonding.	A. *Description:* This regulation will set forth requirements (including the establishment of bonding or escrow accounts) that home health agencies must meet in order to minimize financial risk. B. *Why Significant:* This regulation will assure that home health agencies are financially viable enough to participate in the program. C. *Regulatory Analysis:* Not required D. *Need:* To implement Sec. 930(n) of P.L. 96-499, "Omnibus Reconciliation Act of 1980". E. *Legal Basis:* Sec. 1861 of the Social Security Act and Sec. 930 of P.L. 96-499. F. *Chronology:* The final rule with comment period is currently under review. When the review is completed, it will be submitted to the Department for approval. G. *Covered by the Regulatory Flexibility Act:* Yes	Bill Goeller, Branch Chief, RPB, BPP, Room 1-D-1 ELR, 6401 Security Blvd., Baltimore, MD 21207, 301-597-1802.
HCFA—Medicare/Medicaid Program: Conditions of Participation for Home Health Agencies.	A. *Description:* This regulation would eliminate the present requirement that proprietary home health agencies can participate in Medicare only in those States that license home health agencies and set forth requirements for a formal training program for home health aides. B. *Why Significant:* This regulation would provide equity between proprietary and non-profit agencies and improve program administration. C. *Regulatory Analysis:* Not required D. *Need:* To implement Sec. 930(n)(2) of P.L. 96-499, "Omnibus Reconciliation Act of 1980". E. *Legal Basis:* Sec. 1861(o) of the Social Security Act F. *Chronology:* The final rule with comment period is currently under review. When the review is completed, it will be submitted to the Department for approval. G. *Covered by the Regulatory Flexibility Act:* Yes	Stefan Miller, Program Analyst, HSQB, 2nd Floor, Dogwood East Bldg., 1849 Gwynn Oak Avenue, Baltimore, MD 20207, 301-594-9741.
HCFA—Medicare Program: Preadmission Diagnostic Testing, Same Hospital.	A. *Description:* This regulation will provide full coverage under Medicare for diagnostic services provided in a hospital's outpatient department which the beneficiary then enters as an inpatient. B. *Why Significant:* This regulation would provide incentives for delivering services in lower cost settings. C. *Regulatory Analysis:* Not required D. *Need:* To implement Sec. 932 of P.L. 96-499, "Omnibus Reconciliation Act of 1980". E. *Legal Basis:* Sec. 1833 of the Social Security Act and Sec. 932 of P.L. 96-499. F. *Chronology:* The final rule with comment period is currently under review. When the review is completed, it will be submitted to the Department for approval. G. *Covered by the Regulatory Flexibility Act:* No	Henry Hehir, Director, DMSCP, BPP, Room 489 EHR, 6401 Security Blvd., Baltimore, MD 21207, 301-594-8561.
HCFA—Medicare Program: Preadmission Diagnostic Testing; Different Hospital; Physician's Office.	A. *Description:* This regulation would cover diagnostic testing in the outpatient department of another hospital or in a physician's office within 7 days prior to the patient's admission as an outpatient. B. *Why Significant:* This regulation would provide incentives for delivering services in lower cost settings. C. *Regulatory Analysis:* Not required D. *Need:* To implement Sec. 932 of Pub. L. 96-499, "Omnibus Reconciliation Act of 1980". E. *Legal Basis:* Sec. 1833 of the Social Security Act and Sec. 932 of Pub. L. 96-499. F. *Chronology:* The proposed rule is currently under review. When the review is completed, it will be submitted to the Department for approval. G. *Covered by the Regulatory Flexibility Act:* No	Henry Hehir, Director, DMSCP, BPP, Room 489 EHR, 6401 Security Blvd., Baltimore, MD 21207, 301-594-8561.
HCFA—Medicare Program: Outpatient Surgery	A. *Description:* This regulation will provide for 100 percent reimbursement for surgical services performed in free-standing ambulatory surgical centers and in physicians' offices subject to certain restrictions. It will also set forth health and safety standards for ambulatory surgical centers participating in the Medicare program. B. *Why Significant:* This regulation would provide incentives for delivering services in lower cost settings. C. *Regulatory Analysis:* Not required D. *Need:* To implement Secs. 934 (a) and (b) of Pub. L. 96-499, "Omnibus Reconciliation Act of 1980". E. *Legal Basis:* Secs. 1832, 1833, 1863 and 1864 of the Social Security Act and Sec. 934 of Pub. L.96-499. F. *Chronology:* The final rule with comment period is currently under review. When the review is completed, it will be submitted to the Department for approval. G. *Covered by the Regulatory Flexibility Act:* Yes	Robert Streimer, Chief, DARS, BPP, Room 1-A-1 EHR, 6401 Security Blvd., Baltimore, MD 21207, 301-597-1337.
HCFA—Medicare/Medicaid Program: Outpatient Surgery (Physician's Office).	A. *Description:* This regulation would set forth a reimbursement methodology for determining overhead amounts, and all-inclusive rates per procedures in each outpatient surgery setting. B. *Why Significant:* This regulation would provide incentives for delivering services in lower cost settings. C. *Regulatory Analysis:* Not required	Robert Streimer, Chief, DARS, BPP, Room 1-A-1 ELR, 6401 Security Blvd., Baltimore, MD 21207, 301-597-1337.

