Title/Topic of Document	Contact
Guide to Inspections of Source Plasma Establishments.	Elizabeth A. Waltrip, Division of Emergency and Investigational Operations (HFC–132), Office of Regional Operations, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5662.
Guide to Inspections of Aseptic Processing and Packaging (Food).	Jody Robinson, Division of Emergency and Investigational Operations (HFC–132), Office of Regional Operations, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7691.
CATEGORY—REGULATORY PROCEDURES MANUAL	
Regulatory Procedures Manual (Revision), Chapter 10, Subchapter: Application Integrity Policy.	Sharon Sheehan, Division of Compliance Policy (HFC–230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0412.
CATEGORY—LABORATORY PROCEDURES MANUAL	
Chapter 1, Sample Accountability.	Jim Yager, Division of Field Science (HFC–140), Office of Regional Operations, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1025.
Chapter 2, Sample Analysis.	Do.
Chapter 3, Laboratory Reporting.	Do.
Chapter 4, Sample Disposition.	Do.
Chapter 21, Guidance on the Review of Analytical Data Generated by Private Laboratories.	Leonard Valenti, Division of Field Science (HFC–140), Office of Regional Operations, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–7103.

Dated: November 4, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–29699 Filed 11–12–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–3027–N]

Medicare Program; Meeting of the Executive Committee of the Medicare Coverage Advisory Committee—December 8, 1999

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

ACTION: Notice of meeting.

SUMMARY: This notice announces a public meeting of the Executive Committee of the Medicare Coverage Advisory Committee (MCAC). The Committee provides advice and recommendations to the agency about clinical coverage issues. The Committee will hear reports from recent meetings of MCAC medical specialty panels. The Committee will also consider how to provide guidance to, and substantive coordination among, MCAC panels. For example, the Committee will consider the levels of evidence, types of information needed, and the nature of issues that will be considered by the medical specialty panels at future public meetings. Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. App. 2, section 10 (a)(1) and (a)(2)).

DATES:

The Meeting: December 8, 1999, from 8 a.m. until 4 p.m., E.D.T.

Deadline for Presentations and Comments: Submit formal presentations and written comments to the **FOR FURTHER INFORMATION CONTACT** by November 18, 1999, 5 p.m., E.S.T.

Special Accomodations: Persons attending the meeting who are hearing or visually impaired and have special requirements, or a condition that requires special assistance or accommodations, must notify the Executive Secretary by November 18, 1999, 5 p.m., E.D.T.

ADDRESSES:

The Meeting: The meeting will be held at the Health Care Financing Administration, Main Auditorium, 7500 Security Boulevard, Baltimore, Maryland 21244.

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

Website: You may access up-to-date information on this meeting at www.hcfa.gov/quality/8b.htm.

SUPPLEMENTARY INFORMATION:

On August 13, 1999, we published a notice (64 FR 44231) to establish the Medicare Coverage Advisory Committee (MCAC) to provide advice and recommendations to us about clinical coverage issues. This notice announces the following public meeting of the MCAC:

Current Members of the Committee

Thomas V. Holohan, M.A., M.D., (FACP); Leslie P. Francis, JD, Ph.D.; John H. Ferguson, M.D.; Robert L. Murray, Ph.D.; Alan M. Garber, M.D., Ph.D.; Michael D. Maves, M.D., M.B.A.; David M. Eddy, M.D., Ph.D.; Frank J. Papatheofanis, M.D., Ph.D.; Harold C. Sox, M.D.; Ronald M. Davis, M.D.; Daisy Alford-Smith, Ph.D.; Joe W. Johnson, D.C.; Robert H. Brook, M.D., Sc.D.; Linda A. Bergthold, Ph.D.; and Randel E. Richner, M.P.H.

Meeting Topic

The Committee will hear reports from recent meetings of MCAC medical specialty panels. The Committee will also consider how to provide guidance to, and substantive coordination among, MCAC panels. For example, the Committee will consider the levels of evidence, types of information needed, and the nature of issues that will be considered by the medical specialty panels at future public meetings.

Procedure and Agenda

This meeting is open to the public. The Committee will hear oral presentations from the public for approximately 90 minutes on the day of the meeting. The Committee may limit the number and duration of oral presentations to the time available. If you wish to make formal presentations, you must notify the **FOR FURTHER INFORMATION CONTACT**, and submit the following by the Deadline for Presentations and Comments date listed in the Dates section of this notice: a brief statement of the general nature of the information 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 public presentation, we will make a presentation to the Committee. After our presentation, the Committee will deliberate openly on the topic. Interested persons may observe the deliberations, but the Committee will not hear further comments during this time except at the request of the chairperson. At the end of the Committee deliberations, the Committee will allow a 30-minute open public session for any attendee to address issues specific to the topic. After which, the members will vote and the Committee will make its recommendation.

