IV. Regulatory Impact Statement

We have examined the impacts of this proposed notice as required by Executive Order 12866 and the Regulatory Flexibility Act (RFA) (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis must be prepared for major rules with economically significant effects ($100 million or more annually). The reductions in total expenditures over the next 5 years are estimated to be: $10 million in 1999; $20 million in 2000; $30 million in 2001; $30 million in 2002; and $30 million in 2003. Since the proposed notice results in reductions in total expenditures of less than $100 million per year, this notice is not a major rule as defined in Title 5, United States Code, section 804(2) and is not an economically significant rule under Executive Order 12866.

RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, non-profit organizations, and government agencies. Most hospitals and most other providers and suppliers are small entities either by non-profit status or by having revenues of $5 million or less annually. Individuals and States are not included in the definition of a small entity. Based on data from the Small Business Administration (SBA), we estimate that 98 percent of suppliers of DME and prosthetic devices would be defined as small entities for purposes of the RFA. We estimate that 106,000 entities bill Medicare for DME, prosthetics, orthotics, surgical dressings, and other equipment and supplies each year. We believe the impact on small businesses will be minimal because the implementation of the payment amounts will be phased in over several years. The annual adjustment in payment will be no greater than 15 percent per year. Total Medicare expenditures for DME and prosthetics devices is approximately $5 billion per year. As indicated above, we estimate that the proposed payment reductions, when fully implemented, will reduce these expenditures by approximately $30 million per year. Therefore, the overall impact on the total industry annual receipts will be small, that is, less than 1 percent reduction in Medicare revenue. However, while the overall impact is small, some suppliers would be seriously affected as a result of the mix of DME and prosthetics that they furnish to Medicare beneficiaries.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a proposed notice may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has less than 50 beds. We are not preparing a rural impact analysis since we have determined that this proposed notice would not have a significant economic impact on the operation of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any proposed notice that may result in an annual expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100 million. The proposed notice would not have an effect on the governments mentioned, and private sector costs would be less than the $100 million threshold.

In accordance with the provisions of Executive Order 12866, this notice was reviewed by the Office of Management and Budget.

Authority: Sections 1834(a) and 1842(b) of the Social Security Act (42 U.S.C. 1395m and 1395u).

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: January 27, 1999.

Nancy-Ann Min DeParle,

Administrator, Health Care Financing Administration.

Dated: April 28, 1999.

Donna E. Shalala,

Secretary.

[FR Doc. 99–20989 Filed 8–12–99; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–3022–N]

Medicare Program; Meeting of the Drugs, Biologics, and Therapeutics Panel of the Medicare Coverage Advisory Committee—September 15 and 16, 1999

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

ACTION: Notice of meeting.

SUMMARY: This notice announces a meeting of the Drugs, Biologics, and Therapeutics Panel of the Medicare Coverage Advisory Committee. The Panel will discuss presentations from interested persons regarding the combination of high dose chemotherapy and stem cell transplantation for the treatment of multiple myeloma. This meeting is open to the public and complies with the Federal Advisory Committee Act (5 U.S.C. App. 2, section 10(a)(1) and (a)(2)).

DATES: *The Meeting:* September 15, 1999, from 1 p.m. until 4 p.m., E.D.T., and September 16, 1999, from 8 a.m. until 4 p.m., E.D.T.

Deadline for Presentation Submissions: August 20, 1999, 5 p.m., E.D.T.

Deadline for Submission of Final Comments: September 30, 1999, 5 p.m., E.D.T.

ADDRESSES: *The Meeting:* The meeting will be held at the Baltimore Convention Center, One West Pratt Street, Rooms 327–329, Baltimore, Maryland 21201–2499.

Presentations and Comments: Submit written presentations and comments to Lauren K. Geyer, MHS, Executive Secretary; Office of Clinical Standards and Quality; Health Care Financing Administration; 7500 Security Boulevard; Mail Stop S3–02–01; Baltimore, MD 21244.

FOR FURTHER INFORMATION CONTACT: Lauren K. Geyer, MHS, Executive Secretary, (410) 786–2004.

SUPPLEMENTARY INFORMATION: We have established the Medicare Coverage Advisory Committee (MCAC) to provide advice and recommendations to us about clinical coverage issues. The MCAC is composed of an Executive Committee and six panels, each containing members with expertise in one or more of the following fields: clinical and administrative medicine, biologic and physical sciences, public health administration, health care data and information management and

analysis, the economics of health care, medical ethics, and other related professions. Each panel is composed of a chairperson, voting members, a nonvoting consumer representative, and a nonvoting industry representative.