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

Significant Regulations—New Initiatives

Title	Summary	Contact
	D. *Need:* To implement Sec. 934(b) of Pub. L. 96-499, "Omnibus Reconciliation Act of 1980". E. *Legal Basis:* Secs. 1832, 1833, 1863 and 1864 of the Social Security Act and Sec. 934 of Pub. L. 96-499. F. *Chronology:* The proposed rule is currently under review. When the review is completed, it will be submitted to the Department for approval. G. *Covered by the Regulatory Flexibility Act:* Yes	
HCFA—Medicare/Medicaid Program: Professional Standards Review Organizations (PSRO) Hospital Review—Outpatient Surgery.	A. *Description:* This regulation would amend existing regulations on PSRO hospital review and PSRO assumption of review responsibilities for inpatient ancillary services, inpatient physician services, and quality review. This regulation would also provide for PSRO review of selected surgical procedures performed in physicians' offices. B. *Why Significant:* This regulation would reduce unnecessary costs C. *Regulatory Analysis:* Not required D. *Need:* To implement Sec. 934(a) of Pub. L. 96-499, "Omnibus Reconciliation Act of 1980". E. *Legal Basis:* Secs. 1832 and 1833 of the Social Security Act F. *Chronology:* The proposed rule is currently under review. When the review is completed, it will be submitted to the Department for approval. G. *Covered by the Regulatory Flexibility Act:* No	Sharman Stephens, Program Analyst, HSQB, 1st Floor, Dogwood East Bldg., 1849 Gwynn Oak Ave., Baltimore, MD 21207, 301-594-3101.
HCFA—Medicare Program: Optometrists' Services.	A. *Description:* This regulation would provide coverage for previously uncovered services furnished by optometrists related to the condition of aphakia (absence of the natural lens of the eye). B. *Why Significant:* This regulation would extend coverage to a previously uncovered service. C. *Regulatory Analysis:* Not required D. *Need:* To implement Sec. 937 of Pub. L. 96-499, "Omnibus Reconciliation Act of 1980". E. *Legal Basis:* Sec. 1861(r)4 of the Social Security Act and Sec. 937 of Pub. L. 96-499. F. *Chronology:* The proposed rule is currently under review. When the review is completed, it will be submitted to the Department for approval. G. *Covered by the Regulatory Flexibility Act:* Yes	Henry Hehir, Director, DMSCP, BPP, Room 489 EHR, 6401 Security Blvd., Baltimore, MD 21207, 301-594-8561
HCFA—Medicare Program: Payment Service Date.	A. *Description:* This regulation will provide that the determination of Medicare reasonable charges for physician services be based on the date the medical service was furnished rather than the date on which the claim was processed. B. *Why Significant:* This regulation will adjust payment levels to those in effect when services were furnished. C. *Regulatory Analysis:* Not required D. *Need:* To implement Sec. 946 of Pub. L. 96-499, "Omnibus Reconciliation Act of 1980". E. *Legal Basis:* Sec. 1842 of the Social Security Act and Sec. 946 of Pub. L. 96-499. F. *Chronology:* The proposed rule is currently under review. When the review is completed, it will be submitted to the Department for approval. G. *Covered by the Regulatory Flexibility Act:* No	Paul Riesel, Branch Chief, PPRB, BPP, Room 1-A-1 ELR, 6401 Security Blvd., Baltimore, MD 21207, 301-597-1843.
HCFA—Medicare/Medicaid Program: Reimbursement of Physician's Services in Teaching Hospitals.	A. *Description:* This regulation would permit reasonable charge reimbursement to physicians in teaching hospitals under certain circumstances, and would allow cost reimbursement to hospitals where all physicians elect it. It would also provide for computation of reasonable charges for purposes of Medicare reimbursement. B. *Why Significant:* This regulation would clarify and refine physician charge reimbursement policies. C. *Regulatory Analysis:* Not required D. *Need:* To implement Sec. 948 of P.L. 96-499, "Omnibus Reconciliation Act of 1980". E. *Legal Basis:* Secs. 1832, 1842, and 1861 of the Social Security Act and Sec. 948 of P.L. 96-499. F. *Chronology:* The final rule with comment period is currently under review. When the review is completed, it will be submitted to the Department for approval. G. *Covered by the Regulatory Flexibility Act:* Yes	Bill Birnie, Chief, PPRS, PPRB, BPP, Room 1-E-5 ELR, 6401 Security Blvd., Baltimore, MD 21207, 301-594-5431.
HCFA—Medicare/Medicaid Program: Conditions of Participation for Hospitals—Revised Conditions for Participation.	A. *Description:* This regulation will provide for flexibility in the application of health and safety requirements to small and rural hospitals under 50 beds and for midwives to provide medical services in hospitals. B. *Why Significant:* This regulation will eliminate unnecessary procedural requirements for complying with conditions and reduce burden on small providers. C. *Regulatory Analysis:* Not required D. *Need:* To implement Secs. 949 and 965 of P.L. 96-499, "Omnibus Reconciliation Act of 1980". E. *Legal Basis:* Secs. 1102, 1861(e), (f), and (g), 1864, and 1891 of the Social Security Act (42 U.S.C. 1302, 1395 et seq.); Sec. 102 of P.L. 94-182. F. *Chronology:* The final is currently under review. When the review is completed, it will be submitted to the Department for approval. G. *Covered by the Regulatory Flexibility Act:* No	Susan Anderson, Standards and Certification Analyst, HSQB, 2nd Floor, Dogwood East Bldg., 1849 Gwynn Oak Ave., Baltimore, MD 21207, 301-594-9714.
HCFA—Medicare/Medicaid Program: Hospital Utilization Review.	A. *Description:* This regulation will provide for the treatment of podiatrists as physicians under certain circumstances for purposes of utilization. B. *Why Significant:* This regulation will permit enforcement of hospital utilization review requirements designed to reduce medically unnecessary care. C. *Regulatory Analysis:* Not required D. *Need:* To implement Sec. 951 of P.L. 96-499, "Omnibus Reconciliation Act of 1980". E. *Legal Basis:* Secs. 1861(k), 1861(r)(3), 1902(a)(30), 1903(g)(1)(c), and 1903(i)(4) of the Social Security Act. F. *Chronology:* The final is current under review. When the review is completed, it will be submitted to the Department for approval. G. *Covered by the Regulatory Flexibility Act:* No	Beverly Christian, Program Analyst, HSQB 2nd Floor, Dogwood East Bldg., 1849 Gywnn Oak Ave., Baltimore, MD 21207, 301-594-3980.

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

Significant Regulations—New Initiatives

Title	Summary	Contact
HCFA—Medicare Program: Access to Books and Records to Subcontractors.	A. *Description:* This regulation would prohibit Medicare reimbursement to providers for services furnished under contracts (whose cost or value over 12 months is $10,000 or more) to subcontractors unless the Secretary has access to books and records necessary to verify costs. B. *Why Significant:* This regulation would strengthen HCFA's capacity to effectively preclude or detect fraud and abuse and conform Medicare practice to that of other Federal agencies which buy services. C. *Regulatory Analysis:* Not required. D. *Need:* To implement Sec. 952 of P.L. 96-499, "Omnibus Reconciliation Act of 1980". E. *Legal Basis:* Sec. 1861(v)(1)(I) of the Social Security Act; P.L. 96-499. F. *Chronology:* The proposed rule is currently under review. When the review is completed, it will be submitted to the Department for approval. G. *Covered by the Regulatory Flexibility Act:* Yes.	James F. Patton, Director, DVPS, OPV, BOC, Rm. 2-E-5 ELR, 6401 Security Blvd., Baltimore, MD 21207, 301-594-8213.
HCFA—Medicare Program: Provider Reimbursement Review Board (PRRB): Expedited Judicial.	A. *Description:* This regulation will require the PRRB to determine within 30 days whether it has jurisdiction over an issue brought before it by a provider and authorize judicial reviews without further administrative review where the Board decides it lacks jurisdiction. B. *Why Significant:* This regulation will expedite the administrative appeals process. C. *Regulatory Analysis:* Not required. D. *Need:* To implement Sec. 955 of P.L. 96-499, "Omnibus Reconciliation Act of 1980". E. *Legal Basis:* Sec. 1878 of the Social Security Act and Sec. 955 of P.L. 96-499. F. *Chronology:* The final rule with comment period is currently under review. When the review is completed, it will be submitted to the Department for approval. G. *Covered by the Regulatory Flexibility Act:* No.	Stanley Katz, Chief, DTPL, BPP, 2nd Floor, Dogwood West Bldg., 1848 Gwynn Oak Ave., Baltimore, MD 21207, 301-594-9595
HCFA—Medicare Program: Beneficiary Not at Fault.	A. *Description:* This regulation would require that payment be made for inpatient services under Part A where a beneficiary requiring a higher level of care is erroneously placed in a distinct part of an institution that provides a lower level of care. B. *Why Significant:* This regulation would reimburse at the appropriate level when a beneficiary received covered care but was in an erroneous placement through no fault of his own. C. *Regulatory Analysis:* Not required. D. *Need:* To implement Sec. 956 of P.L. 96-499, "Omnibus Reconciliation Act of 1980". E. *Legal Basis:* Sec. 1879 of the Social Security Act and Sec. 956 of P.L. 96-499. F. *Chronology:* The proposed rule is currently under review. When the review is completed, it will be submitted to the Department for approval. G. *Covered by the Regulatory Flexibility Act:* No.	Stanley Katz, Chief, DTPL, BPP, 2nd Floor, Dogwood West Bldg., 1848 Gwynn Oak Ave., Baltimore, MD 21207, 301-594-9595.
HCFA—Medicare/Medicaid Program: Technical ESRD Amendments (Technical Amendment).	A. *Description:* This regulation will authorize HCFA to enter into agreements with approved nonprofit entities to provide dialysis equipment to individuals who dialyze at home. B. *Why Significant:* This regulation will provide equipment economically and efficiently. C. *Regulatory Analysis:* Not required. D. *Need:* To implement Sec. 957 of Pub. L. 96-499, "Omnibus Reconciliation Act of 1980". E. *Legal Basis:* Sec. 1881(e) of the Social Security Act. F. *Chronology:* The final rule with comment period is currently under review. When the review is completed, it will be submitted to the Department for approval. G. *Covered by the Regulatory Flexibility Act:* No.	Joe Jackson, Program Analyst, OSP, 1st Floor, Dogwood West Bldg., 1848 Gwynn Oak Ave., Baltimore, MD 21207, 301-597-3151.
HCFA—Medicaid Program: Disputed Medicaid Claims; Interest Charge on Final Determination.	A. *Description:* This regulation would set forth the requirement for interest payments on disputed Medicaid funds after a final determination of allowability. B. *Why Significant:* This regulation would establish the payment of interest as an equitable solution to the use of funds pending a final determination of allowability. It would also expedite the processing of State appeals from notices of disallowances. C. *Regulatory Analysis:* Not required. D. *Need:* To implement Sec. 961 of Pub. L. 96-499, "Omnibus Reconciliation Act of 1980". E. *Legal Basis:* Sec. 1903(d) of the Social Security Act. F. *Chronology:* The proposed rule is currently under review. When the review is completed, it will be submitted to the Department for approval. G. *Covered by the Regulatory Flexibility Act:* No.	David McNally, Director, DFO, OPA, BPO, Rm. 350, Meadows East Bldg., 6300 Security Blvd., Baltimore, MD 21207, 301-597-1397.
HCFA—Medicaid Program: Skilled Nursing Facilities/Intermediate Care Facilities (SNFs/ICFs)—Medicaid Reimbursement.	A. *Description:* This regulation would require States to reimburse SNFs and ICFs at rates that are reasonable and adequate to meet the costs incurred by facilities in order to provide care. This regulation would implement certain provisions of the "Omnibus Reconciliation Act of 1980" affecting repeal of Sec. 249 of Pub. L. 92-603 that required most States to pay SNFs and ICFs on a reasonable cost-related basis. B. *Why Significant:* This regulation would provide States with more flexibility in developing methodologies to reimburse nursing homes. C. *Regulatory Analysis:* Not required. D. *Need:* To implement Sec. 962 of Pub. L. 96-499, "Omnibus Reconciliation Act of 1980". E. *Legal Basis:* Sec. 1902(a)(13)(E) of the Social Security Act and Sec. 962 of Pub. L. 96-499. F. *Chronology:* The proposed rule is currently under review. When the review is completed, it will be submitted to the Department for approval. G. *Covered by the Regulatory Flexibility Act:* Yes.	Alan Spielman, Acting Chief, SIS, SPB, BPP, Room 1-A-1 ELR, 6401 Security Blvd., Baltimore, MD 21207, 301-597-1804.