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: November 5, 1999.

Jeffrey L. Kang,

Director, Office of Clinical Standards and Quality, Health Care Financing Administration.

[FR Doc. 99–29670 Filed 11–12–99; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Publication of the OIG's Compliance Program Guidance for Medicare+Choice Organizations Offering Coordinated Care Plans

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Notice.

SUMMARY: This **Federal Register** notice sets forth the Compliance Program Guidance for Medicare+Choice Organizations Offering Coordinated Care Plans (''Medicare+Choice organizations'') that was recently issued by the Office of Inspector General (OIG). The OIG has previously developed and published compliance program guidance focused on other areas of the health care industry. We believe that the development and issuance of this compliance program guidance for Medicare+Choice organizations will continue to serve as a positive step toward promoting a high level of ethical and lawful conduct throughout the entire health care industry.

FOR FURTHER INFORMATION CONTACT: Barbara Frederickson, Office of Counsel to the Inspector General, (202) 619–2078.

SUPPLEMENTARY INFORMATION:

Background

The creation of compliance program guidance continues to be a major initiative by the OIG in its effort to engage the health care community in combating fraud and abuse. In formulating compliance guidance, the OIG has worked closely with the Health Care Financing Administration (HCFA), the Department of Justice (DOJ) and various sectors of the health care industry to provide clear guidance to the industry. The previously-issued compliance program guidances addressed six areas: the hospital industry; home health agencies; clinical laboratories; third-party medical billing companies; the durable medical equipment, prosthetics, orthotics and supply industry; and hospices. The development of these compliance program guidances is based on our belief that a health care provider can use internal controls to more efficiently monitor adherence to applicable statutes, regulations and program requirements.

Guidance for Medicare+Choice Organizations

On September 22, 1998, the OIG published a solicitation notice seeking information and recommendations for developing formal guidance for Medicare+Choice organizations (63 FR 50577). In response to that solicitation notice, the OIG received five comments from the industry and their representatives. After careful consideration of those initial comments, and in an effort to ensure that all parties had a reasonable opportunity to provide input into a final product, the OIG published draft guidance for Medicare+Choice organizations on June 24, 1999 (64 FR 33869) for further comment and recommendations. A total of 16 timely-filed comments were received for consideration by the OIG in response to the publication of that draft guidance.

Elements for an Effective Compliance Program

Through experience, the OIG has identified seven fundamental elements to an effective compliance guidance program that are being reflected in this latest issuance. They are:

- Implementing written policies, procedures and standards of conduct;
- Designating a compliance officer and a compliance committee;
- Conducting effective training and education;
- Developing effective lines of communication;
- Enforcing standards through well-publicized disciplinary guidelines and developing policies addressing dealings with sanctioned individuals;
- Conducting internal monitoring and auditing; and
- Responding promptly to detected offenses, developing corrective action, and reporting to the Government.

The OIG is offering specific compliance measures that may be implemented by Medicare+Choice organizations in an effort to curtail or eliminate fraud and abuse. While HCFA regulations require Medicare+Choice organizations to implement compliance programs, adoption of the Compliance Program Guidance for Medicare+Choice Organizations Offering Coordinated Care Plans set forth below is voluntary.

A reprint of this newly-issued compliance program guidance follows:

Office of Inspector General's Compliance Program Guidance for Medicare+Choice Organizations Offering Coordinated Care Plans (November 1999)

I. Introduction

In its ongoing effort to work collaboratively with the health care industry to achieve the mutual goals of quality health care and the elimination of fraud, waste and abuse, the Office of Inspector General (OIG) of the Department of Health and Human Services (HHS) encourages voluntarily developed and implemented compliance programs for the health care industry. Fundamentally, compliance efforts are designed to establish a culture within an organization that promotes prevention, detection and resolution of instances of conduct that do not conform to Federal and State law and Federal health care program requirements, as well as the organization's ethical and business policies. In practice, the compliance program should effectively articulate and demonstrate the organization's commitment to legal and ethical conduct.

As a demonstration of the OIG's commitment to compliance, the OIG has issued recommendations, in the form of compliance program guidances, that provide suggestions regarding how specific segments of the industry can