Rules	Federal Register citation	Date published
Proposed amendments to the Virginia Permanent Regulatory Program.	53 FR 30450	Aug. 12, 1988.

Further notice to solicit comments on revisions and additional information to the Virginia permanent regulatory program will be provided at a later date.

List of Subjects in 30 CFR Part 946

Intergovernmental relations, Surface Mining, Surface Mining Reclamation and Enforcement Office, Underground mining.

Date: January 18, 1989.

Carl C. Close,

Assistant Director, Eastern Field Operations.

[FR Doc. 89-2085 Filed 1-27-89; 8:45 am]

BILLING CODE 4310-05-M

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 47

[DoD Directive 1000.20]

Active Duty Service Determinations for Civilian or Contractural Groups

AGENCY: Department of Defense.

ACTION: Proposed rule.

SUMMARY: 32 CFR Part 47 was last published on August 26, 1983 (48 FR 38816). Formerly titled "Demonstrations of Active Military Service and Discharge: Civilian or Contractual Personnel," it implemented Pub. L. 95-202 and established DoD policy and procedures to determine whether the civilian employment or contractual services of a civilian or contractual group shall be considered active military service for the purpose of laws administered by the Veterans Administration. This document clarifies the factors used by the DoD Civilian/Military Service Review Board and the Secretary of the Air Force (DoD Executive Agent for this program) in making administrative determinations of active duty service for the purpose of VA benefits under Pub. L. 95-202. Changes and clarifications stem from a Federal Court determination that the Department of Defense had failed to clarify factors and criteria in their implementing directive concerning Pub. L. 95-202.

DATE: Comments must be received by March 1, 1989.

ADDRESSES: Office of the Assistant Secretary of Defense (Force Management and Personnel), the Pentagon, Room 3E764, Washington, DC 20301-4000.

FOR FURTHER INFORMATION CONTACT: Colonel R.E. Nitzche, telephone 202-697-7197.

SUPPLEMENTARY INFORMATION:

List of Subjects in 32 CFR Part 47

Military personnel.

Accordingly, 32 CFR Part 47 is proposed to be revised as follows:

PART 47—ACTIVE DUTY SERVICE DETERMINATIONS FOR CIVILIAN OR CONTRACTURAL GROUPS

Sec.

47.1 Purpose.
47.2 Applicability.
47.3 Definitions.
47.4 Responsibilities.
47.5 Policy.
47.6 DoD Civilian Military Service Review Board and Advisory Panel.
47.7 Application Procedures.
Appendix—Instructions for Submitting Group Applications Under Public Law 95-202.

Authority: 38 U.S.C. 106 note.

§ 47.1 Purpose.

This part implements section 401, Pub. L. 95-202. It directs the Secretary of the Air Force to determine if an establish group of civilian employees or contract workers provided service to the U.S. Armed Forces in a manner considered "active duty." It establishes the DoD Civilian/Military Service Review Board and Advisory Panel, assigns responsibilities, develops policy, prescribes application procedures for groups and individuals, and clarifies the factors used to determine of active duty service.

§ 47.2 Applicability.

This part applies to the Office of the Secretary of Defense, the Secretaries of the Military Departments, and by agreement with the Secretary of Transportation, the Commandant of the U.S. Coast Guard. It also applies to any group application considered under Pub. L. 95-202 after the effective date of this directive and to any individual who applies for discharge documents as a member of a group recognized by the Secretary of the Air Force.

§ 47.3 Definitions.

Armed Conflict. A prolonged period of sustained combat involving members of the U.S. Armed Forces against a foreign belligerent. The term connotes more than a military engagement of limited duration or for limited objectives and involves a significant use of military and civilian forces. Examples of armed conflict are World Wars I and II and the Korean and Vietnam Conflicts. Examples of military actions that are not armed conflicts are the incursion into Lebanon in 1958 and the peacekeeping force there in 1983 and 1984, the incursions into the Dominican Republic in 1965 and Libya in 1986, and the intervention into Grenada in 1983.

Civilian or Contractual Group. An organization similarly situated to the Women's Air Forces Service Pilots (a group of federal civilian employees attached to the U.S. Army Force in World War II). Those organization members rendered service to the U.S. Armed Forces of the United States during a period of armed conflict in a capacity, which was then considered civilian employment with the Armed Forces or the result of a contract with the U.S. Government, to provide direct support to the Armed Forces.

Recognized Group. A group whose service the Secretary of the Air Force has administratively has determined to have been "active duty for the purposes of all laws administered by the Veterans Administrations (VA);" i.e., VA benefits under 38 U.S.C. 101.

Similarly Situated: A civilian or contractual group is "similarly situated" to the Women's Air Forces Service Pilots, when it existed as an identifiable group at the time the service was being rendered to the U.S. Armed Forces during a period of armed conflict. Persons who individually provided support through civilian employment or contract but who were not members of an identifiable group at the time the services were rendered are not "similarly situated" to the Women's Air Forces Service Pilots of World War II.

§ 47.4 Responsibilities.

(a) *The Secretary of the Air Force.* As the designated Executive Agent of the Secretary of Defense for the administration of section 401, Pub. L. 95-202, the Secretary of the Air Force shall:

(1) Establish the DoD Civilian/Military Service Review Board and the Advisory Panel.

(2) Appoint as board president a member, or employee, of the Air Force in grade O-6 and/or GM-15 or higher

(3) Request the Secretary of Transportation to appoint an additional voting member from the U.S. Coast Guard, when the board is considering the application of a group claiming active Coast Guard service.

(4) Provide a recorder and assistant to maintain the records of the board and administer the functions of this part.

(5) Provide non-voting legal advisors and historians.

(6) Publish notices of group applications and other Pub. L. 95–202 announcements in the Federal Register.

(7) Consider the rationale and recommendations of the DoD Civilian/Military Service Review Board.

(8) Determine whether the service rendered by a civilian or contractual group shall be considered active duty service to the U.S. Armed Forces for all laws administered by the Veterans Administration.

(9) Notify the following persons in writing, when a group determination is made (if the Secretary disagrees with the rationale or recommendations of the board, the Secretary shall provide the decision and reasons for it in writing to these persons):

(i) The applicant(s) for the group.

(ii) The Administrator of Veterans Affairs.

(iii) The Secretaries of the Army and Navy.

(iv) The Assistant Secretary of Defense (Force Management and Personnel (FM&P)).

(v) The Secretary of Transportation (when a group claims active Coast Guard service).

(b) *The Assistant Secretary of Defense (Force Management and Personnel (ASD(FM&P))* shall:

(1) Appoint a primary and an alternate member in the grade of 0–6 and/or GM–15 to the DoD Civilian/Military Service Review Board.

(2) Exercise oversight over the Military Departments and the U.S. Coast Guard for compliance with the provisions of this part and in the issuance of discharge documents and casualty reports to members of recognized groups.

(c) *The Secretaries of the Army, Navy, and Air Force and the Commandant of the Coast Guard* shall:

(1) Appoint a primary and an alternate member in the grades of 0–6 and/or GM–15 from their respective Military services to the board.

(2) Process applications for discharge documents from individuals claiming membership in a recognized group in accordance with applicable laws, directives, the Secretarial rationale and instrument effecting a group determination, and any other instruction of the board.

(3) Determine whether the applicant was a member of a recognized group after considering the individual's evidence of membership, and verifying the Military service, against available Government records.

(4) Issue a DD Form 214, "Certificate of Release or Discharge from Active Duty," and a DD Form 256, "Honorable Discharge Certificate," or a DD Form 257, "General Discharge Certificate," as appropriate, consistent with 32 CFR Parts 45 and 41, and the implementing documents of the appropriate statutes of the Military Department concerned or the Department of Transportation, and instructions of the DoD Civilian/Military Service Review Board.

(5) Issue a DD Form 1300, "Report of Casualty," or equivalent document in accordance with DoD Instruction 1300.9 [1] if a verified member was killed during the period of active duty service.

(6) Ensure that each DD Form 214, "Certificate of Release or Discharge from Active Duty," and each DD Form 1300, "Report of Casualty," have the following statement entered in the "Remarks" section: "This document, issued under Pub. L. 95–202 (38 U.S.C. 106 Note), administratively establishes active duty service for the purposes of Veterans Administration benefits."

(7) Determine the equivalent military pay grade, when required by the Veterans Administration. For the purpose of Veterans Administration benefits, a pay grade is needed only in cases when an individual was killed, or received service-connected injuries or disease, during the recognized period of active duty service. A DD Form 1300, or equivalent, shall be issued with the equivalent pay grade annotated for a member who died during the recognized period of service. A DD Form 214 shall not include pay grade, unless the Veterans Administration requests that a grade determination shall be made. Determinations of equivalent grade shall be based on the following criteria in order of importance:

(i) Officially recognized organizational grade or equivalent rank.

(ii) The corresponding rank for civilian pay grade.

(iii) If neither paragraph (c)(7)(i) nor (ii) of this section applies, only one of three grades may be issued: 0–1, E–4, or E–1. Selection depends on the nature of the job performed, the level of supervision exercised, and the military to which the individual was entitled.

(8) Adjudicate applicant challenges to the period of active duty service, characterization of service, or other administrative aspects of the discharge documents issued.

[1] Copies may be obtained, if needed, from the U.S. Naval Publication and Forms Center, Attn: Code 1062, 5801 Tabor Avenue, Philadelphia, PA 19120.

§ 47.5 Policy.

(a) A determination of active duty service is made on the extent to which the group was under the control of the U.S. Armed Forces in support of a military operation, or mission, during an armed conflict. The extent of control exerted over the group must be similar to that exerted over military personnel and shall be determined by, but not necessarily limited to, the following factors:

(1) *Uniqueness of Service.* Civilian service (civilian employment or contractual service) is a vital element of the war-fighting capability of the Armed Forces. Civilian service during a period of armed conflict is not necessarily equal to active Military service, even when performed in a combat zone. Service must be beyond that generally performed by civilian employees and must be occasioned by unique circumstances. For civilian service to be recognized under this Part, the following factors must be present:

(i) The group was created or organized specifically to fill a wartime need.

(ii) If the application is based on service in a combat zone, the mission of the group in a combat zone substantially must have been different from the mission of similar groups not in a combat zone.

(2) *Organizational Authority Over the Group.* The concept of military control is reinforced if the military command authority determines that the structure of the civilian organization, the location of the group, the mission and activities of the group, and the staffing requirements shall include the length of employment and pay grades of the members of the group.

(3) *Integration into the Military Organization.* Integrated civilian groups are subject to the regulations, standards, and control of the military command authority. Examples include:

(i) Exchanging of military courtesies.

(ii) Wearing of military clothing, insignia, and devices.

(iii) Assimilation of the group into the military organization structure.

(iv) Emoluments associated with military personnel; i.e., the use of commissaries and exchanges, and membership in military clubs. A group fully integrated into the military would give the impression that the members of the group were military, except that they were paid and accounted for as civilians. Integration into the military may lead to an expectation by members of the group that the service of the group imminently would be recognized as

active military service. Such integration militates in favor or recognition.

(4) *Subject to Military Discipline.* During past armed conflicts, U.S. military commanders sometimes restricted the rights or liberties of civilian members as if they were military members. Examples include:

(i) Placing members under a curfew.

(ii) Requiring members to work extended hours or unusual shifts.

(iii) Changing duty assignments and responsibilities.

(iv) Restricting proximity travel to and from the military installation.

(v) Imposing dress and grooming standards. Consequences for noncompliance might include a loss of some privilege, dismissal from the group, or trial under military law. Such military discipline militates in favor of recognition.

(5) *Subject to Military Justice.* Military members are subject to the military criminal justice system. During times of war, "persons serving with or accompanying an Armed Force in the field" are subject to the military criminal justice code. Some groups may have been treated as if they were military and subjected to court-martial jurisdiction to maintain discipline. Such treatment militates in favor of recognition.

(b) Other factors that may be considered in determining whether the service of a civilian or contractual group is equivalent to active duty service shall include:

(1) *Alliance with the Armed Forces for Protection.* A group that aligns itself with the Armed Forces and submits to military control for its own well-being is not deemed to have provided service to the Armed Forces tantamount to active duty Military Service, even though the group may have been:

(i) Armed by the U.S. military for defensive purposes.

(ii) Routed by the U.S. military to avoid the enemy.

(iii) Instructed by the U.S. military for the defense of the group when attacked by, or in danger of attack by, the enemy, or

(iv) Otherwise submitted themselves to the U.S. military for sustenance and protection.

(2) *Permitted to Resign.* The ability of members to resign at will and without penalty militates against military control. Penalty may direct and severe, such as confinement, or indirect and moderate, such as difficult and costly transportation from an overseas location.

(3) *Prohibition against Members of the Group Joining the Armed Forces.* Organizations formed to serve in a military capacity to overcome the operation of existing law or treaty militates in favor of recognition under Pub. L. 95–202. During World Wars I and II some persons could not be members of the United States Armed Forces. Women, for example, were prohibited by law from serving in the Armed Forces. Other persons were prohibited by treaty from being military members.

(4) *Benefits Already Provided Members of a Group.* Recognition of a group's service by agencies of the Federal, State, or local government does not militate in favor of recognition under this Part.

(c) *Eligibility for Consideration.* To be eligible to apply for consideration under Pub. L. 95–202 and this Part, a group must have been:

(1) Similarly situated to the Women's Air Forces Service Pilots of World War II.

(2) Rendered service to the U.S. Armed Forces in a civilian employment or contractual service capacity.

(3) Rendered that service during a period of armed conflict.

(d) *Reconsideration.* Groups previously denied a favorable Secretarial determination under the law, shall be reconsidered under this Part if the group submits evidence that is new, relevant, and substantive. Any request that the Board determines does not provide new, relevant, and substantive evidence shall be returned to the applicant with the reasons for nonacceptance.