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

Significant Regulations—New Initiatives

Title	Summary	Contact
HCFA—Medicare/Medicaid Program: Nurse-Midwife Services.	A. *Description:* This regulation will specify Federal requirements under Medicaid (title XIX of the Social Security Act) for the provision of nurse-midwife services. This regulation will define nurse-midwife services and specify how States are to provide for these services. B. *Why Significant:* Revised requirements will improve access to a cost-effective source of maternity care. C. *Regulatory Analysis:* Not required. D. *Need:* To implement Sec. 965 of Pub. L. 96-499, "Omnibus Reconciliation Act of 1980". E. *Legal Basis:* Sec. 1905 of the Social Security Act and Sec. 965 of Pub. L. 96-499. F. *Chronology:* The final rule with comment period is currently under review. When the review is completed, it will be submitted to the Department for approval. G. *Covered by the Regulatory Flexibility Act:* No.	Marinos Svalos, Deputy Director, DMSCP, BPP, Room 480 EHR, 6401 Security Blvd., Baltimore, MD 21207, 301-594-6719.
HCFA—Medicare Program: Conditions of Participation for Hospitals; Conditions for Coverage of Services of Independent Laboratories; Immunohematological Testing, Transfusion Services and Bloodbanking.	A. *Description:* This regulation clarifies standards and responsibilities governing the survey and certification of laboratory transfusion and bloodbanking services. B. *Why Significant:* This regulation will reduce unnecessary Departmental and industry expenditures caused by duplicate HCFA and FDA surveys and provide uniformity in standards for transfusion and bloodbanking requirements. C. *Regulatory Analysis:* Not required. D. *Need:* To implement a memorandum of understanding between HCFA and FDA published by the Department on March 25, 1980. E. *Legal Basis:* Secs. 1102, 1861(e)(9), 1861(s)(11), and 1871 of the Social Security Act (42 U.S.C. 1302, 1395(e)(9), 1395x(s)(11), and 1395hh). F. *Chronology:* Memorandum of Understanding was published March 25, 1980 (45 FR 19316). A Notice of Decision to Develop Regulations was published December 19, 1980 (45 FR 83579). The proposed rule has been waived. The final regulation is currently under review. When the review is completed, it will be forwarded to the Department for approval. G. *Covered by the Regulatory Flexibility Act:* No.	Stanley Edinger, Ph.D, Program Analyst, 2nd Floor, Dogwood East Bldg., 1849 Gwynn Oak Ave., Baltimore, MD 21207, 301-594-7931.
HCFA—Medicaid Program: Expanded Phase Out Provisions of Intermediate Care Facilities for the Mentally Retarded (ICF/MR); Correcton Plans.	A. *Description:* This regulation would allow States to negotiate new corrective action plans for publicly-owned ICFs/MR that do not comply with current standards. The regulation would permit States to negotiate extended plans to phase out beds but require compliance by July 1982 with standards for beds not scheduled for phase out. B. *Why Significant:* This regulation would allow States more flexibility in securing the most appropriate living arrangements for ICF/MR residents. C. *Regulatory Analysis:* Not required. D. *Need:* To provide incentives for deinstitutionalization of residents in ICFs/MR and ensure that the health and safety of residents remaining in ICFs/MR is protected. E. *Legal Basis:* Secs. 1102, 1905(c) and (d) of the Social Security Act (42 U.S.C. 1302, 1396d(c) and d(d)). F. *Chronology:* The proposed rule is currently under review. When the review is completed, it will be submitted to the Department for approval. G. *Covered by the Regulatory Flexibility Act:* No.	Wayne Smith, Program Analyst, HSQB, 2nd Floor, Dogwood East Bldg., 1849 Gwynn Oak Ave., Baltimore, MD 20207, 301-594-7651.
HCFA—Medicare Program: Determination of Payment Amount for Services Furnished by Independent Rural Health Clinics.	A. *Description:* This regulation revises payment procedures with respect to situations in which a beneficiary has not met the Medicare Part B deductible. This regulation also clarifies the relationship between the amount paid to a clinic on an interim basis and the total amount due the clinic at final cost settlement. B. *Why Significant:* This regulation would resolve confusion causes by inaccuracies in current rules. Final cost settlements that have been postponed pending resolution of the issue of interim payments could be settled once that issue is resolved. C. *Regulatory Analysis:* Not required. D. *Need:* To correct and clarify regulations implementing P.L. 95-210, the Rural Health Clinic Services Act of 1977. E. *Legal Basis:* Secs. 1102, 1833, 1861(aa), and 1871 of the Social Security Act. F. *Chronology:* The final rule is currently under review in the Department. G. *Covered by the Regulatory Flexibility Act:* Yes.	Bernadette Schumaker, Chief, ARSB, BPP, Room 1-C-1 ELR, 6401 Security Blvd., Baltimore, MD 21207, 301-597-1048.
HCFA—Transfer of Assets.	A. *Description:* This regulation will impose a new eligibility requirement on aged, blind, and disabled applicants for Medicaid. It will allow States to deny Medicaid to individuals who dispose of assets for less than fair market value. B. *Why Significant:* This regulation will assure that available income and assets are applied to medical needs before Medicaid is granted. C. *Regulatory Analysis:* Not required. D. *Need:* To implement Sec. 5 of P.L. 96-611. E. *Legal Basis:* Sec. 1613 of the Social Security Act (42 U.S.C. 1382b) and Sec. 5 of P.L. 96-611. F. *Chronology:* The proposed rule is currently under review. When the review is completed, it will be submitted to the Department for approval. G. *Covered by the Regulatory Flexibility Act:* No.	Richard Cody, Director, DMEP, BPP, Room 440 EHR, 6401 Security Blvd., Baltimore, MD 21207, 301-594-9050.
HCFA—Conditions of Coverage of Suppliers: End Stage Renal Disease (ESRD).	A. *Description:* This regulation revises the conditions which ESRD facilities must meet to be approved as suppliers of end-stage renal disease services. B. *Why Significant:* This regulation will recognize recent developments in medical practices. C. *Regulatory Analysis:* Not required. D. *Need:* Clarify and expand the types of dialysis service facilities that will be approved to furnish and facilitate program administration. E. *Legal Basis:* Secs. 226A, 1102, 1871, 1881 of the Social Security Act (42 U.S.C. 426-1, 1302, 1395hh, 1395rr). F. *Chronology:* The proposed rule was published on January 15, 1981 (46 FR 3794). The comment period closed on March 16, 1981. G. *Covered by the Regulatory Flexibility Act:* Yes.	Bob Moore, Program Analyst, HSQB, 2nd Floor, Dogwood East Bldg., 1849 Gwynn Oak Ave., Baltimore, MD 21207, 301-594-9736.

