alternative approach may be used if such approach satisfies the requirement of the applicable statute, regulations, or both.

Interested persons may submit written comments on the draft guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 16, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy Coordination.

[FR Doc. 99–16139 Filed 6–23–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–1738]

Draft Guidance for Industry on Bioavailability and Bioequivalence Studies for Nasal Aerosols and Nasal Sprays for Local Action; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Bioavailability and Bioequivalence Studies for Nasal Aerosols and Nasal Sprays for Local Action.'' This draft guidance document provides recommendations to applicants intending to provide studies to document bioavailability (BA) or bioequivalence (BE) in support of new drug applications (NDA's), or abbreviated new drug applications (ANDA's) for locally acting nasal aerosols (metered-dose inhalers) and nasal sprays (metered-dose spray pumps).

DATES: Written comments on the draft guidance document may be submitted by September 22, 1999. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of this draft guidance are available on the Internet at ''http://www.fda.gov/cder/guidance/index.htm''. Submit written requests for single copies of the draft guidance for industry to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one-self addressed adhesive label to assist the office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Wallace P. Adams, Center for Drug Evaluation and Research (HFD–350), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5651.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled ''Bioavailability and Bioequivalence Studies for Nasal Aerosols and Nasal Sprays for Local Action.'' This draft guidance provides recommendations to applicants intending to provide studies to document BA or BE in support of NDA's or ANDA's for locally acting nasal aerosols and nasal sprays. This guidance covers prescription corticosteroids, antihistamines, anticholinergic drug products, and the over-the-counter (OTC) mast-cell stabilizer cromolyn sodium. This guidance does not cover studies of nasal sprays included in applicable OTC monographs or studies of: (1) Metered-dose products intended to deliver drug systemically via the nasal route, or (2) drugs in nasal nonmetered dose atomizer (squeeze) bottles that require premarket approval.

This draft level 1 guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). The draft guidance represents the agency's current thinking on BA and BE product quality information related to nasal inhalation aerosols and nasal metered-dose spray pumps. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. Alternative approaches to documentation of BA and BE may be used if such approaches satisfy the requirements of the applicable statute, regulations, or both.

Interested persons may, on or before September 22, 1999, submit to the Dockets Management Branch (address above) written comments with evidence to support or refute approaches on the draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance document and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 16, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy Coordination.

[FR Doc. 99–16140 Filed 6–23–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Draft OIG Compliance Program Guidance for Certain Medicare+Choice Organizations

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

ACTION: Notice and comment period.

SUMMARY: This **Federal Register** notice seeks the comments of interested parties on draft compliance program guidance developed by the Office of Inspector General for Medicare+Choice Organizations that offer Coordinated Care Plans (M+CO/CCPs). Through this notice, the OIG is setting forth its general views on the value and fundamental principles of M+CO/CCP compliance programs, and the specific elements that each M+CO/CCP should consider when developing and implementing an effective compliance program.

DATES: To assure consideration, comments must be delivered to the address provided below by no later than 5 p.m. on July 26, 1999.

ADDRESSES: Please mail or deliver written comments to the following address: Office of Inspector General, Department of Health and Human Services, Attention: OIG–4N–CPG, Room 5246, Cohen Building, 330 Independence Avenue, S.W., Washington, D.C. 20201.

We do not accept comments by facsimile (FAX) transmission. In commenting, please refer to file code OIG–4N–CPG. Comments received timely will be available for public inspection as they are received, generally beginning approximately 2 weeks after publication of a document, in Room 5541 of the Office of Inspector General at 330 Independence Avenue, S.W., Washington, D.C. 20201 on Monday through Friday of each week from 8:00 a.m. to 4:30 p.m.