(e) *Counsel Representation.* Neither the Department of Defense nor the Department of Transportation shall provide counsel representation or defray the cost of such on any matters covered by this part.

§ 47.6 DoD Civilian and/or Military Service Review Board and Advisory Panel.

(a) *Organization and Management.* (1) The Board shall consist of a president from the Department of the Air Force and one representative from the Office of the Secretary of Defense, the Departments of the Army, Navy, and Air Force, and the U.S. Coast Guard (when the group claims active Coast Guard service). Each member shall have one vote except that the president shall vote only to break a tie. The president and two voting members shall constitute a quorum.

(2) The advisory panel shall act as a nonvoting adjunct to the board. It shall consist of historians selected by the Secretaries of the Military Departments and, if required, by the Secretary of Transportation. The respective Military Departments and the Department of Transportation shall ensure that the advisory panel is provided with administrative and legal support.

(b) *Functions.*

(1) The board shall meet in executive session at the call of the president and shall limit its reviews to:

(i) Written submissions by an applicant on behalf of a civilian or contractual group.

(ii) Written report(s) prepared by the Advisory Panel.

(iii) Any other relevant written information available.

(iv) Factors established in this Part for determining active duty service.

(2) The board shall return to the applicant any application that does not meet the eligibility criteria established in § 47.5(c). The board only needs to state the reasons why the group is ineligible for consideration under this Part.

(3) If the board determines that an application is eligible for consideration under the provisions of § 47.5(c), the board shall provide the Secretary of the Air Force a recommendation on the active duty service determination for the group and the rationale for that recommendation that shall include, but not be limited to, a discussion of the factors listed in § 47.5.

(i) No factors shall be established that require automatic recognition. Neither the board nor the Secretary shall be bound by any quantitative methodology of weighting factors in reaching a decision.

(ii) Prior group determinations do not bind the board or the Secretary. The board and the Secretary shall fully and impartially consider each group on its own merit in relation to the factors listed in § 47.5.

§ 47.7 Application procedures.

(a) *Submitting group applications.* Applications on behalf of a civilian or contractual group shall be submitted to the Secretary of the Air Force using the instructions at the Appendix to this part.

(b) *Processing group applications.* (1) When received, the recorder shall review the application for sufficiency and either return it for more information or accept it for consideration and announce acceptance in the **Federal Register**.

(2) The recorder shall send the application to the appropriate advisory panel for historical review and analysis.

(3) When received, the recorder shall send the advisory panel's report to the applicant for comment. The applicant's comments shall be referred to the advisory panel if significant disagreement requires resolution. Additional comments from the historians also shall be referred to the applicant for comment.

(4) The DoD Civilian/Military Service

Review Board shall consider the group application as established in § 47.6.

(5) After a Secretarial decision the recorder shall notify the applicant of the decision and announce it in the **Federal Register.**

(c) *Submitting Individual Applications.* When a group is recognized, individual members may apply to the appropriate Military Department, or to the Coast Guard, for discharge documents. Submit applications on DD Form 2168, "Application for Discharge of Member or Survivor of Member of Group Certified to Have Performed Active Duty with the Armed Forces of the United States." An application on behalf of a deceased or incompetent member submitted by the next of kin must be accompanied by proof of death or incompetence.

Appendix—Instructions for Submitting Group Applications Under Public Law 95–202

In submitting a group application:

(1) Define the group to include the time period that your group provided service to the U.S. Armed Forces.

(2) Show the relationship that the group had with the U.S. Armed Forces, the manner in which members of the group were employed, and the services the members of the group provided to the U.S. Armed Forces.

(3) Address each of the factors in § 47.5 of this part.

(4) Substantiate and document the application. (The burden of proof rests with the applicant.)

Send completed group applications to: Secretary of the Air Force (SAF/MRC), DoD Civilian/Military Service Review Board, Washington, DC 20330–1000.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

January 25, 1989.

[FR Doc. 89–2087 Filed 1–27–89; 8:45 am]

BILLING CODE 3810-01-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[FRL–3511–5]

Approval and Promulgation of Implementation Plans; Ohio State Implementation Plan; Extension of Comment Period

AGENCY: United States Environmental Protection Agency (USEPA).

ACTION: Notice of extension of the public comment period.

SUMMARY: USEPA is giving notice that the public comment period for a notice of proposed rulemaking published November 16, 1988 (53 FR 46094), has been extended 30 days. This notice proposed to disapprove a revision to the Ohio State Implementation Plan, which would allow the ATEC Industries, Incorporated's architectural aluminum extrusion coating line to meet the volatile organic compounds (VOC) limitation of 3.5 pounds of VOC per gallon coating, minus water, as required by Ohio Administrative Code (OAC) 3745–21–09(U)(1)(a)(iii), on a monthly volume-weighted average in lieu of the daily volume-weighted average required by OAC Rule 3745–21–09(B). This source is located in Mahoning, Ohio. USEPA is taking this action based on an extension request by a commentor.

DATE: Comments are now due on or before January 16, 1989.

FOR FURTHER INFORMATION CONTACT: Uylaine E. McMahan, Air and Radiation Branch (5AR–26), U.S. Environmental Protection Agency, Region V, 230 South Dearborn Street, Chicago, Illinois 60604, (312) 886–6031.

Date: January 13, 1989.

Valdas V. Adamkus,

Regional Administrator.

[FR Doc. 89–2024 Filed 1–27–89; 8:45 am]

BILLING CODE 6560-50-M

40 CFR Part 52

[FRL–3510–8]

Approval and Promulgation of Implementation Plans; Wisconsin State Implementation Plan; Extension of Comment Period

AGENCY: United States Environmental Protection Agency (USEPA).

ACTION: Notice of extension of the public comment period.

SUMMARY: USEPA is giving notice that the public comment period for a notice of proposed rulemaking published December 2, 1988 (53 FR 48654), has been extended 30 days. This notice proposed to disapprove a revision to the Wisconsin State Implementation Plan, which would allow a temporary relaxation from Wisconsin's volatile organic compound reasonably control technology regulations for a General Motors facility located in Janesville, Wisconsin. USEPA is taking this action based on an extension request by a commentor.

DATE: Comments are now due on or before January 31, 1989.

FOR FURTHER INFORMATION CONTACT: Uylaine E. McMahan, Air and Radiation Branch (5AR–26), U.S. Environmental Protection Agency, Region V, 230 South Dearborn Street, Chicago, Illinois 60604, (312) 886–6031.

Dated: January 13, 1989.

Valdas V. Adamkus,

Regional Administrator.

[FR Doc. 89–2022 Filed 1–27–89; 8:45 am]

BILLING CODE 6560-50-M

40 CFR Part 52

[FRL–3511–4]

Approval and Promulgation of Implementation Plans; Wisconsin State Implementation Plan; Extension of Comment Period

AGENCY: United States Environmental Protection Agency (USEPA).

ACTION: Notice of extension of the public comment period.

SUMMARY: USEPA is giving notice that the public comment period for a notice of proposed rulemaking published December 6, 1988 (53 FR 49209), has been extended 30 days. This notice proposed to disapprove a revision to the Wisconsin State Implementation Plan, which would allow for a site-specific reasonably available control technology determination for volatile organic compounds emissions from two miscellaneous metal parts and products spray coating lines at General Electric Company, Medical Systems. This source is located in Milwaukee, Wisconsin. USEPA is taking this action based on an extension request by a commentor.

DATE: Comments are now due on or before February 6, 1989.

FOR FURTHER INFORMATION PLEASE CONTACT: Uylaine E. McMahan, Air and Radiation Branch (5AR–26), U.S. Environmental Protection Agency, Region V, 230 South Dearborn Street, Chicago, Illinois 60604, (312) 886–6031.

Date: January 13, 1989.

Valdas V. Adamkus,

Regional Administrator.

[FR Doc. 89–2023 Filed 1–27–89; 8:45 am]

BILLING CODE 6560-50-M

40 CFR Part 300

[FRL-3509-1]

Clarification of the Intent To Delete the New Castle Steel Site, New Castle, DE, From the National Priorities List

AGENCY: Environmental Protection Agency (EPA).

ACTION: Clarification.

SUMMARY: Due to the possible confusion created by the differing dates, and in order to ensure a full period of thirty days for comment, EPA announces that an additional two weeks of public comment, beginning from the date of this clarification notice, will be allowed on EPA's "Notice of Intent to Delete the New Castle Steel Site from the National Priorities List", 53 FR 36869, September 22, 1988. Comments should be provided to the address for the Regional Docket specified below.

DATE: Comments concerning the site may be submitted for two weeks from the date of this clarification notice.

ADDRESSES: Comments may be mailed to the Regional Docket. Comprehensive information on the site is maintained and available through the EPA Regional Docket Clerk.

The Regional Docket is located at the U.S. EPA Region III office and is available for viewing by appointment only from 9:00 a.m. to 4:00 p.m. Monday through Friday, excluding holidays. Requests for copies of the information from the Regional public docket should be directed to the EPA Region III docket office.

Addresses for the Regional and Local Docket office are:

U.S. EPA Region III, 841 Chestnut Building, Philadelphia, PA 19107
Wilmington Library, 10th & Market Streets, Wilmington, DE 19801
DNREC, 715 Grantham Lane, New Castle, DE 19720.

FOR FURTHER INFORMATION CONTACT: Barbara Brown at (215) 597-8593.

For background information on the site contact: Randy Sturgeon, DELMARVA/DC/WV CERCLA, Remedial Enforcement Section (3HW16), U.S. Environmental Protection Agency, Region III, 841 Chestnut Building, Philadelphia, PA 19107, (215) 597-0978.

SUPPLEMENTARY INFORMATION: The Environmental Protection Agency (EPA) Region III issues this clarification notice on the public comment period provided for the New Castle Steel Site in its "Notice of Intent to Delete the New Castle Steel Site from the National Priorities List", 53 FR 36869, September 22, 1988. EPA's "Notice of Intent" of September 22, 1988, stated that a local notice had been published announcing a thirty (30) day public comment period on the deletion package, starting on October 6, 1988, and concluding on October 24, 1988. EPA's local notice, published in local papers, appeared on September 22, 1988, and announced a period for public comment ending on October 21, 1988.

Date: January 11, 1989.

Stanley L. Laskowski,

Acting Regional Administrator.

[FR Doc. 89-1791 Filed 1-27-89; 8:45 am]

BILLING CODE 6560-50-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 400 and 405

[BERC-432-P]

Medicare Program; Criteria and Procedures for Making Medical Services Coverage Decisions That Relate to Health Care Technology

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would establish in regulations generally applicable criteria and procedures for HCFA decisions as to whether and under what circumstances specific health care technologies could be considered "reasonable" and "necessary" and therefore covered under Medicare. It would provide for more openness and streamlining of the decisionmaking process through increased public participation and expedited review of new breakthrough technologies. It expands upon the description of the process used in reaching coverage decisions that was published in the **Federal Register** on April 29, 1987 (52 FR 15560).

DATE: Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5:00 p.m. on March 31, 1989.

ADDRESS: Mail comments to the following address:

Health Care Financing Administration, Department of Health and Human Services, Attention: BERC-432-P, P.O. Box 26676, Baltimore, Maryland 21207.

If you prefer, you may deliver your comments to one of the following addresses:

Room 309-G, Hubert H. Humphrey Building, 200 Independence Ave., SW., Washington, DC, or

Room 132, East High Rise Building, 6325 Security Boulevard, Baltimore, Maryland.

In commenting, please refer to BERC-432-P. Comments received timely will be available for public inspection as they are received, generally beginning approximately three weeks after publication of a document, in Room 309-G of the Department's offices at 200 Independence Ave., SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5:00 p.m. (phone 202-245-7890).

If you wish to submit comments on the information collection requirements contained in this proposed rule, you may submit comments to: Office of Information and Regulatory Affairs, Office of Management and Budget, Room 3002, New Executive Office Building, Washington, DC 20503, Attention: Desk Officer for HCFA.

FOR FURTHER INFORMATION CONTACT: Sam Della Vecchia, (301) 966-5316.

SUPPLEMENTARY INFORMATION: Under the Medicare program, the benefits available to eligible beneficiaries are called *covered* services and include those medical supplies and procedures that are referred to as "items". Medicare program funds cannot generally be used to pay for services furnished to Medicare beneficiaries that are not covered under the Social Security Act (the Act). This proposed rule deals primarily with issues related to coverage of services, rather than to payment for services; that is, with determining the services to be paid for as benefits under the Medicare program rather than the method or level of payment. The primary statutory basis for these coverage decisions appears in section 1862(a)(1)(A) of the Act, which prohibits payment under the Medicare program for any expenses incurred for services "which are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."

This proposed rule is being published to establish in regulations generally applicable criteria and procedures for determining whether a service is "reasonable" and "necessary" under the Medicare program; to set forth the coverage decisionmaking process that we propose to include in regulations; and to summarize and provide an analysis of the public comments that we received in response to the April 29, 1987 notice (52 FR 15560) that announced our current process for making coverage decisions.

That notice was published in accordance with the terms of an agreement settling a lawsuit, *Jameson* v. *Bowen*, C.A. No. CV-F-83-547-REC (E.D. Cal.). Under the settlement, we agreed to publish for public comment a description of the process we use to make Medicare coverage decisions. We invited the public to comment on the coverage process currently in use and specifically to comment on procedures allowing for public input into the coverage decisionmaking process if appropriate. The notice described the current process only, because of the limited time available for meeting the court deadline of May 1, 1987 for publication of the notice. In publishing that notice, we also solicited comments on how the current process could be improved.