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

Significant Regulations—New Initiatives

Title	Summary	Contact
HCFA—Certification of Long Term Care Facilities with Repeat Deficiencies.	A. *Description:* This regulation eliminates the provision that prohibits the renewal of long term care provider agreements if the same deficiency, regardless of how minor, appears in successive certification surveys. B. *Why Significant:* This regulation will improve program administration as long as there is no jeopardy or adverse affect to the health and safety of patients. C. *Regulatory Analysis:* Not required D. *Need:* To make the rules for skilled nursing facilities and intermediate care facilities consistent with the rules governing other providers and reduce burden. E. *Legal Basis:* Secs. 1102, 1814, 1861, 1865, 1866, and 1910 of the Social Security Act (42 U.S.C. 1302, 1395f, 1395x, 1395bb, 1395cc, 1395hh and 1396i). F. *Chronology:* The proposed rule was published on March 18, 1980 (45 FR 16505). The comment period closed on May 13, 1980. The final rule is currently under review. When the review is completed, it will be submitted to the Department for approval. G. *Covered by the Regulatory Flexibility Act:* No	Terrence Skelly, Program Analyst, HSQB, 2nd Floor, Dogwood East Bldg., 1849 Gwynn Oak Ave., Baltimore, MD 21207, 301-594-7942.
HCFA—Medicare Program: Recordkeeping and Cost Reporting Requirements for Dialysis and Training.	A. *Description:* This regulation sets forth recordkeeping and cost reporting requirements for renal dialysis facilities furnishing maintenance renal dialysis and self-care dialysis training. These requirements apply to all ESRD services furnished in or under the supervision of Medicare-certified dialysis facilities, whether hospital-based or independent. B. *Why Significant:* This regulation implements portions of the ESRD Program Amendments of 1978 (P.L. 95-292) that require us to prescribe in regulations, methods and procedures to determine costs incurred by renal dialysis facilities in furnishing ESRD services. C. *Regulatory Analysis:* Not required D. *Need:* To implement certain provisions of the ESRD Program Amendments of 1978 (P.L. 95-292). E. *Legal Basis:* Secs. 1881(b)(II)(B)(i) of Social Security Act; P.L. 95-292 F. *Chronology:* The proposed rule was published on September 26, 1980 (45 FR 64006) as Incentive Reimbursement for Outpatient Dialysis and Self-Care Dialysis Training (HCFA-31). The comment period closed on November 25, 1980. G. *Covered by the Regulatory Flexibility Act:* No	Bernadette Schumaker, Chief, ARSB, BPP, Room 1-C-1 ELR, 6401 Security Blvd., Baltimore, MD 21207, 301-597-1048.
HCFA—Medicare Program: Methodology and Rates for Reimbursing End Stage Renal Disease Facilities.	A. *Description:* This notice would set forth a proposed methodology and rates for reimbursing ESRD facilities for furnishing outpatient dialysis services. B. *Why Significant:* This regulation implements portions of the ESRD Program Amendments of 1978 (P.L. 95-292) to develop and establish a method of incentive reimbursement for renal dialysis facilities furnishing outpatient or home dialysis ESRD services. C. *Regulatory Analysis:* Yes, being conducted D. *Need:* To implement certain provisions of the ESRD Program Amendments of 1978 (P.L. 95-292). E. *Legal Basis:* Secs. 1881(b)(II)(B)(ii) of the Social Security Act, P.L. 95-292 F. *Chronology:* The proposed rule was published on September 26, 1980 (45 FR 64006). The comment period closed November 25, 1980. G. *Covered by the Regulatory Flexibility Act:* Yes	Bernadette Schumaker, Chief, Alter. Reim. Systems Branch, Rm. 1-C-1 ELR, 6401 Security Blvd., Baltimore, MD 21207, 301-597-1048.

Office of Human Development Services, HHS

Title	Summary	Contact
HDS-6—Native American Program: General Rules.	A. *Description:* This proposed regulation would simplify and clarify existing regulations in line with "Operation Common Sense" and implement significant changes in policies and operation to reflect program experience. B. *Why Significant:* The Native American Grants provide valuable resources to Native Americans in their efforts to achieve economic and self-sufficiency. C. *Regulatory Analysis:* Not required D. *Need:* Regulations are needed to make administrative improvements which include a simplified appeals process; improved management control and paperwork reduction; and the removal of unnecessary provisions. E. *Legal Basis:* 42 U.S.C. 2991 F. *Chronology:* None G. *Covered by the Regulatory Flexibility Act:* Yes	David Litton, Acting Director, Policy Planning and Budget Division, Administration for Native Americans, Rm. 5300, HHS North Bldg., 330 Independence Ave., S.W., Washington, D.C. 20201, (202) 245-7776.
HDS-23—Work Incentive Program: Amendments to Implement Statutory Changes.	A. *Description:* This regulation will amend the regulations to the Work Incentive Program for AFDC recipients in order to make them conform with legislative amendments. Changes would include employment search authority and related social services, establishing a fixed sanction period, and other minor changes required by the statute. 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. E. *Legal Basis:* 42 U.S.C. 630 et seq F. *Chronology:* None G. *Covered by Regulatory Flexibility Act:* No	Nancy Snyder, Acting Executive Director, National Coordination Committee Work Incentive Program, Rm. 5102, Patrick Henry Building, 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 grantees 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	Nancy Snyder, Acting Executive Director, National Coordination Committee Work Incentive Program, Rm. 5102, Patrick Henry Building, 601 D St., N.W., Washington, D.C. 20201, (202) 387-6694.

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

Office of Human Development Services, HHS

Title	Summary	Contact
	E. *Legal Basis:* Section 1132 of the Social Security Act as amended by Pub. L. 96-272. F. *Chronology:* None G. *Covered by the Regulatory Flexibility Act:* No	

