involved in the field of infant nutrition (e.g., American Academy of Pediatrics (AAP), the Food and Nutrition Board (FNB) of the National Academy of Sciences), will perform a review of the scientific and medical literature with a particular emphasis on studies published since 1986, when Congress last amended the infant formula provisions of the act. Requirements of other governmental bodies will also be considered in this review. Specifically, LSRO will address the following issues:

(1) What scientific basis is there to support requirements for energy and macronutrients (protein, fat, and carbohydrate) in infant formulas intended for use by preterm infants as distinct from the requirements for energy and macronutrients in formulas for term infants? The American Academy of Pediatrics, the European Society for Pediatric Gastroenterology and Nutrition, and the Canadian Pediatric Society have proposed some nutrient requirements for preterm infants distinct from those for term infants. Has scientific knowledge advanced to the point that distinct composition standards for energy and macronutrients in formulas for these preterm infants are warranted?

(2) Nutrient requirements of hospitalized preterm infants who are fed enteral formulas are sometimes described according to stages such as a first or transition stage (between birth and 10 days of age), a stable growing stage (from about 10 days until discharge from hospital, 6 to 8 weeks after birth), and a post-discharge stage (from discharge home to approximately 1 year of age). Is there scientific evidence to justify more than one set of energy and macronutrient requirements to support growth and development of the hospitalized preterm infant at the different stages of development? If so, how should the stages be defined? Are the energy and macronutrient requirements for infant formulas for term infants sufficient for healthy post-discharge preterm infants? Is there scientific evidence to support specific deviations from current nutrient standards for healthy post-discharge preterm infants and if so, what would they be and to what stage (age/weight) should these special formulas be given?

(3) Does available evidence establish the essentiality of addition of subcomponents of the macronutrients (specifically, taurine, carnitine, and LCPUFA's) to formulas for preterm infants, and if so, does the evidence establish what the amount and ratios of these compounds should be in the formula? For example, the Canadian ''Guidelines for the Composition and Clinical Testing for Formulas for Preterm Infants'' (p. 17) finds that term infant formulas containing adequate and balanced 18:2n-6 and 18:3n-3 fatty acids do not require addition of the 20 and 22 carbon n-6 and n-3 fatty acids. Is there evidence to suggest that this finding has application to preterm infant formulas? If so, is there an optimum level and ratio of 18:2n-6 and 18:3n-3 fatty acids in formulas for preterm infants?

Does the available evidence address the issue of safety of various sources of these LCPUFA's for use in preterm infant formulas? If so, is there a safe source of LCPUFA's?

(4) Does available evidence establish the essentiality of addition of nucleotides to formulas for preterm infants, and if so, does the evidence establish what the amounts should be in the formulas?

LSRO will use these questions as a guide in its research and in the drafting of its report. LSRO notes that the recommendations derived from the answers to the above questions will be made in consultation with liaisons from the American Academy of Pediatrics' Committee on Nutrition and the Institute of Medicine's Food and Nutrition Board. A comprehensive final report that documents and summarizes the results of the evaluation will be prepared.

FDA and FASEB are announcing that the LSRO/FASEB expects to hold an open meeting on this topic during the period January 2, 1997 to March 31, 1997. FDA and FASEB will announce the date of the meeting as soon as it is set. The open meeting will be held in the Chen Auditorium, Lee Bldg., FASEB (address above). FASEB anticipates that the open meeting will last 1 day, depending on the number of requests to make oral presentations. Requests to make oral presentations at the open meeting must be submitted in writing by December 23, 1996. Written requests to make oral presentations of scientific data, information, and views at the open meeting should be submitted to Daniel J. Raiten (address above) and to the Dockets Management Branch (address above). Two copies of the material to be presented must be submitted to each office on or before the date of the open meeting.

FDA and FASEB are also inviting submission of written presentations of scientific data, information, and views. These materials should be submitted on or before the date of the open meeting. Two copies of the written materials must be submitted to each office.

Under its contract with FDA, FASEB will provide the agency with a scientific report on or about September 30, 1997.

Dated: November 5, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–29303 Filed 11–14–96; 8:45 am]

BILLING CODE 4160–01–F

Health Care Financing Administration

[HCFA–8003]

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposals for the collection of information. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Request:* Extension, without change, of a previously approved collection for which approval has expired; *Title of Information Collection:* Home and Community-Based Services Waiver Requests; *Form No.:* HCFA–8003; *Use:* Under a Secretarial waiver, States may offer a wide array of home and community-based services to individuals who would otherwise require institutionalization. States requesting a waiver must provide certain assurances, documentation and cost & utilization estimates which are reviewed, approved and maintained for the purpose of identifying/verifying States' compliance with such statutory and regulatory requirements; *Frequency:* Other—When a State requests a waiver or amendment to a waiver; *Affected Public:* State, local, or tribal government; *Number of Respondents:* 50; *Total Annual Responses:* 140; *Total Annual Hours:* 8,200.

To request copies of the proposed paperwork collection referenced above, E-mail your request, including your address, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410)

786–1326. Written comments and recommendations for the proposed information collections should be sent within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Financial and Human Resources, Management Analysis and Planning Staff, Attention: Linda Mansfield, Room C2–26–17, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: November 7, 1996.