These regulations are intended to clarify our coverage decisions policy and improve the method for making national coverage decisions. In addition, they are intended to assure that Federal funds are expended only for medical services that are appropriate to meet an individual's medical needs. We believe that it is important to set forth these policies and procedures in regulations since decisions on coverage can have a bearing on the availability of a medical service. Further, some groups, including the Health Industry Manufacturers Association (HIMA), have urged us to make public the process for national coverage decisions since they argue that these decisions directly affect the diffusion of new technology.

In addition, we believe it is important that beneficiaries understand fully the considerations underlying program coverage decisions. Finally, the Administrative Conference of the United States, in a December 30, 1986 **Federal Register** publication (51 FR 46987), recommended, in part, that more "openness and regularity" be introduced into the process for issuing national coverage decisions pertaining to new medical technologies and procedures.

In view of the significant considerations noted above, we propose to establish in regulations generally applicable criteria and procedures for determining coverage of specific health care technologies under the Medicare program; and to invite public comment on them. We are soliciting comments on all aspects of the Medicare coverage process including:

- The criteria for coverage decisions, including cost-effectiveness, and their application.
- The identification and selection of health care technologies for national coverage decisions.
- Methods for assuring appropriate public participation in the various phases of the technology assessment process.
- The length of time required for review.
- The relationship between determinations by Public Health Service (PHS) agencies, including the Food and Drug Administration (FDA) and the Office of Health Technology Assessment (OHTA) and Medicare coverage decisions.

We have explained in much detail our current process for making coverage decisions, as well as the changes that we propose to make to this process. To assist readers in referencing sections contained in this proposed rule, we are providing a table of contents below:

I. Medicare Coverage—General
  A. Statutory Basis
  B. Implementation of the Law
II. The Current Process for Making National Coverage Decisions
  A. Referral and Identification of Coverage Issues for National Decisions
  B. Criteria for Selection of Coverage Issues for National Decisions
  C. HCFA Analysis
    1. General
    2. Initial Consideration—Background Papers
    3. HCFA Physicians Panel
  D. PHS Assessment Process
    1. Drugs and Biologicals
    2. Devices
  E. Criteria for Making National Coverage Decisions
    1. Safety and Effectiveness
    2. Experimental or Investigational
    3. Appropriateness
  F. Publication of National Coverage Decisions
  G. Reevaluation and Reconsideration of National Coverage Decisions
III. Regulation Provisions of this Proposed Rule
  A. Reason for Codifying the Coverage Decisions Process
  B. Definitions of Commonly Used Terms
  C. Cost-effectiveness as an Additional Criterion for Medicare Coverage of Reasonable and Necessary Services
  D. Procedures for Medicare Contractors in Making Coverage Decisions
  E. HCFA Procedures for Making National Coverage Decisions
  F. Carrier Coverage Process
  G. Conforming Changes
IV. Relationship with Other Agencies
  A. Food and Drug Administration
  B. Prospective Payment Assessment Commission (ProPAC)
  C. National Institutes of Health
V. Contractor Functions and the Claims Process
  A. General
  B. Contractor Functions
  C. Criteria and Procedures for Contractor Coverage Decisions
  D. Appeals Procedures
    1. Part A
    2. Part B
VI. Analysis of and Responses to Public Comments for April 29, 1987 Notice
  A. Inconsistent Medicare Contractor Decisions
  B. Define "Reasonable", "Necessary", and "Experimental"
  C. Issue Contractor Criteria for Making Decisions
  D. Coverage Criteria
  E. Absence of Public Input and Comment in the Coverage Process
  F. Composition of HCFA Physicians Panel
  G. Time Frame for Process
  H. Improving Coordination with FDA
  I. Coverage Exclusions Deter Research
  J. Interim Payments during the Coverage Decisions Process
  K. Carrier Screens
  L. Monitoring Contractor Performance
  M. Physician Review of Adverse Decisions
  N. Equipment and Coverage for Long Term Disabilities
  O. Confidentiality of Data
VII. Proposed Uncodified Changes to the Current Coverage Decisions Process
  A. HCFA Physicians Panel
  B. Improved Coordination and Communication
VIII. Regulatory Impact Statement
IX. Information Collection Requirements
X. Responses to Comments on this Proposed Rule
List of Subjects

In addition, because of the many agencies and terms that we reference by an acronym in this proposed rule, we have listed those acronyms and their corresponding terms in alphabetical order below:

ADAMHA—Alcohol, Drug Abuse and Mental Health Administration
ALJ—Administrative Law Judge
BERC—Bureau of Eligibility, Reimbursement and Coverage, HCFA
CDC—Centers for Disease Control
CMP—Competitive Medical Plan
DME—Durable medical equipment
FDA—Food and Drug Administration
FFDCA—Federal Food, Drug, and Cosmetic Act
HCFA—Health Care Financing Administration
HHA—Home health agency
HHS—Health and Human Services, Department of
HIMA—Health Industry Manufacturers Association
HMO—Health maintenance organization

HRSA—Health Resources and Services Administration
NCI—National Cancer Institute
NIH—National Institutes of Health
OHTA—Office of Health Technology Assessment
OMAR—Office of Medical Applications of Research
OMB—Office of Management and Budget
PHS—Public Health Service
PMA—Premarket approval application
ProPAC—Prospective Payment Assessment Commission
PROs—Utilization and Quality Control Peer Review Organizations
PRRB—Provider Reimbursement Review Board
RFA—Regulatory Flexibility Act
SMI—Supplementary Medical Insurance (Part B of the Medicare Program)
SNF—Skilled nursing facility
TAG—Coverage/Payment Technical Advisory Group

I. Medicare Coverage—General

A. Statutory Basis

The Medicare program was established by Congress in 1965 with the enactment of title XVIII of the Social Security Act (the Act). The program provides payment for certain medical services for persons 65 years of age or over, disabled beneficiaries, and persons with end-stage renal disease. The program currently covers 28.8 million aged and almost three million disabled individuals.

The Medicare program consists of two separate but complementary insurance programs, a Hospital Insurance Program, known as Part A, and a Supplementary Medical Insurance program, known as Part B. Although Part A is called hospital insurance, covered benefits also include medical services furnished in skilled nursing facilities (SNFs) or by home health agencies (HHAs) and hospices. For purposes of the Medicare program, we refer to these institutional entities as "providers". These providers must be certified as qualified providers of services and must sign an agreement to participate in the program. Part B covers a wide range of medical services and supplies such as those furnished by physicians or others in connection with physicians' services, outpatient hospital services, outpatient physical therapy and occupational therapy services, and home health services. Physicians' services covered under Part B include visits to patients in the home, office, hospital, and other institutions. Part B also covers certain drugs and biologicals that cannot be self-administered, diagnostic x-ray and laboratory tests, purchase or rental of durable medical equipment, ambulance services, prosthetic devices, and certain medical supplies.

While the Medicare law provides coverage for the broad categories of benefits described above, it also places general and categorical limitations on the coverage of the services furnished by certain health care practitioners, such as dentists, chiropractors, and podiatrists, and it specifically excludes some categories of services from coverage, such as cosmetic surgery, personal comfort items, custodial care, routine physical checkups, and services that are not reasonable and necessary for diagnosis or treatment of an illness or injury. The statute also provides direction as to the manner in which payment is made for Medicare services, the rules governing eligibility for services, and the health, safety, and quality standards to be met by institutions providing services to Medicare beneficiaries.

The Medicare law does not, however, provide an all-inclusive list of specific items, services, treatments, procedures, or technologies covered by Medicare. Thus, except for the examples of durable medical equipment in section 1861(n) of the Act, and some of the medical and other health services listed in sections 1861(s) and 1862(a) of the Act, the statute does not specify medical devices, surgical procedures, or diagnostic or therapeutic services that should be either covered or excluded from coverage.

The intention of Congress, at the time the Medicare law was enacted in 1965, was that Medicare would provide health insurance to protect the elderly or disabled from the substantial costs of acute health care services, principally hospital care. The law was designed generally to cover services ordinarily furnished by hospitals, SNFs, and physicians licensed to practice medicine. Congress understood that questions as to coverage of specific services would invariably arise and would require a specific decision of coverage by those administering the program. Thus, it vested in the Secretary the authority to make those decisions. Section 1862(a)(1)(A) of the Act states: "Notwithstanding any other provisions of this title, no payment may be made under Part A or Part B for any expenses incurred for items or services which * * * are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." This is a key provision since the words "notwithstanding any other provision of this title * * *" make this an overriding exclusion that may be applicable in a given situation despite the existence of provisions that would otherwise permit coverage. Thus, while Congress provided for the coverage of services such as inpatient hospital care and physicians' services, coverage for those services is prohibited unless they are "reasonable" and "necessary".

B. Implementation of the Law

Historically, HCFA has interpreted section 1862(a)(1)(A) of the Act to exclude from Medicare coverage those medical and health care services that are not demonstrated to be safe and effective by acceptable clinical evidence. However, current regulations are general and we have not defined the terms "reasonable" and "necessary", nor have we described in regulations a process for how these terms must be applied. (See Medicare regulations at 42 CFR 405.310(k)(1).)

In practice, Medicare contractors (that is, fiscal intermediaries, carriers, health maintenance organizations (HMOs), competitive medical plans (CMPs), and Utilization and Quality Control Peer Review Organizations (PROs)) are charged with the responsibility to assure that payments are made only for services that are covered under Medicare Part A or Part B. (See section V below for a further description of contractor functions.) Therefore, they must determine whether a particular service is covered under Medicare in the course of adjudicating a Medicare claim or conducting utilization and quality review.

Our policy on the implementation of section 1862(a)(1)(A) of the Act is set forth in Part A Intermediary Letter 77–4 and Part B Intermediary Letter 77–5 (January 1977). These documents translate the statutory terms "reasonable" and "necessary" into a test as to whether the service in question is "safe" and "effective" and not "experimental"; that is, whether the service has been proven safe and effective based on authoritative evidence, or alternatively, whether the service is generally accepted in the medical community as safe and effective for the condition for which it is used. For Medicare coverage purposes, the term "experimental" is used synonymously with the term "investigational". Further guidelines for contractors administering the program are contained in the Intermediary (HCFA Pub. 13–3), Carrier (HCFA Pub. 14–3), and Utilization and Quality Control Peer Review Organization (HCFA Pub. 19) manuals. These manuals are updated periodically through the instruction issuance process and comprise the primary source of information from HCFA central office to the contractors on claims adjudication and utilization and quality review.

In addition to these general guidelines, we have issued over 200 specific national Medicare coverage decisions on individual health care technologies. The term "national coverage determination" refers to a coverage decision that HCFA makes and issues as national policy. The term "health care technology" refers to any discrete and identifiable regimen or modality used to diagnose or treat illness, prevent disease, maintain patient well-being, or facilitate the provision of health care services. These technologies range from practices that appear to be obsolete or of questionable effectiveness to new technologies, recently introduced into medical practice, still in an experimental stage, or that are new applications of established technologies. We publish national coverage decisions on health care technologies in the Medicare Coverage Issues Manual (HCFA Pub. 6), and may also publish these decisions in other HCFA program manuals or as HCFA Rulings in the **Federal Register**. National coverage decisions are binding on our contractors and must be applied.

II. The Current Process for Making National Coverage Decisions

This section expands upon the description of the *current* process we use in making national coverage decisions that was published in the **Federal Register** on April 29, 1987 (52 FR 15560).

A. Referral and Identification of Coverage Issues for National Decisions

The process for determining whether a health care technology or service is covered has been in place for many years. Over time, certain refinements and revisions have been made in that process, but the basic structure has remained the same. Decisions on coverage are made mostly by carriers, fiscal intermediaries, and PROs that contract with the Secretary to review and adjudicate claims for Medicare services. (Section V of this preamble describes the functions of Medicare contractors.) We estimate that almost 400 million individual claims were processed by our carriers and intermediaries in fiscal year 1987. Most of the individual claims processed by Medicare contractors do not raise serious questions about coverage. However, a small number of services (usually 20 to 30 per year) are the subject of a national coverage decisionmaking and technology assessment process.

Coverage issues of national significance regarding health care technologies are raised in a variety of ways. Some are raised by individual Medicare beneficiaries, physicians, equipment manufacturers, public officials, professional associations, or government entities. Other coverage issues are raised during our ongoing review of current medical literature. However, most coverage issues are brought to our attention by our program's contractors.

If a contractor cannot resolve a coverage question satisfactorily, or believes a national coverage decision may be necessary, the issue is referred to HCFA central office through a HCFA regional office. In general, the more expensive a service is or promises to become, either in an individual case or in the aggregate, or the more prone it is to raising public health and safety concerns, the more likely it is to be referred to HCFA central office. Also, the more likely a service is to be subject to overutilization or other abuse, the more likely it is that the contractor will seek our guidance on a coverage policy. A frequent source of contractor referrals is the Coverage/Payment Technical Advisory Group (TAG). The TAG, which is made up of medical directors and other officers of the carriers and intermediaries, meets every six to eight weeks with HCFA staff to discuss its experience with various coverage and payment issues, and to discuss with us the disposition of specific coverage questions, including the need for a national coverage decision when appropriate.

B. Criteria for Selection of Coverage Issues for National Decisions

When a coverage question arises regarding a health care technology, the issue is referred to the Bureau of Eligibility, Reimbursement and Coverage (BERC) within HCFA. BERC may identify a service or technology for our centralized coverage process if there are no statutory bars to coverage of the service and one or more of the following conditions is present: (1) The service represents a significant advance in medical science; (2) the service can be described as a new product (that is, a device, drug, or procedure for which there is no similar technology already covered under Medicare); (3) the service is likely to be used in more than one region of the country; (4) the service is likely to represent a significant expense to the Medicare program; (5) the service has the potential for rapid diffusion and application; (6) there is substantial disagreement among experts regarding the safety, effectiveness, or appropriateness of a service; (7) the service has been treated inconsistently by contractors and a conflict can be resolved only by a national decision; or (8) the service was "commonly accepted" by the medical profession in the past or a national decision to cover the service was made previously, but appears to have become outmoded or questions about its safety and effectiveness have been raised.