Food and Drug Administration—Significant Regulations

Title	Summary	Contact
Revise Inspection Frequency: Licensed Blood Banks.	A. *Description:* This proposed regulation would reduce the frequency of inspections for licensed blood banks from once every year to at least once every two years. B. *Why Significant:* The regulation would reduce the frequency of inspections for licensed blood banks from once every year to once every two years. C. *Regulatory Impact Analysis:* Not required. D. *Need:* To reduce the inspection burden on licensed blood banks. E. *Legal Basis:* Sections 201, 510, 701, 704, 52 Stat. 1055–1056 (21 U.S.C. 321, 360, 371, 374) and Section 351, 58 Stat. 702 (42 U.S.C. 262). F. *Chronology:* A proposed regulation is expected to publish by October 31, 1981. G. *Covered by Regulatory Flexibility Act:* Yes.	Rada Proehl, Regulations Branch (HFB-620), Bureau of Biologics, Food and Drug Administration, 8800 Rockville Pike, Bethesda, MD 20205, 301-443-1306
Procedures for Reclassifying Category IIIA Biologicals.	A. *Description:* This final regulation would reclassify Category IIIA biological products as either safe, effective, and not misbranded (Category I), or unsafe, ineffective, or misbranded (Category II). The regulation would permit interim marketing pending completion of clinical studies for any biological product reclassified into Category II for which there is a compelling medical need and no suitable alternative therapeutic, prophylactic, or diagnostic agent. B. *Why Significant:* The regulation would establish Agency procedures to reclassify Category IIIA biological products into either Category I or Category II. C. *Regulatory Impact Analysis:* Not required. D. *Need:* The document responds to a petition for action filed by the Health Research Group. E. *Legal Basis:* Sections 201, 502, 505, 701, 52 Stat. 1041–1042, 1050–1051, 1055–1056 (21 U.S.C. 321, 352, 355, 371); Section 351, 58 Stat. 702 (42 U.S.C. 262); Sections 4 and 10, 60 Stat. 238 and 243 (5 U.S.C. 553, 702, 703, 704). F. *Chronology:* The proposed regulation was published January 16, 1981 (46 FR 4634). Comment period extended from March 17, 1981 to May 18, 1981 (46 FR 17063). A final regulation is expected to publish by October 31, 1981. G. *Covered by Regulatory Flexibility Act:* No.	Albert Rothschild, Regulations Branch (HFB-620), Bureau of Biologics, Food and Drug Administration, 8800 Rockville Pike, Bethesda, MD 20205, 301-443-1306
Panel on Review of Blood and Blood Products—Product Effectiveness.	A. *Description:* This proposed regulation would 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:* The regulation would establish the safety and effectiveness of currently marketed products. It would assure the public of receiving only those products found to be safe and effective. C. *Regulatory Impact 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. 252). F. *Chronology:* The proposed regulation is expected to publish by October 31, 1981. G. *Covered by Regulatory Flexibility Act:* FDA will consider the need for an initial regulatory flexibility analysis.	Steven Falter, Regulations Branch (HFB-620), Bureau of Biologics, Food and Drug Administration, 8800 Rockville Pike, Bethesda, MD 20205, 301-443-1306
Panel on Review of Bacterial Toxoids and Bacterial Vaccines with U.S. Standards of Potency—Product Effectiveness.	A. *Description:* This proposed regulation would 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:* The regulation would establish the safety and effectiveness of currently marketed products. It would assure the public of receiving only those products found to be safe and effective. C. *Regulatory Impact 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 proposed regulation is expected to publish by October 31, 1981. G. *Covered by Regulatory Flexibility Act:* FDA will consider the need for an initial regulatory flexibility analysis.	Steven Falter, Regulations Branch (HFB-620), Bureau of Biologics, Food and Drug Administration, 8800 Rockville Pike, Bethesda, MD 20205, 301-443-1306.
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 Impact Analysis:* Not required.	Marilyn Watson (HFD-30), Bureau of Drugs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3640.

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

Food and Drug Administration—Significant Regulations

Title	Summary	Contact
	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, 356, 357, 360, 360b-360f, 360h-360j, 361, 371(a), 378, 381, 42 U.S.C. 216, 262, 263b-263n.	
	F. *Chronology:* The proposed regulations were published on September 27, 1977 (42 FR 49612). The final regulations are expected to publish by October 1981.	
	G. *Covered by Regulatory Flexibility Act:* No.	
Abbreviated New Drug Applications for Post-1962 Drugs.	A. *Description:* This proposed regulation would permit applicants to file abbreviated new drug applications (ANDA's) for products indentical 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 Drug Affairs (HFD-30), Bureau of Drugs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3640.
	B. *Why Significant:* This would 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 Impact Analysis:* Yes.	
	D. *Need:* This action has the potential to increase competition among drug sources when patents have expired and lower costs of drug products.	
	E. *Legal Basis:* 21 U.S.C. 355, 371(a).	
	F. *Chronology:* The proposed regulation is expected to publish by October 31, 1981.	
	G. *Covered by Regulatory Flexibility Act:* FDA will consider the need for an initial regulatory flexibility analyses..	
New Drug Evaluation; Revision of NDA Regulations.	A. *Description:* Under section 5(a)(3) of E.O. 12291, FDA is reviewing and will propose to revise the existing regulations for 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 of NDA's.	Michael McGrane, General Regulations Branch (HFD-30), Bureau of Drugs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5200.
	B. *Why Significant:* These revisions can be expected to aid NDA applicants by expediting the review process, reducing paperwork, and redefining the NDA requirements in line with FDA's experiences and current practices. They should also result in simpler and more useful reporting requirements.	
	C. *Regulatory Impact Analysis:* Threshold assessment underway.	
	D. *Need:* Experience with these regulations after a number of years has identified areas where the NDA procedure and requirements need updating and improving.	
	E. *Legal Basis:* 21 U.S.C. 355, 357, 371(a).	
	F. *Chronology:* A public meeting was held on November 7, 1979. The proposed regulation is expected to publish by October 31, 1981.	
	G. *Covered by Regulatory Flexibility Act:* Yes.	
Over-the-Counter (OTC) Category III Policy.	A. *Description:* This final regulation would revise the OTC procedural regulations to delete the provision that authorized the marketing of a Category III ingredient or labeling claim in an OTC drug product after a final monograph is established. Any testing necessary to resolve the safety or effectiveness issues for Category III ingredients and claims would have to be completed and the data submitted to FDA within a limited time period during the OTC drug rulemaking process, and before the establishment of a final monograph, for a drug product containing these ingredients or claims to be legally marketed.	Marilyn Watson (HFD-30), Bureau of Drugs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3640.
	B. *Why Significant:* This revision would revise a regulation found unlawful by a court. The revision also is expected to expedite the OTC drug review process.	
	C. *Regulatory Impact Analysis:* Threshold assessment underway.	
	D. *Need:* This action is necessary to conform to the holding and order of the United States District Court for the District of Columbia in *Cutler v. Kennedy*, 475 F. Supp. 838 (D.D.C. 1979).	
	E. *Legal Basis:* 21 U.S.C. 321, 352, 355, 371(a).	
	F. *Chronology:* The proposed regulation was published on May 13, 1980 (45 FR 31422). The comment period closed on July 14, 1980. The regulation is expected to be published during the 3rd quarter (April-June, 1981).	
	G. *Covered by Regulatory Flexibility Act:* No.	
Over-the-Counter (OTC) Drug Review.	A. *Description:* These regulations provide for monographs that specify which OTC drug ingredients and labeling claims are generally recognized as safe and effective.	William E. Gilbertson, Division of OTC Drug Evaluation (HFD-510), Bureau of Drugs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4960.
	B. *Why Significant:* These regulations will assure consumers that OTC drug products on the market have their claimed effect and bear adequate labeling for safe and effective use.	
	C. *Regulatory Impact Analysis:* Threshold assessment planned for each monograph.	
	D. *Need:* To review all OTC drug ingredients and labeling claims to determine which of these can be considered generally recognized as safe and effective.	
	E. *Legal Basis:* 21 U.S.C. 321, 352, 355, 371.	