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

SUPPLEMENTARY INFORMATION:

Background

The creation of compliance program guidance has become a major initiative of the OIG in its efforts to engage the private health care community in addressing and fighting fraud and abuse. In the last several years, the OIG has developed and issued the following compliance program guidance directed at various segments of the health care industry:

- Clinical Laboratories (62 FR 9435; March 3, 1997, as amended in 63 FR 45076; August 24, 1998),
- Hospitals (63 FR 8987; February 23, 1998),
- Home Health Agencies (63 FR 42410; August 7, 1998), and
- Third-Party Medical Billing Companies (63 FR 70138; December 18, 1998).

In addition, the OIG published a draft compliance guidance for Durable Medical Equipment, Prosthetics, Orthotics and Supply Industry (64 FR 4435; January 28, 1999). The guidance can also be found on the OIG web site at http://www.dhhs.gov/progorg/oig.

On September 22, 1998, the OIG published a solicitation notice seeking information and recommendations for developing formal guidance for M+CO/CCPs (63 FR 50577). In response to that solicitation notice, the OIG received 5 comments from various parts of the industry and their representatives. In developing this notice for formal public comment, we have considered those comments, as well as previous OIG publications, such as other compliance program guidances, Special Fraud Alerts, reports issued by the OIG's Office of Audit Services and Office of Evaluation and Inspections. We also took into account past and recent fraud investigations conducted by the OIG's Office of Investigations and the Department of Justice, and have consulted directly with HCFA.

Elements Addressed in the Draft M+CO/CCP Guidance

This draft of M+CO/CCP guidance contains the following 7 elements that the OIG has determined are fundamental to an effective compliance program:

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

These elements are contained in the other guidances issued by the OIG, indicated above. As with the other guidances, this draft compliance program guidance represents the OIG's suggestions on how M+CO/CCPs can best establish internal controls and monitoring to correct and prevent fraudulent activities. The contents of this guidance should not be viewed as mandatory or as an exclusive discussion of the advisable elements of a compliance program. While elements put forth in this draft compliance guidance are similar to elements HCFA has included in its conditions to contract as an M+C organization, the guidance is intended to present voluntary guidance to the industry, and not represent binding standards for M+CO/CCPs.

Public Input and Comment in Developing Final Guidance

In an effort to ensure that all parties have an opportunity to provide input into the OIG's guidance, we are publishing this guidance in draft form. We welcome any comments from interested parties regarding this guidance.′

We will consider all comments that are received within the above-cited time frame, incorporate any recommendations as appropriate, and will prepare and publish a final version of the M+CO/CCP guidance.

Draft Compliance Program Guidance for M+CO/CCPs (June 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) has encouraged voluntarily developed and implemented compliance programs for the health care industry. 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 best implement compliance programs.[1]

As a result of the changing nature of the health care delivery system and the growing trend toward reliance on the managed care industry in the provision of such health care delivery, the OIG believes it is appropriate to issue a guidance focusing on Medicare+Choice organizations[2] offering coordinated care plans[3] (Medicare+Choice organizations). The OIG believes that the implementation of compliance plans in the managed care industry can provide a mechanism for further improving the quality, productivity and efficiency of the health care industry as a whole. This guidance is intended to assist Medicare+Choice organizations and their agents and subcontractors in developing effective internal controls that promote adherence to applicable Federal and State law and the program requirements of Federal health plans.

While the regulations implementing the Medicare+Choice program, or Part C, require a Medicare+Choice organization to establish a compliance plan,[4] the OIG's program guidance is voluntary and simply is intended to provide assistance for Medicare+Choice organizations looking for additional direction in the development and implementation of a compliance program. As such, this guidance addresses the OIG's view on comprehensive compliance programs pertaining to Medicare+Choice organizations.

The OIG formulated this guidance specifically for Medicare+Choice organizations because these organizations are well-defined and somewhat limited in the statutory and regulatory jurisdiction of the States, as evidenced by the pre-emption

---

[1] *See* 64 FR 4435 (1/28/99) for the draft compliance program guidance for the durable medical equipment, prosthetics, orthotics and suppliers industry; 63 FR. 70138 (12/18/98) for compliance program guidance for third-party medical billing companies; 63 FR 45076 (8/24/98) for compliance program guidance for clinical laboratories; 63 FR 42410 (8/7/98) for compliance program guidance for home health agencies; and 63 FR 8987 (2/23/98) for compliance program guidance for hospitals. These documents are also located on the Internet at http://www.dhhs.gov/progorg/oig.