After preliminary analysis, BERC may conclude that the coverage issue does not meet any of the criteria specified above and that a national coverage decision is not appropriate or necessary for that specific health care technology. If BERC concludes that a national coverage decision is not appropriate or necessary, the individual or organization that requested a national coverage decision is informed of the basis of the conclusion. In addition, if the request for a national coverage decision was made by one of our contractors, BERC may provide information to contractors as to the opinion of other third party payors, specialty societies, or recognized medical authorities regarding the appropriateness of coverage of the health care technology in question. However, that information, in the absence of a national coverage decision is not binding on the contractors who retain the discretion to cover or not cover, taking into account the circumstances of the individual case. For example, a contractor may question whether a new surgical procedure to treat a rare medical condition should be covered. BERC may decide that a national coverage decision is not necessary since only a few patients are likely to ever need the procedure. However, as part of its analysis, it may learn that the procedure is considered experimental by other third party payors and various specialty societies. The contractor would be informed that a national coverage decision will not be made and also informed that the procedure is considered experimental by other entities. The contractor also would be informed that the information is not binding and that coverage could be provided if the contractor determines that the procedure is reasonable and necessary in a particular case.

C. HCFA Analysis

1. General

HCFA has used various methods for seeking medical and scientific advice in determining whether a health care technology is reasonable and necessary. The fundamental test has been whether the technology is safe and effective or commonly accepted by the medical community. They have included, at one time or another, the use of PHS advisory

councils, ad hoc groups of representative physicians, and various forms of consultation and liaison with national medical associations. At present, a structured process of review and assessment involves HCFA central office staff physicians, PHS representatives, a contractor medical advisory group, and the medical community.

2. Initial Consideration—Background Papers

If BERC determines that consideration should be given to issuing a national coverage decision for a specific health care technology, BERC conducts a medical literature search, meets with interested parties (proponents and opponents) as needed, determines the status of any FDA action, and prepares a background summary on the service.

The background paper stresses the information obtained from the medical literature search and the administrative aspects of the issue. Current Medicare coverage guidelines are discussed, as well as any information obtained regarding published decisions by other groups involved in technology assessment.

3. HCFA Physicians Panel

The next step in the process involves presenting the background paper to the HCFA Physicians Panel for review. This Panel, a group composed of staff physicians and other health professionals in HCFA's central office and counterparts from PHS, meets approximately once every six to eight weeks. These sessions are designed to permit the free exchange of ideas among knowledgeable staff within the Department and are not open to the public. The HCFA Physicians Panel serves in a purely advisory role to BERC. Although BERC utilizes the Panel's expertise in determining whether to develop a coverage question as a national policy, BERC retains responsibility for making judgments about referring items to PHS for further study and for making recommendations on coverage for the approval of the HCFA Administrator.

Upon weighing background information and medical literature, the Panel may recommend to BERC that the service should be: (1) Referred to PHS (specifically to the Office of Health Technology Assessment (OHTA) in the National Center for Health Services Research and Health Care Technology Assessment (the National Center), Office of the Assistant Secretary for Health) on either an "inquiry" basis, or for a full assessment as to safety and effectiveness; or (2) that no national coverage decision be made at that time.

A recommendation to refer an issue to OHTA on an inquiry basis may be made if the Panel is uncertain that there is sufficient evidence available to warrant a full assessment, or if only limited information is needed in the context of specific questions. Upon receipt of an inquiry, OHTA typically gathers background information from other PHS and governmental agencies and conducts a more indepth review of the medical literature than the BERC staff is able to do. OHTA contacts FDA for information on the regulatory status of the health care technology, if appropriate, and the National Institutes of Health (NIH), the Centers for Disease Control (CDC), and other agencies for information on its medical and scientific status.

The information gathered by OHTA is then forwarded to BERC. The response generally includes a brief statement of the steps taken in obtaining the information and of the organizations consulted. It responds to all questions raised by BERC, but does not include a recommendation as to coverage or noncoverage.

The following parameters are among the major considerations by the Panel in recommending that an issue be referred to OHTA on an assessment basis:

- The issue is of such importance, that a national coverage decision will likely be required upon completion of the assessment;
- The technology involves significant expenditures for Medicare, that is, the technology has the potential for rapid diffusion in a large patient population or the technology is very expensive on a per case basis;
- The data base appears adequate, that is, there is sufficient scientific evidence to permit conclusions regarding safety and effectiveness (The definition of adequacy will vary according to the nature and course of the disease and the difficulty or complexity of the intervention in conducting clinical trials.); and
- FDA has accepted the technology if it consists of drugs, biologics, or medical devices.

The Panel may recommend that a national coverage decision not be made at that time. In that case, the individual contractor would continue to make coverage decisions on a case-by-case basis. In general, this recommendation is made if the issue involves a new or emerging technology or practice for which it appears there is limited clinical data on which to base a firm coverage decision or when claims have been received from few contractor areas. Coverage decisions in these situtations are best made by the contractor's medical staff, taking into account the unique circumstances of the individual case as well as local standards of care.

D. PHS Assessment Process

When HCFA initiates an assessment by referring an issue to OHTA for a coverage recommendation, OHTA announces the assessment in the **Federal Register**, allowing a 90-day period for public comment. OHTA collects information from a wide variety of sources, including medical literature, Federal agencies, clinical medical specialty groups, and manufacturers associations. All relevant information is analyzed and synthesized in order to develop conclusions regarding the safety and clinical effectiveness of the subject technology. OHTA then prepares an assessment report that contains the information on which a coverage recommendation is based. That report forms the basis for a PHS coverage recommendation that is submitted to HCFA in conjunction with the report. After HCFA makes its coverage decision, the OHTA report is made available to the public.

Note.—PHS has informed HCFA that a revised set of guidelines for this process is being prepared, and this material will, after appropriate internal review, be made available for subsequent public comment.

1. Drugs and Biologicals

Questions regarding coverage of drugs and biologicals are rarely referred to PHS since we have determined as a matter of national policy that drugs or biologicals approved for marketing by FDA are safe and effective when used for indications specified in their labeling. In addition, FDA-approved drugs also may be covered when used for indications other than those specified on their labeling as long as FDA has not specified such use as non-approved. Coverage of non-labeled uses is determined by our contractors taking into consideration the generally accepted medical practice in the community. Treatment Investigational New Drugs (INDs) are approved by FDA but are still considered experimental and not covered by Medicare. Drugs that have not received FDA approval for marketing are considered experimental or investigational and are not covered except for certain cancer drugs distributed by the National Cancer Institute (NCI).

Under its Cancer Therapy Evaluaton, the Division of Cancer Treatment within NCI, in cooperation with FDA, approves

and distributes certain drugs for use in treating terminally ill cancer patients. One gorup of these drugs, designated as Group C drugs, unlike other drugs distributed by the NCI, are not limited to use in clinical trials for the purpose of testing their efficacy. In view of NCI controls on their distribution and use, Group C drugs are covered by Medicare if all other applicable coverage requirements are satisfied.

In accordance with section 202(k)(1)(A) of the Medicare Catastrophic Coverage Act of 1988 (Pub. L. 100–360, enacted July 1, 1988), the Secretary must conduct a study and report to Congress by January 1, 1990 on the possibility of covering certain experimental drugs and biologicals (for example, those used in the treatment of cancer or in immunosuppressive therapy) as outpatient drugs under the Medicare program. Consequently, we are interested in receiving comments on our position concerning Treatment INDs.

2. Devices

FDA approval for the marketing of a medical device will not necessarily lead to a favorable coverage recommendation, particularly if FDA requirements have been met by means of a notice issued under section 510(k) of the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. 360(k)), rather than by means of a premarket approval application (PMA) made under section 515 of the FFDCA. This is because a section 510(k) notice generally does not involve clinical data showing safety and effectiveness. Only limited safety and effectiveness data are generally required by FDA for purposes of a section 510(k) notice. FDA findings of safety and effectiveness focus on the labeled use of a device only, while our decisions may focus on other uses of a device under average conditions of use (that is, other than in a clinical setting).

In accordance with paragraphs (a)(2)(C) and (a)(3)(A) of section 513 of the FFDCA (21 U.S.C. 360c) regarding PMAs, FDA determines the safety and effectiveness of a device by "weighing any probable benefit to health from the use of the device against any probable risk of illness or injury from such use," and effectiveness "on the basis of well-controlled investigations, including clinical investigations where appropriate, * * * from which investigations it can fairly and responsibly be concluded by qualified experts that the device will have the effect that it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling of the device."

E. Criteria for Making National Coverage Decisions

After considering OHTA's recommendation, HCFA decides whether or not the service should be covered. During the decisionmaking process, a number of issues must be considered, in interpreting the "reasonable" and "necessary" requirements of the Medicare statute. In making national coverage decisions, HCFA interprets the term "reasonable" and "necessary" contained in section 1862(a)(1)(A) of the Act to mean that a service is safe, effective, non-investigational, and appropriate. Not all of the criteria are necessarily pertinent to every coverage issue and each criterion is not necessarily given equal consideration in reaching a final decision. Because of the complexity and variety of issues involved in making coverage decisions, we do not think it is possible, or advisable, to try to set quantitative standards or develop a formula for the application of these criteria.

The criteria are identified below by major headings, with a brief description of each criterion and a detailed, although not exhaustive, list of questions that we try to answer under each criterion. These questions illustrate how the particular criterion is applied. Because it is often impossible to identify absolute benchmarks, it is frequently useful in making these decisions to compare the service in question with other available diagnostic or therapeutic approaches.

1. Safety and Effectiveness

A service may be determined to be safe and effective if it is generally accepted in the medical community as safe and effective. Contrary evidence, however, may support a conclusion that the service is not safe and effective for some or all conditions.

The standards for safety and effectiveness are less stringent when evaluating breakthrough medical or surgical procedures. The more severe and life threatening the disease process, the more acceptable a relatively less safe technology may be when no safer or more effective technologies are available. However, such coverage may have certain limitations, for example, setting, patient selection criteria, or provision to later revise a coverage policy based on subsequent data collection. Medical devices, drugs, and biologicals that have been accepted for marketing by FDA are considered safe and effective for Medicare coverage purposes when used for the conditions prescribed in the labeling.

What is the likelihood that use of the service will cause harm to beneficiaries? Can it be applied safely to a larger proportion of the population than available alternatives? What is the severity of any risks associated with its use? How does the risk associated with this service compare with that of other services designed to accomplish the same or similar purposes? How does the risk associated with this service compare with the severity of the medical condition it is designed to diagnose or treat? What is the source and nature of the evidence to support the safety of this service? How confident are we of our conclusions? What is the likelihood that the service will produce the health benefit it was designed to accomplish? What are the expected outcomes on the morbidity and mortality of beneficiaries to whom it is furnished? What are the indications for its use? Is it equally effective for all indications? How do these outcomes compare with those of available alternatives? If the purpose of the service is diagnostic, is it significantly more accurate or less invasive than available alternatives? If its purpose is therapeutic, is it significantly more reliable or less painful, or does it provide faster healing than available alternatives? How does the effectiveness of this service compare with the severity of the illness or injury it is designed to diagnose or cure? What is the source and nature of the evidence to support the effectiveness of this service? How confident are we of our conclusions? If we are considering a device, has it been approved for marketing by FDA?

If so, what type of review did the device receive (PMA or section 510(k))? Are there any limitations or restrictions on the use of the device? Should the device be used only for certain medical indications?

2. Experimental or Investigational

A service that is furnished for research purposes in accordance with predetermined rules is considered experimental or investigational. A drug (except for certain cancer drugs), biological product, or device that is subject to FDA approval and has not been approved for marketing by FDA is considered experimental or investigational. Except for certain breakthrough medical or surgical procedures, a service that is not used widely because there is inadequate evidence of safety and effectiveness is considered experimental or investigational.

Has the service been generally accepted by the medical community,

and has it emerged from the research stage? Has the drug or biological been used independently or in connection with a medical device approved for marketing by FDA?

3. Appropriateness

A service is considered appropriate if it is furnished in a setting commensurate with the patient's medical needs and condition, and furnished by qualified personnel.

Will the service raise questions of a health and safety nature relating to the appropriate setting? Does use or provision of the service require special qualifications or training?

Among the many relevant considerations, safety and effectiveness are the key factors for our review. Thus, if a health care technology "failed" either of these two criteria, we would decide not to cover it. On the other hand, while the fact that it "passed" both of these tests would clearly have a major influence on our thinking, there are other considerations that affect whether and how broadly a technology might be covered.

Virtually no technology is absolutely without risk or totally effective in all cases. As a general rule in making these coverage decisions, the greater the risk, the greater the need for proven effectiveness. We have noted the interrelationship between the criteria of safety and effectiveness and the nature and severity of the medical condition being treated. Thus, for example, the more severe and life-threatening the condition, the more likely we are to cover a treatment for which clinical effectiveness has not been proven to the usual point of acceptability to us, if there are no other safe and effective treatments available. Similarly, as the level of demonstrated effectiveness drops, the lower is the threshold of acceptable risk.

F. Publication of National Coverage Decisions

HCFA generally requests OHTA's review of any new Medicare coverage instruction that is derived from the OHTA assessment process before its publication. HCFA publishes national coverage decisions in the Medicare Coverage Issues Manual (HCFA Pub. 6). In some cases, HCFA may also publish a coverage decision in other HCFA manuals or as a HCFA Ruling in the **Federal Register**. HCFA makes national coverage decisions available through the issuance of a manual instruction or the publication of a HCFA Ruling in the **Federal Register**. We would also rely on the various medical specialty societies and organizations to disseminate further this information to their members through their organizations' journals and publications.