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

Food and Drug Administration—Significant Regulations

Title	Summary	Contact
	F. *Chronology:* Significant proposed and tentative mohographs published or expected to be published: OTC Cold, Cough, Allergy, Bronchodilator and Antiasthmatic Products (CCABA) proposed monograph, September 9, 1976 (41 FR 38312); (CCABA) Anticholinergic/Expectorant segment tentative final monograph expected to be published May 1981; (CCABA) Bronchodilator segment tentative final monograph expected to publish October 1981; OTC Topical Antimicrobial proposed monograph, September 13, 1974 (39 FR 33103); tentative final monograph, January 6, 1978 (43 FR 1210); External Analgesic Drug Products for OTC Use proposed monograph, December 4, 1979 (44 FR 69788); OTC Internal Analgesic, Antipyretic and Antirheumatic Drug Products proposed monograph, July 8, 1977 (42 FR 35346); OTC nighttime Sleepaid and Stimulant Products proposed monograph, December 8, 1975 (40 FR 57292), tentative final monograph, June 13, 1978 (43 FR 25544); Anorectal Drug Products for OTC Use proposed monograph, May 27, 1980 (45 FR 35576); Vaginal Contraceptive Drug Products for OTC Human Use proposed monograph, December 12, 1980 (45 FR 82014); Relief of Oral Discomfort Drug Products proposed monograph expected to publish June 1981; OTC Oral Cavity Drug Products proposed monograph expected to publish September 1981; OTC Weight Control Drug Products proposed monograph expected to publish May 1981; OTC Antiperspirant Drug Products proposed monograph, October 10, 1978 (43 FR 46604), tentative final monograph expected to publish September 1981; OTC Topical Antibiotic Drug Products proposed monograph, April 1, 1977 (42 FR 17642), tentative final monograph expected to publish September 1981; OTC Topical Antifungal Drug Products proposed monograph expected to publish September 1981. G. *Covered by Regulatory Flexibility Act:* FDA will consider the need for an initial regulatory flexibility analysis for each monograph.	
Use of Food Preservatives	A. *Description:* This final regulation would establish an interim food additive regulation 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. C. *Regulatory Impact Analysis:* Not required. D. *Need:* To determine if the food preservative BHT can continue to be deemed safe for use in foods. E. *Legal Basis:* Sections 201(s), 409, 701(a), 52 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 regulation published on May 31, 1977 (42 FR 27803). The comment period closed July 26, 1977. The final regulation is expected to publish July, 1981. G. *Covered by the Regulatory Flexibility Act:* No.	Linda Taylor, GRAS Review Branch (HFF-335), Bureau of Foods, Food and Drug Administration, 330 Independence Avenue, S.W., Washington, D.C. 20201, 202-472-4750
Prior Sanction of Nitrites in Meat and Poultry Products.	A. *Description:* This final regulation would resolve the issue regarding whether there is a prior sanction for nitrites in meat and poultry products. B. *Why Significant:* There is substantial interest and controversy in the legal status of nitrites. C. *Regulatory Impact 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), 371(a), 376) of the Federal Food, Drug, and Cosmetic Act. F. *Chronology:* The proposed regulation was published on December 21, 1979 (44 FR 75662). The comment period closed on June 18, 1980. The final regulation is expected to publish August, 1981. G. *Covered by the Regulatory Flexibility Act:* No.	John Herrman, 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.
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 Sanitation Program. B. *Why Significant:* An improved voluntary National Shellfish Sanitation Program would help ensure the safety and wholesomeness of shellfish harvested in waters of participating states. C. *Regulatory Impact 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 301, 308, 311, 361, Pub. L. 410; 58 Stat. 691, 693, 703; 74 Stat. 364, as amended (42 U.S.C. 241, 242m, 243, 264) of the Public Health Service Act. F. *Chronology:* The proposed regulation published on June 19, 1975 (40 FR 25916). The comment period closed November 13, 1975. The notice is expected to publish September, 1981. G. *Covered by Regulatory Flexibility Act:* No.	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.
Infant Formulas Quality Control Regulation	A. *Description:* This final regulation would establish specified quality control requirements for infant formula manufacturers. B. *Why Significant:* The nutritional adequacy of infant formulas is a public health issue on which there is substantial public interest. C. *Regulatory Impact 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 regulation was published on December 30, 1980 (45 FR 86362). The comment period was extended to May 1, 1981 (46 FR 17790). The final regulation is expected to publish October, 1981. G. *Covered by the Regulatory Flexibility Act:* No.	Ed Scarbrough, Regulatory Affairs Staff (HFF-204), Bureau of Foods, Food and Drug Administration, 200 C Street, S.W., Washington, D.C. 20204, 202-245-3117.
Infant Formula; Recall Process	A. *Description:* This proposed regulation would establish recall procedures for removing adulterated infant formula from the marketplace.	

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

Food and Drug Administration—Significant Regulations

Title	Summary	Contact
	B. *Why Significant:* There is considerable public interest in infant formulas due to medical problems in infants resulting from inadequate amounts of essential nutrients.	Howard Pippin, 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.
	C. *Regulatory Impact Analysis:* Not required	
	D. *Need:* To protect the public health; regulations are required by state.	
	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 regulation is expected to publish July, 1981	
	G. *Covered by the Regulatory Flexibility Act:* FDA will consider the need for an initial regulatory flexibility analysis.	
Cinnamyl Anthranilate	A. *Description:* These proposed regulations would prohibit cinnamyl anthranilate in human food and ingestible cosmetics because it may pose a risk of cancer.	
	B. *Why Significant:* There is substantial FDA interest due to public health concerns expressed above.	
	C. *Regulatory Impact Analysis:* Not required	Adele Dennis, GRAS Review Branch (HFF-335), Bureau of Foods, Food and Drug Administration, 200 C Street, S.W., Washington, D.C. 20204, 202-472-4750.
	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 regulations are expected to publish October, 1981	
	G. *Covered by Regulatory Flexibility Act:* Yes	
Umbrella GMP	A. *Description:* This revised regulation will establish new, updated or more current good manufacturing practices for the food industry.	F. Leo Kauffman, Plant & Protein Technology (HFF-214), Bureau of Foods, Food and Drug Administration, 200 C Street, S.W., Washington, D.C. 20204, 202-245-1164.
	B. *Why Significant:* Provides industry with requirements designed to prevent or avoid offering a product for sale which might be defective (violative) in a significant respect.	
	C. *Regulatory Impact Analysis:* Required	
	D. *Need:* To ensure a safe and sanitary food supply	
	E. *Legal Basis:* Sections 302, 303, 304, 402(a), 701(a) 52 Stat. 1043-1046 as amended, 1055 (21 U.S.C. 332, 333, 334, 342(a), 371(a)) of the Federal Food, Drug, and Cosmetic Act, and the Public Health Service Act Section 361, 58 Stat. 703 (21 U.S.C. 264).	
	F. *Chronology:* The proposed regulation to revise the umbrella GMP was published June 8, 1979 (44 FR 33228). The comment period closed December 31, 1979. The final regulation is expected to publish October, 1981.	
	G. *Covered by Regulatory Flexibility Act:* No	
Lead in Infant Foods and in Evaporated Milk	A. *Description:* These action guidelines would announce to the public FDA's action levels on lead and withdraw the 1974 proposed tolerance for lead in evaporated milk and evaporated skim milk.	Carl Giannetta, Petitions Control Branch (HFF-334), Bureau of Foods, Food and Drug Administration, 200 C Street, S.W., Washington, D.C. 20204, 202-472-5690.
	B. *Why Significant:* There is a significant public health interest	
	C. *Regulatory Impact Analysis:* Not required	
	D. *Need:* To lower infant exposure to toxic levels of lead	
	E. *Legal Basis:* Sections 406, 409, 701(a), 52 Stat. 1055, 72 Stat. 1785-1790 (21 U.S.C. 346, 348, 371(a)) of the Federal Food, Drug, and Cosmetic Act.	
	F. *Chronology:* The proposed tolerance for lead in evaporated milk and evaporated skim milk published on December 6, 1974 (39 FR 42740). An Advance Notice of Proposed Rulemaking published August 31, 1979 (45 FR 51233). The action guidelines are expected to publish June, 1981.	
	G. *Covered by Regulatory Flexibility Act:* No	
Labeling of Sodium Content of Foods	A. *Description:* This proposed regulation would define terms such as low sodium and reduced sodium and provide for including sodium content in nutrition labeling.	Allen Forbes, Associate Director for 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.
	B. *Why Significant:* There is a substantial public health need for and public interest in consumers being able to regulate intake of sodium.	
	C. *Regulatory Impact Analysis:* Threshold assessment underway	
	D. *Need:* To give consumers an opportunity to regulate their own intake of sodium.	
	E. *Legal Basis:* Sections 201 (n) and (s), 402(a)(2)(C), 403(a), 409(c)(1)(A), and 701(a) (21 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 regulation is expected to publish July, 1981	
	G. *Covered by Regulatory Flexibility Act:* Yes	
New Animal Drugs and Feed Additives Derived from a New Drug Fermentation; Human Food Safety Evaluation Criteria.	A. *Description:* This notice announces the availability of a guidelines that describes testing and evaluation criteria for the approval of complex products derived from a drug fermentation synthesis and proposed for use in food-producing animal.	Marylyn Cordle, Food Animal Additive Staff, (HFF-350), Bureau of Foods, Food and Drug Administration, 200 C Street, S.W., Washington, D.C. 20204, 202-755-1120.
	B. *Why Significant:* The guidelines provides a feasible alterantive means of demonstrating safety for approval for these complex products that are not amendable to the standard criteia.	
	C. *Regulatory Impact Analysis:* Not required	
	D. *Need:* To allow these types of products, which have many potential benefits, to be used in food-producing animals.	
	E. *Legal Basis:* Section 512 (21 U.S.C. 360b) of the Federal Food, Drug, and Cosmetic Act.	
	F. *Chronology:* The notice of availability is expected to publish October, 1981	
	G. *Covered by Regulatory Flexibility Act:* No	
Carcinogenic Constitutents in Food and Color Additives.	A. *Description:* This proposed policy statement would describe a policy for assessing the safety of food and color additives that contain carcinogenic constituents.	Tari Troxell, Petitions Control Branch (HFF-334), Bureau of Foods, Food and Drug Administration, 200 C Street, S.W., Washington, D.C. 20204, 202-472-5690.
	B. *Shy Significant:* There is public interest in the use of risk assessment for evaluating carcinogenic constituents in these additives.	
	C. *Regulatory Impact Analysis:* Not required	
	D. *Need:* To clarify agency policy on carcinogenic constituents in food and color additives.	