Current Members of the Panel

Thomas V. Holohan, MA, MD, FACP (Chairperson); Leslie P. Francis, JD, Ph.D.; Judith A. Cahill, MA; Michael L. Friedland, MD; Kathy J. Helzlsouer, MD, MHS; Robert C. Johnson, MS; Ronald P. Jordan, R.Ph.; Mitchell Sugarman, MBA, MS; Cathleen M. Dooley, MPA; and Christine M. Grant, JD.

Topic of the Meeting

The Panel will discuss presentations from interested persons regarding the combination of high dose chemotherapy and stem cell transplantation for the treatment of multiple myeloma.

Procedure and Agenda

The Panel will hear oral presentations from the public for approximately 90 minutes on each day of the meeting. The Panel may limit the number and duration of oral presentations to the time available. If you wish to make a presentation during one of these sessions, you must submit the following to the Executive Secretary before the Deadline for Presentation Submissions date listed in the Dates section of this notice: a brief statement of the general nature of the evidence or arguments you wish to present, the names and addresses of proposed participants, and an estimate of the time required to make the presentation. We will request that you declare at the meeting whether or not you have any financial involvement with manufacturers of any items or services being discussed (or with their competitors).

After the 90-minute public presentation on Day 2 of the meeting, we will make a presentation to the Panel. After our presentation, the Panel will deliberate openly on the topic. Interested persons may observe the deliberations, but the Panel will not hear further comments during this time except at the request of the chairperson. At the end of the Panel deliberations, the Panel will allow a 30-minute open public session for any attendee to address issues specific to the topic.

Submission of Final Comments

Interested persons not scheduled to make an oral presentation, unable to attend the meeting, or wishing to make further remarks, may submit written comments to the Executive Secretary by the Deadline for Submission of Final Comments in the Dates section of this notice.

HCFA Home Page

You may access detailed information regarding the agenda and schedule of presentations on our home page (www.hcfa.gov/quality/8b.htm) the day after the Deadline for Presentation Submissions in the Dates section of this notice.

Authority: 5 U.S.C. App. 2, section 10(a)(1) and (a)(2).

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: August 9, 1999.

Michael M. Hash,

Deputy Administrator, Health Care Financing Administration.

[FR Doc. 99–20988 Filed 8–12–99; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: A Basal Cell Carcinoma Tumor Suppressor Gene

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(i), that the National Institutes of Health (NIH), Department of Health and Human Services, is contemplating the grant of an exclusive license worldwide to practice the invention embodied in: U.S. Patent Application Serial No. 08/857,636 filed May 16, 1997 entitled ''A Basal Cell Carcinoma Tumor Suppressor Gene'', PCT application US97/08433 filed May 16, 1997 designating all countries, except the U.S., entitled, ''A Basal Cell Carcinoma Tumor Suppressor Gene'' to Ontogeny, Inc., having a place of business in Cambridge, MA. The United States of America is the assignee or the exclusive licensee of the patent rights in this invention.

DATES: Only written comments and/or application for a license which are received by the NIH Office of Technology Transfer on or before October 12, 1999.

ADDRESSES: Requests for a copy of the patent applications, inquiries, comments and other materials relating to the contemplated license should be directed to Richard U. Rodriguez, M.B.A., at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; Telephone: (301) 496–7056, ext. 287; Facsimile: (301) 402–0220; E-mail: rr154z@nih.gov.

SUPPLEMENTARY INFORMATION: In an effort to develop a method of detection and an efficacious treatment for basal cell carcinoma, nevoid basal cell carcinoma syndrome, and medulloblastoma, the inventors posit that the Basal Cell Carcinoma Tumor Suppressor Gene and the disclosed mutations thereof may play a key physiological role.

The prospective exclusive license will be royalty-bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive license may be limited to the fields of human diagnostics and therapeutics for indications consisting of nevoid basal cell carcinoma syndrome, basal cell carcinoma, and medulloblastoma and may be granted unless, within 60 days from the date of this published Notice, NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

Properly filed competing applications for a license filed in response to this notice will be treated as objections to the contemplated license. Comments and objections submitted in response to this notice will not be made available for public inspection, and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: August 6, 1999.

Jack Spiegel,

Director, Division of Technology Development and Transfer, Office of Technology Transfer.

[FR Doc. 99–20938 Filed 8–12–99; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Information Collections Submitted to the Office of Management and Budget for Approval Under the Paperwork Reduction Act

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of information collection; request for comments.

SUMMARY: The U.S. Fish and Wildlife Service (Service) has sent the collection of information described below to the Office of Management and Budget (OMB) for approval under the provisions of the Paperwork Reduction