Additionally, a listing of all manual instructions (which includes national coverage decisions) will be published in a quarterly **Federal Register** notice in accordance with section 4035(c) of the Omnibus Budget Reconciliation Act of 1987 (Pub. L. 100–203). Section 4035(c) requires us to publish quarterly notices that list all manual instructions, interpretative rules, statements of policy, and guidelines of general applicability that implement the Medicare and Medicaid programs.

G. Reevaluation and Reconsideration of National Coverage Decisions

In addition to assessing new services, we might reevaluate a service that is already excluded or covered under the Medicare program. This might occur, for instance, if in a previous assessment, PHS suggests a reevaluation of a service at a later date. The publication of new clinical studies in the medical literature may prompt reevaluation of a service especially if the findings are not consistent with the existing coverage policy. The decison to reevaluate might also occur if a service is considered obsolete. Instances such as these come to our attention in a variety of ways; for example, from other third party payors, through ongoing review of medical literature, or from HCFA central and regional office staff. In all of these instances, the same coverage assessment process is followed as is described above for evaluation of new services, except that if the decision is to withdraw coverage of a service, we would publish a notice for comment in the **Federal Register** announcing that intent.

At any time after publication of a Medicare coverage instruction, interested parties may request reconsideration and submit evidence demonstrating that a reassessment of that coverage decision is warranted. A reassessment would ordinarily only be done if there is acceptable information or evidence available that was not available at the time the most recent assessment was performed. In particular, since an extensive medical literature search was performed in preparation for the initial decision, the documentation for reconsideration would ordinarily include evidence published later than that available at the time of the initial coverage decision. As discussed above, certain types of evidence carry more weight than others in making an assessment of safety and effectiveness. This would also be true of evidence submitted for reconsideration of a coverage decision.

III. Regulation Provisions of this Proposed Rule

A. Reason for Codifying the Coverage Decisions Process

Although the process by which we make Medicare coverage decisons on health care technology has been in place for many years, we believe there are segments of the population that may still benefit from a complete description of the coverage decisionmaking process. We also believe the process should be more open and that the review of breakthrough technologies should be streamlined. It is for these reasons that we are now presenting the coverage decisions process as a public document.

B. Definitions of Commonly Used Terms

We would define the terms "effective", "experimental", "health care technology", "national coverage decision", and "safe" for the purposes of coverage of health care technology under the Medicare program (§ 400.202). These definitions would not apply to the activities of other organizational components of the Department.

C. Cost-effectiveness as an Additional Criterion for Medicare Coverage of Medically Reasonable and Necessary Services

In section II. E. of the preamble, we identified the criteria we currently apply when making national coverage decisions (safety, effectiveness, experimental or investigational considerations, and appropriateness). Also, for each criterion we provided a detailed, although not exhaustive, list of questions we consider in reaching a national coverage decision. In section V. C. of the preamble, we identified and explained the criteria that Medicare contractors currently apply when making coverage decisions in the absence of national coverage decisions by HCFA. In addition to these criteria, we propose that HCFA and Medicare contractors consider the cost-effectiveness of a service when making coverage decisions (§ 405.380). Traditionally, HCFA has interpreted the terms "reasonable and necessary" contained in section 1862(a)(1)(A) of the Act to mean that a service is safe, effective, and widely accepted in the medical community. HCFA is including cost-effectiveness as a proposed criterion because we believe considerations of cost are relevant in deciding whether to expand or continue coverage of technologies, particularly in the context of the current explosion of

high-cost medical technologies. We believe the requirement of section 1862(a)(1) that a covered service be "reasonable" encompasses the authority to consider cost as a factor in making Medicare coverage determinations.

The proper role for cost-effectiveness considerations is an important matter. Cost-effectiveness is one of several potential factors to be weighed in a given situation. In many cases, it may have no bearing at all on our conclusion. However, if a service were to be viewed as marginal with respect to safety and effectiveness, but expensive in comparison with available covered alternatives, we think that cost-effectiveness considerations are appropriate. In this instance, however, outright exclusion from coverage might not be appropriate. To clarify the use of cost-effectiveness as a criterion for coverage as compared to using cost-effectiveness as a criterion for a payment decision, we offer the following example of one possible use of cost-effectiveness as a criterion for a payment decision. Consider the case of a service that is closely comparable with respect to the risks associated with its use and its effectiveness to another already covered service, but the new service is substantially more expensive than the one that is already covered. In this situation, we may wish to cover the new service, while providing the results of our cost-effectiveness evaluation to the payment policy staff and/or Medicare contractors for their use in establishing payment levels. For example, when a claim is filed for durable medical equipment containing features of a nature that are not required by a patient's condition, or when there exists a reasonably feasible and medically appropriate alternative pattern of care that is less costly than that furnished, the amount payable is based on the reasonable cost of the least expensive alternative treatment that appropriately meets the patients' needs.

Formal cost-effectiveness analysis is an analytic tool that seeks to compare the incremental cost with the additional effectiveness of the procedure or technology. Beneficial effects are usually quantified in nonmonetary terms (for example, increased years of life or reduced infection rates per patient), while costs or savings (both medical and nonmedical) are expressed in dollars. We are aware that cost-effectiveness analysis is a complex field that suffers from data limitations and the inability to quantify some costs. Specifically, for many new technologies, accurate measures of patient benefits or economic impacts (for example, incremental hospital costs) are imprecise because the device or procedure has not been used on many patients. Furthermore, even when data are available, methodological difficulties (for example, selecting a method for projecting future costs) and inherent subjectivity can seriously hamper analysis.

We may not consider cost-effectiveness in every coverage decision. For example, if there is a significant breakthrough or lifesaving technology for which there is no comparable alternative, we could not attempt a comparison to other available technologies since none exist. Another example is consideration of the provisions of section 1861(t)(2) of the Act (as added by section 202(a)(2)(C) of Pub. L. 100–360). That section provides Medicare Part B coverage of outpatient prescription drugs, biological products, and insulin which are not presently covered as part of, or as incident to, other covered services. Coverage for this new benefit is effective for drugs used in immunosuppressive therapy and drugs that are intravenously administered to an individual in the home beginning January 1, 1990, and for other covered outpatient prescription drugs beginning January 1, 1991. Specifically, section 1834(c)(5)(C) of the Act (as added by section 202(b)(4) of Pub. L. 100–360), prohibits the exclusion from coverage or denial of payment of a covered outpatient drug or class of outpatient drugs, or of any specific use of such a drug for a specific indication, unless the exclusion is based on a finding by the Secretary that the use is not safe and effective. We believe the Act precludes the application of the cost-effectiveness criterion to covered outpatient drugs, and we do not plan to apply the cost-effectiveness criterion to those drugs, although we request comment on the issue.

We believe that a disciplined effort to assess systematically the cost-effectiveness of technologies under coverage review will be useful. We propose to use a flexible definition of cost-effectiveness that encompasses a wide range of impacts: Cost-effectiveness means having improved health outcomes for Medicare patients that justify additional expenditures. In this regard, we would consider a technology cost-effective if, based on analysis, it demonstrated one of the following results:

- It is less costly and at least as effective as an alternative covered technology.
- It is more effective and more costly than a covered alternative, but improved health outcomes justify additional expenditures.
- It is less effective and less costly than an existing alternative, but is a viable alternative for some patients.

To establish the cost-effectiveness of any intervention, we propose to follow a standard set of analytical steps that are well accepted among economists. These steps are:

- Identify the relevant alternative technologies to which the current intervention is to be compared.
- Identify all the relevant outcomes from the alternative technologies and, when possible, quantify them. These may include clinical outcomes such as reduced morbidity and mortality, or qualitative outcomes such as reduced pain, enhanced personal well being, vigor, etc.
- Identify all the relevant costs expected (both Medicare and non-Medicare) from the interventions, including direct medical costs or savings and indirect costs such as enhanced productivity for the disabled, transportation, etc. These will generally be valued in dollars at standard levels relevant to the Medicare program (for example, Part B charge payments or Part A DRG outlays).
- Consider nonquantifiable factors. Since all technology impacts cannot be fit into a conventional cost-effectiveness formula, the range of nonquantifiable factors (for example, ease of use, and access to ambulatory setting) should be described and considered as modifiers of the analysis.

We believe the regular application of these principles by HCFA, as well as by those proposing new technologies for coverage, would vastly improve our knowledge base and be a deterrent to coverage of procedures that may be costly, but have little or no impact on improving health outcomes. To aid in this process, HCFA's Office of Research and Demonstrations is planning a study to develop an approach for collecting and analyzing primary and secondary data for cost-effectiveness considerations. Based on this study and a review of other existing studies and models, a methodology would also be developed for making periodic policy decisions based on cost-effectiveness considerations. We specifically invite the public to comment on cost-effectiveness methodologies that could be appropriate for Medicare's use.

D. Procedures for Medicare Contractors in Making Coverage Decisions

We would establish a new § 405.381 and outline the procedures Medicare contractors would follow in making

coverage decisions. The regulations would set forth contractor responsibilities, including the review of individual claims and making coverage decisions in the absence of national coverage decisions by HCFA.

E. HCFA Procedures for Making National Coverage Decisions

We have set forth the key criteria and procedures in the coverage decisions process (§§ 405.380 and 405.382) by which, under seciton 1862(a)(1)(A) of the Act, we make coverage decisions that are national in their scope and application. As stated earlier, our purpose is to clarify and inform the public regarding the grounds on which we conclude that a national coverage decision is warranted, the sources of information we use in making these decisions, and the public's opportunity to participate in the process and be informed of its results.

F. Carrier Coverage Process

We are proposing a process for carriers to use in developing utilization review policy. This process would include notifying the appropriate groups of a proposed policy and the need for and basis of establishing it and soliciting comments from them prior to its implementation.

G. Conforming Changes

We also would amend the title and authority citation to Part 405, Subpart D to conform to the new sections being added.

IV. Relationship With Other Agencies

Following is a broad overview of the mission of other agencies and a description of our relationship with them as it applies to the coverage decisionmaking process.

A. Food and Drug Administration

FDA protects the public health of the nation as it may be impaired by foods, drugs, biological products, cosmetics, medical devices, radiological products, poisons, pesticides, and food additives. FDA's regulatory functions are to assure that: Foods are safe, pure, and wholesome; drugs, medical devices, and biological products are safe and effective; cosmetics are harmless; all of the above are honestly and informatively packaged; and that exposure to potentially injurious radiation is minimized. The participation of FDA is critical to the Medicare coverage process since, as discussed earlier, FDA approval of drugs, devices, and equipment must precede Medicare coverage in many cases. FDA staff regularly attend HCFA Physicians Panel meetings in an advisory capacity. Likewise, we monitor FDA advisory panel meetings and attend those that relate to potential Medicare coverage issues.

B. Prospective Payment Assessment Commission (ProPAC)

ProPAC was established by Congress when legislation authorizing implementation of the Medicare prospective payment system was enacted. ProPAC was established as a permanent, independent commission with responsibilities related to monitoring and making recommendations relative to improvements in the prospective payment system.

ProPAC has two primary responsibilities. The first is to recommend annually to the Secretary of HHS the appropriate percentage change in Medicare payments for inpatient hospital care. The second is to consult with and recommend to the Secretary necessary changes in classification and weighting of diagnosis-related groups (DRGs) based on scientific evidence available on the impact of new technologies. All national coverage decisions that potentially affect prospective payment rules or rates are routinely referred to ProPAC for its review and comment prior to publishing the decisions as notices in the **Federal Register** and later as instructions in the Medicare Coverage Issues Manual (HCFA Pub. 6) or other HCFA manuals, or as HCFA Rulings in the **Federal Register.**

C. National Institutes of Health

NIH serves as the principal biomedical research agency of the Federal Government. Through the support and promotion of biomedical research, NIH seeks to improve the health of the American people by: Increasing the understanding of the processes underlying human health, disability, and disease; advancing knowledge concerning the health effects of interactions between man and the environment; developing methods of preventing, detecting, diagnosing, and treating disease; and disseminating research results for critical review and, ultimately, medical application. In the pursuit of this mission, NIH supports biomedical and behavioral research in this country and abroad, conducts research in its own laboratories, trains promising young researchers, and promotes the acquisition and distribution of medical knowledge.

With its budget for development of new technologies and treatment, NIH is a major supporter of clinical trials, a key component of the technology assessment process. NIH also sponsors and coordinates consensus development conferences through its Office of Medical Applications of Research (OMAR). These conferences are routinely attended by HCFA staff because they deal with technologies that, for the most part, have passed the investigational stage and have diffused into practice. OMAR directs questions on technologies being investigated for Medicare coverage to the knowledgeable institute where the latest available information on that issue can be syntheseized quickly. OMAR staff regularly attend our Physicians Panel meetings and inform Panel members of current and future consensus conferences on various topics that might be of interest to the Medicare population. HCFA and OHTA staff often exchange information with NIH staff on current medical developments. Further, OHTA often uses NIH resources as a source of expert opinion on various services under study.

V. Contractor Functions and the Claims Process

A. General

As explained above, the Medicare program covers many medical and health care services, supplies, and procedures in use today, subject to established coverage criteria—the exclusions and limitations in the statute, regulations, and administrative instructions described in section I of this preamble. The claims review process for the Medicare program is designed to identify services that may not be covered. Resolving these issues is usually a matter of deciding whether the service, either in or by itself or under the specific circumstances of a particular use, statisfies the established coverage criteria.