[2] A Medicare+Choice organization is defined as a public or private entity organized and licensed by a State as a risk-bearing entity (with the exception of provider-sponsored organizations receiving waivers) that is certified by the Health Care Financing Administration (HCFA) as meeting the Medicare+Choice contract requirements. *See* 42 CFR 422.2.

[3] For the purposes of this compliance program guidance, a ''coordinated care plan'' is a plan that includes a network of providers that are under contract or arrangement with the organization to deliver the benefit package approved by HCFA. *See* 42 U.S.C. 1395w–28(a)(1); 42 CFR 422.4.

[4] The regulations require that any plan contracting with HCFA implement a compliance plan that encompasses the elements detailed in the Federal Sentencing Guidelines. *See* 42 CFR 422.501(b)(vi). HCFA will release an operational policy letter addressing the compliance requirements detailed in the regulation. In response to concerns from industry representatives on the short time frame for implementing a compliance plan, HCFA delayed the actual implementation date of the compliance plan until January 1, 2000.

provisions.[5] In this guidance, we have focused our attention on Federal health care regulations governing marketing, enrollment, disenrollment, underutilization, data collection, anti-kickback statute and anti-dumping, rather than providing instruction on all aspects of regulatory compliance. The OIG encourages managed care organizations to read the guidance with the whole organization in mind, applying the guidance to whatever departments or divisions, including private-sector managed care areas, that are deemed appropriate. Indeed, many of the suggestions in this guidance can be used by managed care organizations that do not contract with HCFA. In particular, entities that participate in other public health care programs, such as Medicaid, may want to look to the general principles in this document to assist them in developing compliance programs.

Within this document, the OIG first provides its general views on the value and fundamental principles of Medicare+Choice organizations' compliance programs, and then provides specific elements that each Medicare+Choice organization should consider when developing and implementing an effective compliance program.

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 Medicare+Choice 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. Eventually, a compliance program should become part of the fabric of a Medicare+Choice organization's routine operations.

It is incumbent upon a Medicare+Choice organization's officers and managers to provide ethical leadership to the organization and to assure adequate systems and resources are in place to facilitate and promote ethical and legal conduct. Employees, managers and the Government will focus on the words and actions (including decisions made on resources devoted to compliance) of a Medicare+Choice organization's leadership as a measure of the organization's commitment to compliance. Indeed, many organizations have adopted mission statements articulating their commitment to high ethical standards.

Implementing an effective compliance program requires a substantial commitment of time, energy and resources by senior management and the Medicare+Choice organization's governing body. Superficial programs that simply purport to comply with the elements discussed and described in this guidance, or programs hastily constructed and implemented without appropriate ongoing monitoring, will likely be ineffective and could expose the Medicare+Choice organization to greater liability than no program at all. Although an effective compliance program may require significant additional resources or a reallocation of existing resources, the long term benefits of implementing such a program significantly outweigh the costs. Undertaking a compliance program is a beneficial investment that advances the Medicare+Choice organization, the health of Medicare+Choice enrollees and the stability and solvency of the Medicare program.