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

Food and Drug Administration—Significant Regulations

Title	Summary	Contact
	E. *Legal Basis:* Sections 201(s), 201(t), 402, 409, 701, 706, 52 Stat. 1046–1047, as amended; 72 Stat. 1784–1788, as amended (21 U.S.C. 321(s), 321(t), 342, 348, 371, 376) of the Federal Food, Drug, and Cosmetic Act. F. *Chronology:* The proposed policy statement is expected to publish during the 3rd quarter (April–June, 1981). G. *Covered by Regulatory Flexibility Act:* Yes	
Prosthetic Fiber for Implantation into the Human Scalp; Banning.	A. *Description:* This proposed regulation would 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 Impact Analysis:* Threshold assessment underway. D. *Need:* To protect the public from dangerous side effects following implantation of prosthetic fibers. E. *Legal Basis:* 21 U.S.C. 352(r), 360f, 360h, 360i, 371(a). F. *Chronology:* The proposed regulation is expected to publish September, 1981 .... G. *Covered by Regulatory Flexibility Act:* FDA will consider the need for an initial regulatory flexibility analysis.	Pamela Woytowicz (HFK–114), Bureau of Medical Devices, Food and Drug Administration, 8758 Georgia Avenue, Silver Spring, MD 20910, 301–427–7218.
User Labeling of Menstrual Tampons	A. *Description:* This final regulation would establish labeling requirements for menstrual tampons about the dangers of toxic shock syndrome (TSS) a rare, but sometimes fatal, disease that affects menstruating women. B. *Why Significant:* The regulation would provide women with information on the risks of TSS. C. *Regulatory Impact Analysis:* Threshold assessment planned D. *Need:* To inform consumers of the risk of TSS, a serious and sometimes fatal disease. E. *Legal Basis:* 21 U.S.C. 321(n), 352 371(a). F. *Chronology:* The proposed regulation was published October 21, 1980 (45 FR 69640). The comment period closed November 20, 1980. The final regulation is expected to publish October, 1981. G. *Covered by Regulatory Flexibility Act:* No.	Joseph Sheehan (HFK–70), Bureau of Medical Devices, Food and Drug Administration, 8757 Georgia Avenue, Silver Spring, MD 20910, 301–427–7114.
Premarket Approval Procedural Regulation	A. *Description:* This final regulation would set our procedures for submission of premarket approval applications (PMAs), including safety and effectiveness requirements for all Class III medical devices. B. *Why Significant:* The regulation would inform the public of the requirements to obtain FDA approval of Class III devices. It will shorten FDA review time if manufacturers know in advance what must be included in a PMA. C. *Regulatory Impact Analysis:* Threshold assessment underway. D. *Need:* To implement section 515 of the Medical Device Amendments of 1976. E. *Legal Basis:* 21 U.S.C. 351, 352, 353, 360, 360c–360j, 371(e), 373, 374, 375, 379, 381. F. *Chronology:* The proposed regulation was published December 12, 1980 (45 FR 84769). The comment period closes April 13, 1981. The final regulation is expected to publish August, 1981. G. *Covered by Regulatory Flexibility Act:* No.	Henry Goldstein (HFK–402), Bureau of Medical Devices, Food and Drug Administration, 8757 Georgia Avenue, Silver Spring, MD 20910, 301–427–7445.
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 determine the regulatory controls to ensure the safety and effectiveness of medical devices. The classification regulations advise manufacturers whether their devices are subject to general controls, performance standards, or premarket approval. C. *Regulatory Impact 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 and 371(a). 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 regulations 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 closed June 23, 1980; Dental, December 30, 1980 (45 FR 85962), comment period closed April 1, 1981; Gastroenterology/Urology, January 23, 1981 (46 FR 7562), comment period closed March 24, 1981. Expected publication dates of final regulations are: Physical Medicine, May 1981; Anesthesiology, May 1981; Microbiology/Immunology, August 1981; Gastroenterology/Urology, October 1981; Dental, October 1981. Proposals not yet published and expected publication dates: Clinical Chemistry/Toxicology, May 1981; Ear, Nose, and Throat, May 1981; Ophthalmic, May 1981; Radiology, June 1981; General and Plastic Surgery, July 1981; Orthopedic, September 1981. G. *Covered by Regulatory Flexibility Act:* No.	Robert S. Kennedy (HFK–400), Bureau of Medical Devices, Food and Drug Administration, 8757 Georgia Avenue, Silver Spring, MD 20910, 301–427–7230.
Recommendations for State and Local Agencies Concerning Accidental Radioactive Contamination of Human Food and Animal Feeds.	A. *Description:* These 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 and Human Services 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 HHS, 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 Impact 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.	Gail Schmidt, Immediate Office of the Bureau Director (HFX–1), Bureau of Radiological Health, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–2850.