B. Contractor Functions

The separation of the Medicare program into an institutional component (Part A) and a noninstitutional component (Part B) was patterned after a program alignment used by Blue Cross/Blue Shield Associations in paying for services to their subscribers. In order to assure that the Federal health insurance program would benefit from the longstanding experience of health insurance carriers in the private sector, the Secretary decided that most claims-processing and administrative functions for both Part A and Part B of Medicare should be handled by public or private insurance organizations (commercial insurers or Blue Cross/Blue

Shield Associations) acting as fiscal agents or contractors for the Medicare program.

The contractors responsible for the administration of hospital insurance or Part A benefits are termed fiscal intermediaries. The major role of the intermediaries is to review and pay claims submitted by providers (such as hospitals, SNFs, and HHAs) for covered services furnished to beneficiaries. The intermediary makes payments for inpatient services under the prospective payment system and makes payments for outpatient services by reviewing submitted cost reports and making reasonable cost determinations following policies set by HCFA.

Under Part B, the contractors are called carriers. Since Part B services are reimbursed primarily on a reasonable charge (as opposed to reasonable cost or the prospective payment system) basis, one of the major functions of carriers is to determine the reasonable charges in their respective areas for each medical care service paid for under the program. Carriers also are responsible for reviewing and paying claims to or on behalf of beneficiaries for the services provided.

The functions performed by Medicare fiscal intermediaries and carriers include utilization review, beneficiary hearing and appeals, professional relations, and statistical activities, in addition to claims review and processing. Currently, there are 48 carriers, 57 intermediaries, and some HMOs and CMPs under contract with HCFA that perform reviews and process claims for their Medicare members. In addition to these contractors, we also contract with PROs.

Before describing the functions of PROs, it is necessary to provide a brief history of utilization review under Medicare. In designing the Medicare program, Congress was concerned about controlling the costs of the program and ensuring that Medicare beneficiares received only those services that were medically necessary. However, Congress also wanted to assure that judgements regarding the medical necessity of specific services would be based on the specific knowledge, skills, and experience that only physicians and related health practitioners could provide. Therefore, Congress initially required that hospitals and SNFs have utilization review committees, staffed by physicians, to review the admissions, duration of stay and professional services furnished to Medicare beneficiaries according to the criteria of medical necessity and most efficient use of available health facilities and services. In 1972, Congress amended the Medicare law to improve the medical review function by establishing a utilization review program that relied upon organizations (Professional Standards Review Organizations (PSROs)) outside of the individual facilities serving Medicare beneficiaries.

In order to improve further the conduct of medical review of Medicare claims, Congress enacted the Peer Review Improvement Act in 1982 and required the Secretary to contract with PROs, which are private entities composed of licensed physicians in a geographical area who are engaged in the practice of medicine and surgery and who represent the practicing physicians in that area. Currently there are 54 PROs. Subject to the terms of its contract, a PRO is responsible for the review of specified professional activities in its area for which payment may be made by Medicare, for the purpose of determining whether: (1) The services are or were reasonable and medically necessary; (2) the quality of the services meets or met professionally recognized standards of health care; and (3) services that are proposed to be furnished or were furnished on an inpatient basis, could be provided effectively on an outpatient basis.

C. Criteria and Procedures for Contractor Coverage Decisions

Contractors make Medicare coverage decisions within parameters set by statutory authority, regulations, and program instructions prepared by HCFA to implement regulations and statutory authority.

If we have issued a national coverage decision, contractors are bound by that decision. If no national coverage decision has been issued, a contractor must decide whether the service in question appears to be reasonable and necessary and therefore covered by Medicare.

As stated previously most of the individual claims processed by Medicare contractors do not raise serious questions about coverage. When questions of coverage do arise, they relate primarily to whether the service was medically necessary for the individual and was furnished in an appropriate manner and setting, rather than to broader coverage issues. Even when a claim for a new, or otherwise questionable, service is received, the contractor is authorized to make reasonable and necessary decisions with respect to the service, in the absence of applicable national policy. These decisions are usually made in consultation with the contractor's own medical staff and local medical specialty groups. It should be noted that, since each contractor makes decisions only for Medicare claims that are submitted to it, coverage of a particular service may vary among contractors. In fact, coverage decisions made by the same contractor may appear to vary from claim to claim reflecting relevant differences in the circumstances in which the service is furnished or the need of the particular patient for that service. This variation is consistent with the legislative intent that the administration of the Medicare program take into account both differences in local medical practice and the types of treatment feasible individual patient situations.

Over time, written guidelines have been issued to Medicare contractors to assist them in making initial decisions as to whether, in individual cases, services are reasonable and necessary and therefore covered under Medicare. In addition to considering the criteria that must be considered when making any coverage decision (that is, the service must be safe and effective, not experimental, and appropriate), Medicare contractors must determine whether the service under consideration is—

- Medically necessary in the particular case and the duration and frequency of the use or application of the service are medically appropriate;
- Furnished in accordance with accepted standards of medical practice; and
- Furnished in a setting appropriate to the patient's medical needs and condition (such as inpatient care at a hospital or SNF, outpatient care at a hospital or physician's office, or home care).

D. Appeals Procedures

Sections 1155, 1869, 1876, 1878 and 1879 of the Act authorize administrative and judicial review for beneficiaries and providers (in certain cases) to challenge certain adverse coverage decisions. Since certain parts of these sections are now under review, a detailed description of their application is not being presented. Refer to the specific sections of the Act for information or appeals procedures.

VI. Analysis of and Responses to Public Comments for April 29, 1987 Notice

In response to the April 29, 1987 notice that we published in the **Federal Register**, we received 62 timely items of correspondence. Of these, 30 were identical letters from health professionals and administrators in facilities providing rehabilitation

services, two others were from rehabilitation professionals, 10 were from professional associations or councils, six where from Medicare providers (including three from the same provider), three were from law firms, three were from medical equipment suppliers, and one each was from a medical consultant, a management firm, a State Governor, a State office for the handicapped, a Medicaid State agency, and a private individual.

HCFA also received two letters from the Administrative Conference of the United States, one of which enclosed an informational outline of a study of the Medicare coverage decision process that the Administrative Conference has commissioned.

Several of the comments referred to the coverage of or payment for specific services. Because the inent of the notice was to describe the general coverage decisionmaking process and to solicit comments on that process, we have not responded to those comments on the coverage or payment of specific services in this proposed rule.

A. Inconsistent Medicare Contractor Decisions

Comment: Forty of the 62 commenters (including the 30 identical pieces of correspondence) suggested that Medicare contractors should not have the discretion they currently have in making coverage decisions. They argued that inconsistencies between the differenct contractors lead to inequitable treatment of beneficiaries.

Response: We are aware that coverage of a particular service may vary among contractors. This variation is to be expected, we believe, in view of Congressional intent that the Medicare program be administered to some extent by numerous contractors who could make decentralized determinations and take into account differences in local medical practice. We also note that decisions with respect to some services may appear to vary because what is medically necessary for one patient may not be medically necessary for another. Further, we cannot develop guidelines that are sufficiently detailed to encompass all possible coverage decisions. However, in view of the number and consistency of the comments on this issue, we believe that we must take certain steps to improve consistency in contractor coverage decisions. First and foremost, we expect the publication of this proposed rule and subsequent final rule to reduce significantly the inconsistency in contractor coverage decisions, since, as described in greater detail in our responses to other comments below, we are proposing to define the terms "safe" and "effective" (§ 400.202) when used in the context of making a national coverage decison on any health care technology, and to specify the criteria and procedures to be applied by contractors in making coverage decision (§§ 405.380 and 405.381). We also propose to convene annually the medical directors and other officers of all our carriers, intermediaries, and PROs, as well as representatives of our regional offices, to review all aspects of the coverage process including recently issued national coverage decisions. Finally, we are proposing a process for contractors to follow in developing utilizaiton review policy. This should facilitate greater consistency in the standards and criteria used by all carriers and the program which they follow.

B. Define "Reasonable", "Necessary", and "Experimental"

Comment: Several commenters recommended that we define the terms "reasonable," "necessary," "experimental," and other commonly used terms.

Response: We partially agree with the commenters and we have included several definitions in these proposed regulation (§ 400.202) as these terms relate to health care technology. Although we do not define specifically the terms "reasonable" and "necessary," we do specify the criteria that a health care technology would have to meet in order to be considered reasonable and necessary, as well as how the criteria would be applied in the coverage decisionmaking process. We believe that the uniform application of these definitions and criteria by our contractors would reduce inconsistencies in their coverage decisions. We also believe it is important to define in regulations the terms "safe" and "effective," since our definitions differ slightly from those of FDA. That difference has not been clearly stated in the past, giving the public the impression that an FDA finding that a device is safe and effective should be a sufficient basis for Medicare coverage. As discussed in this preamble, safety and effectiveness are not the only criteria applied when deciding whether a given technology can be considered reasonable and necessary. Further, FDA findings of safety and effectiveness focus on the labeled use of a device only, while our decisions may focus on other uses of a device under average conditions of use.

C. Issue Contractor Criteria for Making Decisions

Comment: Several commenters recommended that we issue contractor criteria for making coverage decisions.

Response: In view of the comments that inconsistencies in coverage decisions among Medicare contractors are related in part to a lack of clear criteria, we propose to define the criteria and their application in regulations (§§ 405.380 and 405.381).

D. Coverage Criteria

Comment: One commenter, in recommending that our coverage criteria be explicit, also suggested that we specify that neither experimental status nor cost is a criterion on which coverage decisions are made. It was argued that we cannot use criteria for coverage that extend beyond what the medical experts think are reasonable and necessary for an individual's medical needs, and that the statute does not authorize us to deny coverage of a service on the basis that it is experimental or not cost-effective.

Response: We believe that experimental services cannot be considered reasonable and necessary since, by definition, their safety and effectiveness are not established. As discussed in this preamble, the reasonable and necessary language of the law permits the inclusion of costs as a criterion in making Medicare coverage decisions. We invite comments on the issue of cost-effectiveness.

E. Absence of Public Input and Comment in the Coverage Process

Comment: Several commenters suggested that the public be given the opportunity to provide input at every step of the coverage process, while others focused their requests for public input on selected steps only.

Response: While we are in basic agreement with the value of public input, we are concerned that public input at every step of the process through notice and comment in the **Federal Register** would delay significantly a process that many of the same commenters argue is already too lengthy. We are interested in receiving public comment on this issue and specific suggestions on how to balance these two conflicting objectives. Our responses to suggestions for public input at specific points in the process follow.

Comment: It was suggested that the public should have the opportunity to petition us to consider a service for a coverage decision and that we routinely publish the agendas of HCFA Physicians Panel meetings.

Response: Under our current process, requests from the general public are handled in the same manner as any other request for a coverage decision and, if they meet our criteria for a national coverage decision, may be placed on the agenda of the HCFA Physicians Panel for its consideration. We agree that routine publication of the Panel agenda would be desirable. While the fact that we frequently add agenda items 3 to 4 weeks before the meeting precludes providing timely notification to the public through the **Federal Register**, we plan to identify other more appropriate and timely vehicles for announcing upcoming HCFA Physicians Panel meeting agenda to the public.

Comment: Commenters expressed concern that there is no assurance that knowledgeable professionals are involved in the process and suggested that a health professional familiar with the particular area of health care be a member of the Panel. Other commenters suggested that HCFA Physicians Panel meetings be open to public participation.

Response: As described earlier, the HCFA Physicians Panel has regular representation from the medical and scientific experts at FDA and NIH to contribute specialized knowledge on all agenda items. In response to the comments that the Panel meetings be open to the public, we believe that the current HCFA Physicians Panel process should be modified. We do believe the functioning of the Panel could be improved by allowing some public input. We propose to permit the presentation, by interested parties, of information related to agenda items prior to deliberations by the Panel. We believe this process would assure that the Panel hear from, and have the ability to submit questions to, a health professional familiar with the particular area of consideration, while continuing to allow it the necessary benefits of a closed decisionmaking opportunity.

Comment: It was suggested we solicit public comments on OHTA assessments and coverage recommendations before we make a final coverage decision.

Response: We are opposed to this suggestion because we believe it would lead to considerable delay in a final decision on Medicare coverage with no real benefit. The public is given considerable notice and opportunity to provde input to OHTA during OHTA's assessment process. OHTA's recommendations to HCFA, based on that information, are only a portion of the material that is considered by HCFA in arriving at its final decisions on coverage of a specific service. It is at the time of a HCFA decision, not OHTA recommendation, that public comment would have the greatest value for both the commenters and HCFA. As discussed below, HCFA does solicit public comment on its Medicare coverage decisions through the **Federal Register** when the benefit of public input is sufficient to outweigh the substantial delay of making a final decision.

Comment: It was also suggested that we make available through public notice and comment all coverage decisions on health care technology before issuing them in HCFA manuals.

Response: We are opposed to this procedure affecting all coverage decisions, primarily because it would routinely result in substantial delay in the issuance of final coverage decisions. As noted, we do seek public comment before finalizing a Medicare coverage decision when we believe that the value gained from the public comment process outweighs the delay in making a final decision. We also have requested comment on our decisions when controversy in the scientific community is intense and the impact of the decision on the public and medical community is profound (for example, coverage of heart transplants). Otherwise, we count on gaining the public's views on coverage issues through the opportunity provided in the OHTA assessment process, as well as through public participation prior to the HCFA Physician Panel deliberations. We believe this approach would provide a mechanism for informing the public of national coverage decisions on health care technology without involving the extensive delay associated with formal notice and comment rulemaking.

Comment: Two commenters suggested that we publish coverage decisions on health care technology in medical journals and other publications of the health care industry since our manual instructions are not readily available to beneficiaries, practitioners, and providers.

Response: We agree that our decisions should be more readily available. Therefore, in addition to the publication of quarterly notices in the **Federal Register** listing coverage decisions (§ 405.382(g)), we propose to make national coverage decisions available to the public as soon as they are issued through the **Federal Register**.