A. Benefits of a Compliance Program

The OIG believes an effective compliance program provides a mechanism that brings the public and private sectors together to reach mutual goals of reducing fraud and abuse, improving operational quality, improving the quality of health care and reducing the costs of health care. Attaining these goals provides positive results to business, Government, individual citizens and Medicare beneficiaries alike. In addition to fulfilling its legal duty to ensure that it is not submitting false or inaccurate information to the Government or providing substandard care to Medicare beneficiaries, a Medicare+Choice organization may gain numerous additional benefits by implementing an effective compliance program. These benefits may include:

- The formulation of effective internal controls to assure compliance with Federal regulations and internal guidelines;
- Improved collaboration, communication and cooperation between health care providers and the Medicare+Choice organization, as well as within the Medicare+Choice organization itself;
- Improved communication with and satisfaction of Medicare+Choice enrollees;
- The ability to more quickly and accurately react to employees' operational compliance concerns and the capability to effectively target resources to address those concerns;
- A concrete demonstration to employees and the community at large of the Medicare+Choice organization's strong commitment to honest and responsible corporate conduct;
- The ability to obtain an accurate assessment of employee and contractor behavior relating to fraud and abuse;
- Improved (clinical and non-clinical) quality of care and service;
- Improved assessment tools that could affect many or all of the Medicare+Choice organization's divisions or departments;
- Increased likelihood of identification and prevention of unlawful and unethical conduct;
- A centralized source for distributing information on health care statutes, regulations and other program directives related to fraud and abuse;
- An environment that encourages employees to report potential problems;
- Procedures that allow the prompt, thorough investigation of possible misconduct by corporate officers, managers, employees and independent contractors;
- An improved relationship with the Center for Health Plans and Providers (CHPP) at HCFA;
- Early detection and reporting, minimizing the loss to the Government from false claims, and thereby reducing the Medicare+Choice organization's exposure to civil damages and penalties, criminal sanctions, and administrative remedies, such as program exclusion;[6] and
- An enhancement of the structure of the Medicare+Choice organization's separate business units.

Overall, the OIG believes that an effective compliance program is a sound

[5] *See* 42 U.S.C. 1395w–26(b)(3); 42 CFR 422.402. The Federal preemption provisions in the Medicare+Choice regulations cover: (1) any State statutes, regulations, contract requirements, or any other standards that would otherwise apply to Medicare+Choice organizations only to the extent that such State laws are inconsistent with the standards under 42 CFR part 422; and (2) State laws that are specifically preempted in 42 CFR 422.402(b).

[6] The OIG, for example, will consider the existence of an effective compliance program that pre-dated any governmental investigation when addressing the appropriateness of administrative sanctions. However, the burden is on the Medicare+Choice organization to demonstrate the operational effectiveness of a compliance program. Further, the False Claims Act, 31 U.S.C. 3729–3733, provides that a person who has violated the Act, but who voluntarily discloses the violation to the Government within thirty days of detection, in certain circumstances will be subject to not less than double, as opposed to treble, damages. *See* 31 U.S.C. 3729(a). In addition, an organization will receive sentencing credit for an ''effective'' compliance program under the Federal Sentencing Guidelines. *See* United States Sentencing Commission Guidelines, *Guidelines Manual*, 8C2.5. Thus, the ability to react quickly when violations of the law are discovered may materially reduce the Medicare+Choice organization's liability.

business investment that has the potential of enhancing the efficiency and effectiveness of the Medicare+Choice organization. It may also improve the Medicare+Choice organization's financial structure by addressing not only fraud and abuse concerns, but efficiency and productivity concerns in other operational areas.

The OIG recognizes the implementation of an effective compliance program may not entirely eliminate fraud, abuse and waste from an organization. However, a sincere effort by a Medicare+Choice organization to comply with applicable Federal and State standards, through the establishment of an effective compliance program, significantly reduces the probability of unlawful or improper conduct.

B. Application of Compliance Program Guidance

Before explaining the specific elements of a compliance program, it is important to emphasize several aspects of this document: its voluntary nature, its applicability to Medicare+Choice organizations that offer coordinated care plans, the collaborative nature by which it was developed, and its evolving nature.

First, it should be re-emphasized that while the regulations implementing the Medicare+Choice program, or Part C, require a Medicare+Choice organization to establish a compliance plan, including specified elements,[7] this program guidance is voluntary. Although this document presents basic procedural and structural guidance for designing a compliance program, it is not in itself a compliance program. Rather, it is a set of guidelines for consideration by a Medicare+Choice organization interested in obtaining specific information on implementing a compliance program. This guidance represents the OIG's suggestions on how a Medicare+Choice organization can establish internal controls and monitor company conduct to correct and prevent fraudulent activities.