Edwin J. Glatzel,

Director, Management Analysis and Planning Staff, Office of Financial and Human Resources, Health Care Financing Administration.

[FR Doc. 96–29313 Filed 11–14–96; 8:45 am]

BILLING CODE 4120–03–P

Office of Inspector General

Publication of the Medicare Beneficiary Advisory Bulletin on HMO Arrangements

AGENCY: Office of Inspector General, HHS.

ACTION: Notice.

SUMMARY: This Federal Register notice sets forth a recently issued Medicare Beneficiary Advisory Bulletin, developed in cooperation with the Health Care Financing Administration's Office of Managed Care, that identifies potential fraud and abuse issues related to the enrollment, the provision of services, and the disenrollment of Medicare program beneficiaries in health maintenance organizations (HMOs). This Advisory Bulletin has been made available to many consumer and health care association groups, and is now being reprinted in this issue of the Federal Register as a means of ensuring greater public awareness of beneficiary rights regarding HMO participation and services.

FOR FURTHER INFORMATION CONTACT: Joel J. Schaer, Office of Management and Policy, (202) 619–0089.

SUPPLEMENTARY INFORMATION: The Office of Inspector General was established by Congress to find and eliminate fraud, waste and abuse. It periodically issues Special Fraud Alerts and Advisory Bulletins to show Medicare beneficiaries where and how to look for potential problems. The Health Care Financing Administration's Office of Managed Care works to ensure that Medicare beneficiaries are given quality health care in their HMO plans.

This specific bulletin is designed to help beneficiaries identify and report improper practices, and should be helpful to Medicare beneficiaries who are thinking about joining an HMO as well as to those who are already enrolled. Specifically, this bulletin provides information about HMO obligations and beneficiary rights regarding HMO enrollment, including a Medicare beneficiary's rights to enroll in an HMO regardless of age or health status. It also gives detailed information on a beneficiary's rights to medical services, such as emergency and out-of-area care, their rights to disenroll, and provides examples of situations in which beneficiaries have the right to file a complaint or appeal an HMO's decision.

A reprint of this Medicare Beneficiary Advisory Bulletin follows.

MEDICARE BENEFICIARY ADVISORY BULLETIN

What Medicare Beneficiaries Need To Know About Health Maintenance Organization (HMO) Arrangements: Know Your Rights

Introduction

If you are thinking of joining a Medicare contracting health maintenance organization (HMO), or are enrolled in an HMO, this advisory bulletin gives you important information. In addition, this bulletin also tells you how you can get help and where you can make complaints if you believe any of your rights have been violated or the HMO has acted inappropriately.

What Are Medicare Contracting HMOs?

Medicare contracts with HMOs to provide a full range of Medicare benefits to you. Medicare contracting HMOs must give you all the health care services that are covered under the Medicare program, except hospice services (See your Medicare Handbook for specific details). In addition, HMOs may offer additional benefits, either at no charge or for an additional charge.

There are two types of Medicare contracting HMOs - risk HMOs and cost HMOs. Most HMOs are risk HMOs, and this bulletin deals exclusively with risk HMOs [1].

In general, if you enroll in a risk HMO plan, sometimes called a health plan or plan:

- You must get all of your medical care through the plan's doctors, hospitals, skilled nursing facilities, home health agencies, and other health care providers. You are ''locked-in'' to receive care through your HMO plan. You may, however, get emergency care and unforseen out-of-area urgently needed care when necessary from non-plan providers. Some plans may offer a point-of-service option which allows members to use non-plan providers in certain cases.
- You must select a primary care doctor participating in the plan. This doctor is responsible for coordinating your care. You must obtain a referral from this doctor in order to see a specialist or obtain other services through the plan.

Part I: Enrollment and Disenrollment Rights

Enrollment Rights

When you are considering enrolling in an HMO, the HMO:

- Must provide you with complete and accurate information
- Must enroll you without regard to your health status
- Must not offer you gifts or other financial inducements to encourage you to enroll.

Complete and Accurate Information

Before you decide to enroll in a plan, HMO sales, marketing or other plan representatives must give you complete and accurate information about the benefits and the services their HMO provides.

Make sure the HMO representative tells you whether the HMO offers any additional benefits besides those benefits covered under the Medicare program. If so, there may be limits on how often you can use the benefits or how much the HMO will pay for them.

For example, if you take prescription drugs, you should ask the plan before you enroll if the drugs you take are covered. If the drugs are covered, ask about whether there are limits to the coverage and whether you are required to use certain pharmacies.

[Note: Many plans do not cover all prescription drugs. Plans may set a maximum dollar amount on the drugs they cover each quarter or each year.]

In addition, the HMO representative must tell you if the HMO requires copayments for any services, including drugs, and the amount of such copayments.

[Note: Additional benefits and copayments may change each year.]

Make sure that sales, marketing or other plan representatives tell you about how their HMO operates and about all HMO providers and facilities that will be available to you in your area. This

[1] You should find out whether the HMO you are considering joining is a risk or cost HMO. If it is a cost HMO, be sure to request additional information about the operation and benefits associated with this type of plan. Some of the issues raised in this bulletin may also apply to cost HMOs.