The various medical specialty societies and organizations can disseminate this information to their members through the various journals and publications of their organizations. Also, we are prepared to work closely with national organizations representing beneficiaries and physicians to apprise these organizations of our coverage decisions and to work with them to develop effective means to inform their constituencies about national coverage decisions and Medicare coverage policy in general.

F. Composition of HCFA Physicians Panel

Comment: One commenter suggested that a representative of FDA be a member of the Physicians Panel. Another commenter suggested that a representative from the prepaid health care industry be added.

Response: At the present time, FDA and NIH staff routinely attend HCFA Physicans Panel meetings and actively participate in discussions. We do not believe that a representative from the prepaid health care industry needs to be added to the Panel since we do not specifically include representatives of provider groups. The Physicians Panel is composed of staff physicians and other health professionals in HCFA's central office and counterparts from PHS who have had experience with a variety of health care delivery systems.

G. Time Frame for Process

Comment: Several commenters suggested that each step in the process of making national coverage decisions be limited to a certain number of days. One commenter also suggested that we establish a two track review system that distinguishes technologies that have had Federal review based on documentation of safety and effectiveness from technologies with no such review and that the time frame for these two tracks be different. The commenter suggested reviewing devices accepted by FDA following review of a PMA or a section 510(k) application supported by clinical data on a faster track.

Response: We do not believe it would be feasible to place time limitations on each step of the process. Generally, we cannot anticipate the documentation needs that may apply at the various stages of the process or predict the time required to gather documentation at each stage. Moreover, the data that must be reviewed and analyzed vary so widely from issue to issue that it is not possible to establish standard time frames. Also, the level of evidence for safety and effectiveness may vary, depending on whether a device or procedure is a treatment of last resort or otherwise involves new lifesaving techniques. We do, however, agree that our coverage decisionmaking could be expedited if the service under consideration has received, or is soon expected to receive, FDA acceptance under the PMA or the section 510(k) processes. In that regard, it is our

intention to expedite assessments for breakthrough, well-researched devices and procedures.

H. Improving Coordination with FDA.

Comments: One commenter suggested that for FDA-regulated technologies, HCFA and OHTA review begin when the FDA advisory panel approves a technology since this panel decision indicates a high likelihood of FDA approval. The commenter believes that by starting HCFA and OHTA reviews at the point of approval by the FDA advisory panel, delays would be reduced and agency decisionmaking would be better coordinated.

Response: We agree with this suggestion but only under certain circumstances. First, we do not believe that we should review automatically every technology that is favorably reviewed by an FDA advisory panel since in many cases some of these technologies do not meet our criteria for consideration of a national coverage decision. Second, not all manufacturers would be interested in having their technology subjected to the Medicare coverage process.

Consequently, we prefer to consider for a national coverage decision only those technologies selected by us or referred to us by physicians, manufacturers, or other interested parties. We are prepared to begin that review following a favorable FDA advisory panel recommendation, or earlier if warranted, by placing the issue on the agenda of the next available HCFA Physicians Panel meeting. Also, so that we can better coordinate our national coverage decisionmaking process with FDA, we plan to meet with them on a quarterly basis to discuss issues of mutual concern and to facilitiate our review of technologies under FDA review that potentially may affect the Medicare beneficiary population. We wish to note that we have considered some services for a national coverage decision before they received formal FDA approval. For example, we requested assessments of magnetic resonance imaging and automatic implantable cardioverter/defibrillators many months before they were approved for marketing by FDA.

I. Coverage Exclusions Deter Research

Comment: One commenter suggested that the exclusion of coverage for a service deters further research into the application of that service, making it more difficult to accumulate the data needed for reconsideration or reevaluation.

Response: We recognize that further research may be discouraged if a service is excluded from Medicare coverage, but we cannot approve procedures or devises lacking evidence of safety and effectiveness simply in order to provide a basis for developing that evidence. This approach would be contrary to the statutory provision that we pay only for a service that is determined to be "reasonable" and "necessary".

J. Interim Payments during the Coverage Decisions Process

Comment: One commenter suggested that we establish an interim coverage status allowing payment for certain technologies during the coverage decisions process.

Response: We are opposed to providing, on an interim basis, a national coverage decision of any service during our coverage decisions process because to do so could pose serious legal and practical problems under section 1862(a)(1)(A) of the Act. Section 1862(a)(1)(a) precludes Medicare payment for a service unless it is reasonable and necessary. We believe that reaching an interim decision, which would effectively require us to determine that the service was reasonable and necessary would, as a practical matter, require us to undertake a level of full review virtually tantamount to the review required for making a final national coverage decision before we have the benefit of considering all relevant factors. This procedure would be cumbersome, redundant, and potentially confusing to the public. Moreover, it would place an undue burden on the Medicare program, which could essentially be required to surmount a higher hurdle by finding on full review that a service it has approved on an interim basis as reasonable and necessary does not now meet that standard. On the other hand, we also are opposed to issuing interim noncoverage instructions, since to do so could eliminate the availability of potentially valuable services to our beneficiaries when there may be some credible indications that the service may meet the reasonable and necessary criteria, at least in particular circumstances. Consequently, we believe the prudent approach to the interim coverage of issues under national consideration is to leave the decisionmaking in the hands of the local contractors, who can take into account local medical practice and the unique circumstances of an individual case.

K. Carrier Screens

Comment: Several commenters raised the issue of contractor "screens" and objected to the use of screens for coverage decisions and denials without explanations or requests for additional information. Others objected to the fact that they are generally unaware of these screens and their medical rationale and thus are unable to tailor their services to beneficiaries to comply with screens that comport with good medical practice.

Response: In order to facilitate claims processing and identify possible overutilization, Medicare contractors have developed "screens". These screens alert the contractor that services or procedures performed by a provider have exceeded a treatment norm set by the contractor; that is, it does not fall within a certain predetermined range. When this occurs, the claim for services can then be reviewed more intensely to determine if further medical evidence is necessary to process the claim properly. In general, carriers seek physician consultation from appropriate specialities when developing screens. The policy and related documentation requirements are then communicated to physicians prior to implementing them.

We received comments that some contractors may be developing or applying the screens inappropriately. We therefore have proposed a process for contractors that would involve the local medical community in the development of utilization review policy (§ 405.383(a)). This proposed process would apply to the development of new utilization review policy only; it would not apply to any existing utilization review policy. The local medical community would be notified of the type of information that would be required to be submitted with a claim for any service subject to review. However, they would not be informed of certain operational parameters of the policy, such as the number of claims over a given period of time that would be paid without manual review, since to do so could encourage over-utilization based on the knowledge that claims would not be reviewed.

In response to the concerns that some claims are denied inappropriately, we propose to prohibit the denial of claims that are the subject of medical review in accordance with a utilization review policy without review of all relevant information submitted with the claim (§ 405.383(b)).

L. Monitoring Contractor Performance

Comment: One Commenter recommended that we leave our current process unchanged and direct our attention to the reeducation of claims processors and the careful monitoring of our contractors.

Response: We have not accepted this comment. The claims processing personnel of our contractors are educated on an ongoing basis and our contractor evaluation process undergoes constant scrutiny and revision when needed.

M. Physician Review of Adverse Decisions

Comment: One commenter asked for clarification of the following statement on page 15561 of the April 29, 1987 **Federal Register:** "Only a physician can make an adverse determination and only after consulation with the attending physician." It is unclear to the commenter whether this requirement applies only to PRO decisions or to decisions made by other contractors as well. The commenter believes the requirement should apply to all contractors and all aspects of review under the Medicare program.

Response: We regret that the notice was not clear concerning this statement. The statement as written relates only to PRO decisions and is based on section 1154(a)(2) of the Act. The issue is complicated by the fact that PRO medical necessity decisions are binding on the carriers and intermediaries. However, not all denials are made by the PROs. Except for PRO decisions, there is no statutory requirement that only a physician can make an adverse decision. However, in practice, any claim initially denied by carrier or intermediary review staff generally will be reviewed by qualified medical review staff using written guidelines developed by a physician if the denial is appealed or the claim is resubmitted with additional documentation. We believe this process is a reasonable one since mandatory physician review of all denials by carriers and intermediaries would be prohibitively expensive.

N. Equipment and Coverage for Long Term Disabilities

Comment: Several commenters complained that the program does not cover and pay for the latest equipment needed by the long-term disabled individual.

Response: It is not clear why commenters believe that long-term disabled individuals are denied the benefits of the latest and best technology by the Medicare program. Our program regulations for the coverage of durable medical equipment (DME) and other medical supplies are the same for all Medicare beneficiaries, whether they are among the long-term disabled, the chronically ill, or the acutely ill. It is true, however, that new equipment might not be covered by Medicare as soon as it is introduced. At a minimum, equipment that requires marketing approval by the FDA must receive that approval. In addition, DME must be shown to meet the Medicare program's definition of DME, that is, equipment that (1) can withstand repeated use, (2) is primarily and customarily used to serve a medical purpose, (3) generally is not useful to a person in the absence of an illness or injury, and (4) is appropriate for use in the home.

With respect to the concerns expressed about our alleged willingness to pay for the "best" equipment available (which, in many circumstances, is the most expensive), our policy is a rather straightforward one, and one that we believe does not require revision. An item of durable medical equipment may have certain convenience or luxury features that make it more expensive than a standard item; that is, one which will adequately meet the medical needs of the patient. The reasonable charge for the more expensive item cannot exceed the reasonable charge for the item that is adequate for the patient's medical needs. We will base the reasonable charge for a covered service on the more expensive model only when the special features of the more expensive model are medically reasonable and necessary for the beneficiary.

O. Confidentiality of Data

Comment: One commenter recommended that we publish our policies on confidentiality to facilitate submission of sensitive, not-yet-published research data that document safety and effectiveness.

Response: HCFA regulations regarding the Freedom of Information Act appear in 42 CFR Part 401 and supplement the more general Department regulations that appear at 45 CFR Part 5. These regulations implement Executive Order 12600, "Predisclosure Notification Procedures for Confidential Commercial Information", signed June 23, 1987.

In accordance with these regulations, to facilitate the identification of confidential commercial material, organizations are encouraged to mark relevant sections of submitted material (individual pages, reports, charts, etc.) as "confidential". Blanket statements claiming that all submitted material is confidential should be avoided. Instead, organizations should clearly mark all specific portions of submitted material that in fact contain confidential commercial information.

VII. Proposed Uncodified Changes to the Current Coverage Decisions Process

As a result of our assessment of necessary revisions and in response to the public comments we received on the April 29, 1987 **Federal Register** notice, we propose to make the following changes in our coverage decisionmaking process, which we believe do not require codification in the Code of Federal Regulations (CFR).

A. HCFA Physicians Panel

We propose to identify appropriate vehicles for announcing the date, and agenda of upcoming HCFA Physicians Panel meetings.

B. Improved Coordination and Communication

We propose to convene an annual meeting of the medical directors and other officers of all our carriers, intermediaries, HMOs, CMPs, and PROs as well as representatives of our regional offices, to review all aspects of the coverage process including recently issued national coverage decisions. This should facilitate and reduce any inconsistencies in the implementation of national coverage decisions and allow for the identification of additional issues for which national coverage decisions may be warranted. We also plan to meet with FDA on a quarterly basis to discuss issues of mutual concern and to facilitate our review of health care technologies under their review that may potentially impact on the Medicare beneficiary population.

VIII. Regulatory Impact Statement

Executive Order (E.O.) 12291 requires us to prepare and publish an initial regulatory impact analysis for any proposed regulation that meets one of the E.O. criteria for a "major rule", that is, that would be likely to result in : an annual effect on the economy of $100 million or more; a major increase in costs or prices for consumers, individual industries, government agencies, or geographic regions; or, significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

In addition, we generally prepare an initial regulatory flexibility analysis that is consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612), unless the Secretary certifies that a proposed regulation would not have a significant economic impact on a substantial number of small entities. Also, section 1102(b) of the

Social Security Act requires the Secretary to prepare a regulatory impact analysis if the proposed rule may have a significant impact on the operations of a substantial number of small rural hospitals. Such an analysis also must conform to the provisions of section 603 of the RFA.

This proposed regulation would specify the process through which we make decisions as to whether to cover particular services under Medicare. These decisions are published in the Medicare Coverage Issues Manual and may be published in other HCFA manuals or as HCFA Rulings in the **Federal Register**. This proposed regulation would foster the careful consideration of available scientific and medical information in the coverage determination process. Accordingly, it would serve to ensure that all Medicare coverage determinations are consistent with our statutory obligations. The coverage decision process set forth in this proposed rule would thus of itself, neither promote nor hinder any specific economic outcomes (as opposed to any particular coverage decision, which might have a substantial economic impact). Furthermore, most provisions of this proposed rule conform to the Medicare coverage determination process that has been in place for many years. Therefore this proposed regulation, in itself, would have no direct effect on the economy or on Federal or State expenditures, and no threshold criteria under E.O. 12291 would be exceeded. Consequently, an initial regulatory impact analysis has not been prepared. In addition, we have determined, and the Secretary certifies, that this proposed rule would not have a significant economic impact on a substantial number of small entities, and this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals. We have, therefore, not prepared an initial regulatory flexibility analysis.

IX. Information Collection Requirements

These proposed changes do not impose information collection requirements. Consequently, they need not be reviewed by the Office of Management and Budget (OMB) under the authority of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*).

X. Responses to Comments on this Proposed Rule

Because of the large number of comments we receive on proposed regulations, we cannot acknowledge or respond to them individually. However, in preparing the final rule, we will consider all comments received timely and respond to the major issues in the preamble to that rule.