It is critical for the Medicare+Choice organization to assess its own organization and determine its needs with regard to compliance with applicable Federal and State statutes and Federal health care program requirements. By no means should the contents of this guidance be viewed as an exclusive discussion of the advisable components of a compliance program. On the contrary, the OIG strongly encourages Medicare+Choice organizations to develop and implement compliance components that uniquely address the individual organization's risk areas.

Implementing a compliance program in the managed care industry is a complicated venture. There are significant variances and complexities among Medicare+Choice organizations in terms of the type of services and the manner in which these services are provided to the respective members. For example, some Medicare+Choice organizations cover broad service areas, while others are focused on a particular geographic region. Similarly, the range of benefits covered differ among plans. Clearly, these differences may give rise to different substantive policies to ensure effective compliance. Furthermore, some Medicare+Choice organizations are relatively small (such as provider-sponsored organizations (PSOs)), while others are fully integrated and offer Medicare+Choice plans[8] in a wide variety of areas. Finally, the availability of resources for any one Medicare+Choice organization can differ vastly.

Notwithstanding these differences, this guidance is pertinent for all Medicare+Choice organizations, large or small, regardless of the type of services provided. The applicability of the recommendations and guidelines provided in this document may depend on the circumstances and resources of each particular Medicare+Choice organization. However, regardless of the organization's size and structure, the OIG believes every Medicare+Choice organization can and should strive to accomplish the objectives and major principles underlying all of the compliance policies and procedures recommended within this guidance.

The OIG recognizes that the success of the compliance program guidance hinges on thoughtful and practical comments from those individuals and organizations that will utilize the tools set forth in this document. In a continuing effort to collaborate closely with the private sector, the OIG solicited input and support from the public in the development of this compliance program guidance.[9] Further, we took into consideration previous OIG publications, such as Special Fraud Alerts, the recent findings and recommendations in reports issued by OIG's Office of Audit Services (OAS) and Office of Evaluation and Inspections (OEI),[10] comments from HCFA, as well as the experience of past and recent fraud investigations related to managed care organizations[11] conducted by OIG's Office of Investigations (OI) and the Department of Justice.

As appropriate, this guidance may be modified and expanded as more information and knowledge is obtained by the OIG, and as changes in the law, and in the rules, policies and procedures of the Federal and State plans occur. The OIG understands Medicare+Choice organizations will need adequate time to react to these modifications and expansions and to make any necessary changes to their voluntary compliance programs. New compliance practices may eventually be incorporated into this guidance if the OIG discovers significant enhancements to better ensure an effective compliance program. We recognize the development and implementation of compliance programs in Medicare+Choice organizations often raise sensitive and complex legal and managerial issues.[12] However, the OIG wishes to offer what it believes is critical guidance for those who are sincerely attempting to comply with the relevant health care statutes and regulations.

II. Compliance Program Elements

The elements proposed by these guidelines are similar to those of the other OIG Compliance Program Guidances[13] and our corporate integrity agreements.[14] As noted above, the elements represent a guide that can be tailored to fit the needs and financial realities of a particular Medicare+Choice organization, large or

[7] *See* note 4.

[8] A ''Medicare+Choice plan,'' as defined in this guidance, refers to health benefits coverage offered under a policy or contract by a Medicare+Choice organization that includes a specific set of health benefits offered at a uniform premium and uniform level of cost sharing to all Medicare beneficiaries residing in the service area of the Medicare+Choice plan. *See* 42 CFR 422.2.

[9] *See* Solicitation of Information and Recommendations for Developing the OIG Compliance Program Guidance for Certain Medicare+Choice Organizations. 63 FR 50577 (9/22/98).