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

Food and Drug Administration—Significant Regulations

Title	Summary	Contact
	F. *Chronology:* Proposed recommendations were published December 15, 1978 (43 FR 58790). Comment period closed on February 13, 1979. The final recommendations are expected to publish September, 1981. G. *Covered by Regulatory Flexibility Act:* No.	
Recommendations for National Standards for Medical Radiation Technologists.	A. *Description:* These proposed recommendations would establish recommended qualifications for medical radiation technologists. The Notice of Intent 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 600 comment letters received on the Notice of Intent. C. *Regulatory Impact Analysis:* Not required. D. *Need:* Medical radiation technologists exercise considerable influence over patient exposure during radiological procedures, and their qualifications are essential for producing quality diagnostic images and therapeutic applications. E. *Legal Basis:* Public Health Service Act, 42 U.S.C. 241, 263d. F. *Chronology:* Notice of Intent published on March 13, 1979 (44 FR 14637). The comment period closed on July 11, 1979. The proposed recommendations are expected to publish September, 1981. G. *Covered by Regulatory Flexibility Act:* No.	Charles Froom, Standards and Regulations Branch (HFX-460), Bureau of Radiological Health, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3426.
Notice of Availability of Draft Recommendations on the Use of Potassium Iodide as a Thyroid Blocking Agent in a Radiation Emergency.	A. *Description:* This notice announces the availability of, and solicits comments on, draft proposed recommendations on the use of potassium iodide (KI) as a thyroid blocking agent in a radiation emergency. In December 1978, FDA solicited new drug applications (NDA's) from pharmaceutical manufacturers for producing KI in oral dosage forms. As a result, this thyroid-blocking agent is presently available for commercial distribution in both tablet and solution form. The proposed guidance, accomplishes the following: (1) identifies levels of radiation exposure from a radiation accident that would warrant the use of KI; (2) reiterates specific dosage levels for adults and children and the period of administration contained in the NDA; (3) recommends that State and local authorities establish a system for dissemination of public information on the proper use of KI and the reporting of side effects from the drug; and (4) recommends that the public be advised on how to obtain medical assistance in the event of an adverse reaction to the drug. B. *Why Significant:* The proposed recommendations serve as provisional Federal guidance for State and local health officials and the nuclear industry to use should a serious nuclear accident occur. C. *Regulatory Impact Analysis:* Not required. D. *Need:* To develop guidance under responsibility assigned by the Federal Emergency Management Agency. E. *Legal Basis:* The Department of Health and Human Services responsibilities under the terms of the "National Emergency Preparedness/Response Plan for Commercial Nuclear Power Plant Accidents," issued by the Federal Emergency Management Agency on October 22, 1980 (45 FR 69904). F. *Chronology:* The notice of availability is expected to publish May, 1981. G. *Covered by the Regulatory Flexibility Act:* No.	Bernard Shlein, Office of Health Affairs, Bureau of Radiological Health (HFX-4), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-6220.
Notice of Availability of Draft Report on Referral Criteria for Chest X-Ray Examinations.	A. *Description:* This notice announces the availability of, and solicits comments on, a draft report developed by a panel of physicians on the utility of selected chest x-ray screening procedures. The draft report was developed under procedures which follow recommendations of the National Conference on Referral Criteria for X-ray Examinations (1978). FDA, under this program, acts as a facilitator by providing logistical support to small panels of clinical and scientific experts, convened by outside contractors. The panels assess the literature and, if possible, formulate draft referral criteria. These drafts then undergo extensive review and, if necessary, clinical trials prior to widespread determination of final criteria. The notice describes this development process. B. *Why Significant:* This notice describes the process whereby FDA acts as a facilitator in the development of radiologic referral criteria. C. *Regulatory Impact Analysis:* Not required. D. *Need:* To allow public review of the draft report and the process by which it was developed. E. *Legal Basis:* Public Health Service Act, 42 U.S.C. 241, 242, 243. F. *Chronology:* The notice of availability is expected to publish May, 1981. G. *Covered by the Regulatory Flexibility Act:* No.	Robert Phillips, Standards and Regulations Branch (HFX-460), Bureau of Radiological Health, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3426.
Medicated Feed Task Force Implementation	A. *Description:* This final regulation would revise the existing regulations to provide revised criteria for the need of an approved medicated feed application for the manufacture of medicated feeds. B. *Why Significant:* This regulation would materially change the current requirements for approval for the use of drugs in the manufacture of medicated feeds. C. *Regulatory Impact Analysis:* Not required. D. *Need:* The regulation 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:* The proposed regulation was published on January 9, 1981 (46 FR 2456). Although FDA does not expect to publish a final regulation by October 31, 1981, the Agency is including this regulation in this agenda because it represents a review of existing regulations under section 5(a)(3) of E.O. 12291. G. *Covered by Regulatory Flexibility Act:* No.	George Graber, Division of Animal Feeds (HFV-220), Bureau of Veterinary Medicine, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4438.
Animal Drugs for Minor Species	A. *Description:* This final regulation would define the safety and effectiveness data collection requirements for approval of new animal drug applications for use of a drug in a minor species or for the use of a drug in a major species for treatment of a rare or frequently occurring disease. B. *Why Significant:* To assure the availability of new animal drugs for use in minor species or a minor use in a major species. C. *Regulatory Impact Analysis:* Not required.	Thomas V. Raines (HFV-109), Division of Drugs for Avain Species, Bureau of Veterinary Medicine, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4913.

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

Food and Drug Administration—Significant Regulations

Title	Summary	Contact
	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:* The proposed regulation was published on July 20, 1979 (44 FR 42714). The comment period closed on October 19, 1979. The final regulation is expected to publish September, 1981. G. *Covered by Regulatory Flexibility Act:* No.	
Approval of Supplemental New Animal Drug Applications.	A. *Description:* This final regulation would set forth conditions under which a new animal drug application may be approved without complete reevaluation of all safety and effectiveness data in the parent application. B. *Why Significant:* The regulation would constitute a change in agency policy regarding such approval. C. *Regulatory Impact Analysis:* Not required. D. *Need:* The regulation will speed up approval of certain supplemental applications, including those improving safety and effectiveness of the drug. 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 was published on November 12, 1976 (41 FR 50003) and the proposed regulation was published on December 23, 1977 (42 FR 64367). The comment period closed on March 23, 1978. The final regulation is expected to publish September, 1981. G. *Covered by Regulatory Flexibility Act:* No.	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.
Chemical Compounds in Food-Producing Animals; Availability of New Threshold Assessment Criteria for Guideline.	A. *Description:* This guideline describes the criteria the agency will use to assess the carcinogenic potential of animal drug residues in human food. B. *Why Significant:* The guideline replaces a previously published threshold assessment guideline which would have required virtually all candidate animal drugs to be tested for carcinogenic potential. The new guideline would refine the screening procedures and would reduce the number of candidate drugs requiring such testing. C. *Regulatory Impact Analysis:* Not required. D. *Need:* The guideline will provide a written standard for making an important human food safety decision that arises with each animal drug. It will help petition reviewers make consistent decisions and will inform the regulatd industry as to how these decisions are made. E. *Legal Basis:* Sections 512, 701(a), 52 Stat. 343-351 (21 U.S.C. 360b, 371(a)). F. *Chronology:* An original threshold assessment procedure was published in the preamble of the March 20, 1979 Proposal entitled "Chemical Compounds in Food-Producing Animals." (44 FR 17070) (commonly referred to as "Sensitivity of Method" (SOM)). The guideline is expected to publish May, 1981. G. *Covered by Regulatory Flexibility Act:* No.	Joseph A. Settepani, Acting Associate Director for Human Food Safety (HFV-300), Bureau of Veterinary Medicine, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4500.
National Environmental Policy Act, Policies and Procedures.	A. *Description:* This final regulation would amend agency requirements for compliance with the National Environmental Policy Act to comply with the Council on Environmental Quality's regulations (40 CFR 1500-1508). B. *Why Significant:* The regulation would change the environmental documents and procedures followed for environmental review of actions proposed by or requested by the agency. C. *Regulatory Impact Analysis:* Not required. D. *Need:* Council on Environmental Quality regulations require consistent implementation of NEPA among all Federal agencies. E. *Legal Basis:* Section 701, 52 Stat. 1055-1056 (21 U.S.C. 371); Section 102(2)(C), 83 Stat. 853 (42 U.S.C. 4332); 40 CFR 1500-1508; E.O. 11514, 11991 and 12114. F. *Chronology:* The proposed regulation was published on December 11, 1979 (44 FR 717452). The comment period closed March 12, 1980. The final regulation is expected to publish September, 1981. G. *Covered by Regulatory Flexibility Act:* No.	John Matheson, Acting Chief, Environmental Impact Staff, (HFV-300), Bureau of Veterinary Medicine, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4500.

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