List of Subjects

42 CFR Part 400

Grant programs—health, Health facilities, Health maintenance organizations (HMO), Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Laboratories, Medicare, Nursing homes, Reporting and recordkeeping requirements, Rural areas, X-rays.

For the reasons set forth in the preamble, 42 CFR Chapter IV would be amended as follows:

I. 42 CFR Part 400, Subpart B, is amended as set forth below:

PART 400—INTRODUCTION; DEFINITIONS

Subpart B—Definitions

1. The authority citation for Part 400 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh) and 44 U.S.C. Chapter 35.

§ 400.200 [Amended]

2. Section 400.200 is amended by adding the definition of "PHS" in alphabetical order to read as follows:

* * * * *

"PHS" stands for the Public Health Service.

* * * * *

3. Section 400.202 is amended by adding the definitions of "Effective", "Experimental", "Health care technology", "National coverage decision", and "Safe" in alphabetical order to read as follows:

§ 400.202 Definitions specific to Medicare.

* * * * *

"Effective" means the probability of benefit to individuals in a defined population from a medical technology applied for a given medical problem under average conditions of use.

* * * * *

"Experimental" means a technology that should be confined to a research setting under which human or animal subjects are assigned, in accordance with predetermined rules. A technology that is experimental is not considered safe or effective.

"Health care technology" refers to any discrete and identifiable regimen or modality used to diagnose or treat illness, prevent disease, maintain patient well-being, or facilitate the provision of health care services.

* * * * *

"National coverage decision" as it relates to health care technology means a statement of national policy under section 1862(a)(1) of the Act regarding the coverage status of a specific service made by HCFA. The term has the same meaning as "national coverage determination" that appears in section 1869(b)(3) of the Act.

* * * * *

"Safe" means a judgement of the acceptability of relative risk in a specified situation.

* * * * *

II. 42 CFR Part 405, Subpart C, is amended as set forth below:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

Subpart C—Exclusions, Recovery of Overpayment, Liability of a Certifying Officer, Suspension of Payment, and Coverage Decisions

1. The authority citation for Subpart C is revised to read as follows:

Authority: Secs. 1102, 1862, 1871, and 1887 of the Social Security Act as amended (42 U.S.C. 1302, 1395y, 1395hh, and 1395xx).

2. The title of Subpart C is revised to read as follows: Subpart C—Exclusions, Recovery of Overpayment, Liability of a Certifying Officer, Suspension of Payment, and Coverage Decisions.

3. A new undersignated center leading and new §§ 405.380 through 405.383 are added to read as follows:

Criteria and Procedures For Making Medical Services Coverage Decisions That Relate To Health Care Technology

§ 405.380 Criteria for Medicare coverage of reasonable and necessary services.

(a) *General rules and process.* (1) For purposes of this section, the use of the word "services" means health care technologies as defined in $405.202.

(2) In the absence of statutory bars, a service is covered by Medicare (under section 1862(a)(1) of the Act) only if the service is reasonable and necessary for the diagnosis or treatment of illness or injuryor to improve the functioning of a malformed body member. In determining whether this coverage requirement is met, a service is considered resonable and necessary with reference to the following criteria if—

(i) The service if safe and effective.
(ii) The service is not experimental or investigational.
(iii) The service is cost-effective.
(iv) The service is appropriate.
(3) HCFA makes national coverage decisions in accordance with § 405.382. Medicare carriers, intermediaries HMOs, CMPs, and PROs make coverage decisions, in the absence of national coverage decisions by HCFA, in accordance with § 405.381.

(b) *Application of the criteria for making coverage decisions.* Among the criteria described in paragraph (a) of this section for making coverage decisions, safety and effectiveness are the key criteria. A service that is determined not to be safe and effective is not covered regardless of whether it satisfies the other criteria. A service that is determined to be safe and effective may or may not be covered depending on whether the other criteria are met. In determining whether the criteria are met, we will consider the following:

(1) *Safety and effectiveness.* (i) A service may be determined to be safe and effective if it is generally accepted in the medical community as safe and effective in the setting and for the condition for which it is used, or proven to be safe and effective based on authoritative evidence.

(ii) Even if a service is generally accepted in the medical community as safe and effective for some conditions, evidence may support a conclusion that the service has not been shown to be safe and effective for all conditions, and in these cased Medicare does not cover the service for those conditions.

(iii) To be considered safe and effective, a service must be furnished in a setting commensurate with the patient's medical needs and condition.

(iv) To be considered safe and effective, a service must be furnished by personnel who are qualified to furnished the service by virtue of education, training, experience, certification, or licensure.

(v) When evaluating breakthrough medical or surgical procedures, the standards for safety and effectiveness are less stringent. The more severe and life threatening the illness or injury process for which a particular treatment is applied, the more acceptable a relatively less safe technology may be when no safer or more effective technologies are available. In these cases, treatments whose clinical effectiveness has not been conclusively demonstrated may be determined to be reasonable and necessary if no safer or more effective treatments are available. However, in certain cases, we may provide for coverage but impose such limitations as facility or patient selection criteria, or a provision to later revise a coverage policy based on subsequent data collection.

(vi) Medical devices that have been approved for marketing by FDA on the basis of a premarket approval application (under 21 U.S.C. 360c) or a section 510(k) application submitted with clinical data are considered safe and effective for Medicare purposes when used for the conditions prescribed, recommended, or suggested in the labeling of the devices.

(vii) Drugs and biologicals approved for marketing by FDA are considered safe and effective for Medicare purposes when used for indications specified in their labeling.

(2) *Experimental or investigational considerations.* (i) A service that is furnished for research purposes in accordance with predetermined rules is considered experimental or investigational and is not covered by Medicare.

(ii) Except for certain drugs used in treating terminally ill cancer patients that are identified as Group C cancer drugs distributed by the National Cancer Institute, a drug or biological product that has not been approved under a new drug application for marketing by FDA is considered experimental or investigational by HCFA and is not covered by Medicare.

(iii) A medical device that has not been approved by FDA (under 21 U.S.C. 360k) is considered experimental or investigational and is not covered by Medicare.

(iv) A service, other than breakthrough medical or surgical procedures described in paragraph (b)(1)(v) of this section, that is not used widely because there is inadequate evidence of safety and effectiveness is considered experimental or investigational and is not covered by Medicare.

(3) *Cost-effectiveness.* A technology is considered cost-effective if it is—

(i) Very expensive to the program, but provides significant medical benefits not otherwise available;

(ii) Less costly and at least as effective as an alternative covered intervention;

(iii) More effective and more costly than a covered alternative, but the added benefit is significant enough to justify the added cost; and

(iv) Less effective and less costly than an existing alternative, but a viable alternative for some patients.

(4) *Appropriateness.* (i) A service is considered appropriate if it is furnished in a setting commensurate with the patient's medical needs.

(ii) A service is considered appropriate if it is furnished by qualified personnel.

§ 405.381 Procedures for Medicare carriers, intermediaries, HMOs, CMPs, and PROs in making coverage decisions.

(a) *Presence of a national coverage decision.* In their review of claims for payment, Medicare contractors (carriers, intermediaries, HMOs, CMPs, and PROs) are bound by the statute, regulations, and all HCFA administrative coverage issuances, including all national coverage decisions.

(b) *Absence of a national coverage decision.* In the absence of a national coverage decision, Medicare contractors determine whether the service in question appears to be reasonable and necessary and, therefore, covered in accordance with § 405.380(a)(2).

(c) *Referral of a national coverage decision.* If a Medicare contractor identifies a service for which there appears to be questions of possible national significance in accordance with § 405.382(a), but for which there is no applicable HCFA national coverage decision, the contractor must refer the service to HCFA for review in accordance with guidelines issued to them by HCFA.

(d) *PRO medical necessity determinations.* Medicare carriers and intermediaries are bound by medical necessity determinations of local PROs, under section 1154 of the Act and Part 466 of this title with respect to the application or use of a covered service in a particular case and with respect to services for which HCFA has not issued a national coverage decision.

(e) *Other considerations.* In applying the criteria for making coverage decisions described in § 405.380(a) in individual cases, Medicare carriers, intermediaries, HMOs, and CMPs may specifically consider, among other factors, whether the service is—

(1) Medically necessary in the particular case and whether the amount, duration and frequency of use or application of the service are medically appropriate;

(2) Furnished in accordance with accepted standards of medical practice; and

(3) Furnished in a setting appropriate to the patient's medical needs and condition (such as inpatient care at a hospital or SNF, outpatient care at a hospital or physician's office, or home care).

§ 405.382 HCFA procedures for making national coverage decisions.

This section sets forth the procedures and criteria that HCFA uses to implement section 1862(a)(1)(A) of the Act by making national coverage decisions regarding whether, and to what extent, specific medical services are covered under Medicare.

(a) *Identification of health care technologies.* HCFA may identify a specific health care technology for which a national coverage decision is made under this section if there are no statutory bars to coverage of the service and one or more of the following factors is present:

(1) The service is likely to be used in more than one region of the country.

(2) The service is likely to represent a significant expense to the Medicare program.

(3) The service has the potential for rapid diffusion and application.

(4) There is substantial disagreement among experts regarding the safety, effectiveness, or appropriateness involved in the use of a service.

(5) The service represents a significant advance in medical science.

(6) The service represents a new product, that is, a device, drug, or procedure for which there is no similar technology already covered under Medicare.

(7) The service has been subject to inconsistent coverage decisions by contractors or regional offices and a conflict can only be resolved by a national decision.

(8) The service that was "commonly accepted" by the medical profession has become outmoded or otherwise not in the public's interest.

(b) *HCFA Physicians Panel.* HCFA secures background information and expert opinion from qualified medical and professional sources regarding the criteria set forth in § 405.380. HCFA presents this information to the HCFA Physicians Panel for a recommendation regarding whether to refer the issue to PHS on an inquiry basis or for a full assessment, or whether to leave the coverage judgment to the discretion of the individual Medicare contractor. The Panel is an internal advisory organization, composed of physicians and other health professionals in HCFA's Central Office and counterparts from PHS, that periodically meets in closed session. Presentations by interested parties may be made prior to the Panel's closed meeting.

(c) *PHS process for inquiries and assessments.* When HCFA refers an issue to PHS as an—

(1) Inquiry, PHS researches the issue and forwards any available information on that issue to HCFA.

(2) Assessment, PHS researches the issue, publishes a notice in the **Federal Register** and seeks public comment, consults as necessary with professional individuals and organizations, performs the necessary analysis and assessment, formulates a recommendation as to Medicare coverage and a rationale for that recommendation, and forwards it to HCFA for a coverage decision, as needed.

(d) *HCFA decision regarding coverage.* After review of PHS' recommendation and any other material that HCFA deems appropriate, HCFA decides whether to issue a national coverage decision. If it decides to issue a decision, it announces that decision and the rationale for it under § 405.382(g).

(e) *Notification to requesting party.* HCFA notifies in writing any party that requests its final coverage decision and supporting rationale.

(f) *Right to reconsideration of a national coverage decision.* Any party may request a reconsideration of a determination that a national coverage decision is not warranted under paragraph (a) of this section.

(g) *HCFA announcement of national coverage decisions.* HCFA announces national coverage decisions that relate to health care technology through—

(1) Issuances in the Coverage Issues Manual (HCFA Pub. 6), other HCFA manuals to Medicare contractors, and as HCFA Rulings in the **Federal Register** (when appropriate); and

(2) Quarterly notices published in the **Federal Register** that list all Medicare manual instructions including national coverage decisions.

(h) *HCFA reevaluation of a national coverage decision.* (1) HCFA may reevaluate a service for which a national coverage decision has been made under this section. A reevaluation ordinarily occurs only when significant new information or evidence becomes available that was not available at the time the previous national coverage decision was made.

(2) If HCFA determines under paragraph (g)(1) of this section that coverage of a service, for which a national coverage decision has been made under this section, should be withdrawn, it publishes, in the **Federal Register**, for notice and comment that the service is no longer covered.

§ 405.383 Development of utilization review policy.

(a) When developing utilization review policy to identify claims for services that may need review for medical necessity prior to payment, Medicare carriers and intermediaries must solicit comments (and allow at least a 30-day comment period) from the local medical community (for example, State medical associations or specialty societies) on such factors as appropriate clinical indications and settings for the services under consideration. Upon receipt of comments, carriers and intermediaries must notify the local medical community 30 days before implementing the policy of their responses to the comments, the final policy, and the documentation requirements. The operational parameters of the policy however, will not be disclosed.

(b) Claims subject to medical review in accordance with utilization review policy may not be denied without review of all relevant information submitted with the claim.

(Catalog of Federal Domestic Assistance Program, No. 13.773, Medicare Hospital Insurance; No. 13.774, Medicare Supplementary Medical Insurance)

Dated: September 2, 1988.

William L. Roper,

Administrator, Health Care Financing Administration.

Approved: December 15, 1988.

Otis R. Bowen,

Secretary.

[FR Doc. 89-1695 Filed 1-27-89; 8:45 am]

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DEPARTMENT OF DEFENSE

48 CFR Parts 219, 226, and 252

Department of Defense Federal Acquisition Regulation Supplement; Implementation of Section 1207 of Pub. L. 99-661 and Section 806 of Pub. L. 100-180; Contracting With Small Disadvantaged Business Concerns

AGENCY: Department of Defense (DoD).

ACTION: Proposed rule (extension of comment period).

SUMMARY: The Defense Acquisition Regulatory (DAR) Council is considering a revision to the Defense Federal Acquisition Regulation Supplement (DFARS), Parts 219, 226, and 252, Contracting with Small Disadvantaged Business Concerns. DFARS coverage was published as a proposed rule for public comment on December 8, 1988 (53 FR 49577). The original date for receipt of public comments was January 9, 1989. The DAR Council has decided to extend the period for public comment on this proposed coverage until February 9,