[10] Special Fraud Alerts are available on the OIG website at http://www.dhhs.gov/progorg/oig. The recent findings and recommendations of OAS and OEI can be located on the Internet at http://www.hhs.gov/progorg/oas/cats/hcfa.html and http://www.hhs.gov/progorg/oei, respectively.

[11] These investigations include findings based upon Medicare risk-based Health Maintenance Organizations as defined in 42 U.S.C. 1395mm.

[12] Nothing stated herein should be substituted for, or used in lieu of, competent legal advice from counsel.

[13] *See* note 1.

[14] Corporate integrity agreements are executed as part of a civil settlement agreement between the health care provider and the Government to resolve a case based on allegations of health care fraud or abuse. These OIG-imposed programs are in effect for a period of three to five years and require many of the elements included in this compliance guidance.

small, regardless of the type of services offered.

Every effective compliance program must begin with a formal commitment [15] by the Medicare+Choice organization's governing body to include *all* of the applicable elements listed below. A good faith and meaningful commitment on the part of the Medicare+Choice organization's administration, especially the governing body and the chief executive officer (CEO), will substantially contribute to the program's successful implementation. These elements are based on the seven steps of the Federal Sentencing Guidelines. [16] We believe every Medicare+Choice organization can implement all of the recommended elements and expand upon them, as appropriate.

At a minimum, comprehensive compliance programs should include the following seven elements:

(1) The development and distribution of written standards of conduct, as well as written policies and procedures, that promote the Medicare+Choice organization's commitment to compliance and that address specific areas of potential fraud (*e.g.*, the marketing process, and underutilization);

(2) The designation of a chief compliance officer and other appropriate bodies, *e.g.*, a corporate compliance committee, charged with the responsibility of operating and monitoring the compliance program and who report directly to the CEO and the governing body;

(3) The development and implementation of regular, effective education and training programs for all affected employees;

(4) The development of effective lines of communication between the compliance officer and all employees, including a process, such as a hotline, to receive complaints (and the adoption of procedures to protect the anonymity of complainants and to protect callers from retaliation);

(5) The use of audits or other risk evaluation techniques to monitor compliance and assist in the reduction of identified problem areas;

(6) The development of disciplinary mechanisms to consistently enforce standards and the development of policies addressing dealings with sanctioned and other specified individuals; and

(7) The development of policies to respond to detected offenses and to initiate corrective action to prevent similar offenses.

A. Written Policies and Procedures

Every compliance program should require the development and distribution of written compliance policies, standards and practices that identify specific areas of risk and vulnerability to the Medicare+Choice organization. These policies should be developed under the direction and supervision of the chief compliance officer and the compliance committee and, at a minimum, should be provided to all individuals who are affected by the particular policy at issue, including the Medicare+Choice organization's agents and independent contractors.[17]

Medicare+Choice organizations maintain ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of their contract with HCFA.[18] It is with this in mind that the OIG strongly recommends that the Medicare+Choice organization coordinate with its first tier and downstream providers to establish compliance responsibilities,[19] in addition to the contractual responsibilities required by HCFA.[20] For example, OIG recommends that the Medicare+Choice organization coordinate with its contracting providers regarding the steps that should be taken by the providers to verify and confirm to the Medicare+Choice organization the accuracy of information and data submitted to the Medicare+Choice organization concerning patient encounters and fee-for-service claims. Once the responsibilities have been clearly delineated, they should be formalized in legally enforceable written arrangement between the health care provider and the Medicare+Choice organization. The OIG recommends this document enumerate those functions that are shared responsibilities and those that are the sole responsibility of the Medicare+Choice organization.

1. Standards of Conduct

Medicare+Choice organizations should develop standards of conduct for all affected employees that include a clearly delineated commitment to compliance by the organization's senior management and its divisions. To help communicate a strong and explicit organizational commitment to compliance goals and standards, the Medicare+Choice organization's governing body, CEO, chief operating officer (COO), general counsel, chief financial officer (CFO) and other senior officials should be directly involved in the development of standards of conduct.

The standards should function in the same fashion as a constitution, *i.e.*, as a foundational document that details the fundamental principles, values and framework for action within an organization, as well as the organization's mission and goals. The standards should also articulate the Medicare+Choice organization's commitment to comply with all Federal and State standards, with an emphasis on preventing fraud and abuse. The standards should not only address compliance with statutes and regulations, but should also set forth broad principles that guide employees in conducting business professionally and properly. In short, the standards should promote integrity, support objectivity and foster trust. Furthermore, a Medicare+Choice organization's standards of conduct should reflect a commitment to the highest quality health care delivery, as evidenced by its quality, reliability and timeliness.

2. Written Policies for Risk Areas

As part of its commitment to compliance, Medicare+Choice organizations should establish a comprehensive set of written policies that address all applicable statutes, rules and program instructions that apply to each function or department of the Medicare+Choice organization.[21] The

[15] Formal commitment may include a resolution by the board of directors, where applicable. A formal commitment does include the allocation of adequate resources to ensure that each of the elements is addressed.

[16] *See* United States Sentencing Commission Guidelines, *Guidelines Manual*, 8A1.2, comment. (n.3(k)). The Federal Sentencing Guidelines are detailed policies and practices for the Federal criminal justice system that prescribe appropriate sanctions for offenders convicted of Federal crimes.

[17] According to the Federal Sentencing Guidelines, an organization must have established compliance standards to be followed by its employees and other agents in order to receive sentencing credit. The Guidelines define ''agent'' as ''any individual, including a director, an officer, an employee, or an independent contractor, authorized to act on behalf of the organization.'' *See* United States Sentencing Commission Guidelines, *Guidelines Manual*, 8A1.2, Application Note 3(d).

[18] *See* 42 CFR 422.502(i).

[19] At a minimum, the Medicare+Choice organization should send a copy of its compliance program manual to all of its health care providers. The Medicare+Choice organization should also coordinate with its health care providers in the development of a training program, an audit plan and policies for investigating misconduct.

[20] *See* 42 CFR 422.502(i)(3)–(4).

[21] This includes, but is not limited to, the Medicare+Choice provisions and the fraud and abuse provisions of the Balanced Budget Act of 1997, Pub.L. 105–33; the civil False Claims Act, 31 U.S.C. 3729–3733; the criminal false claims statutes, 18 U.S.C. 287, 1001; the fraud and abuse provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub.L. 104–191; and the civil monetary penalties in the Social

Continued

policies should address specific areas of concern, such as marketing practices and data collection and submission processes. In contrast to the standards of conduct, which are designed to be a clear and concise collection of fundamental standards, the written policies should articulate specific procedures personnel should follow when performing their duties.

In order to determine what policies and procedures are needed, the OIG recommends that Medicare+Choice organizations conduct a comprehensive self-administered risk analysis or contract for an independent risk analysis by experienced health care consulting professionals. This risk analysis should identify and rank the various compliance and business risks the company may experience in its daily operations. A Medicare+Choice organization's prior history of noncompliance with applicable statutes, regulations and Federal health care program requirements may indicate additional types of risk areas where the organization may be vulnerable and may require necessary policy measures to prevent avoidable recurrence.[22]

The fact that Medicare+Choice organizations may be both providers and insurers of health care increases the number and type of risk areas to which a Medicare+Choice organization must be attuned, as well as the type of auditing and monitoring procedures that must be implemented, in the development of its compliance efforts. For example, an individual Medicare+Choice organization may contract with a variety of providers with different specialities and, consequently, must consider a variety of different risk areas.

The regulations and operational policies issued by HCFA that implement the Medicare+Choice program are very comprehensive and should serve as the basis for the policies and procedures of a Medicare+Choice organization.[23] The legal and policy requirements that organizations must meet to qualify as a Medicare+Choice organization are articulated in documentation promulgated by HCFA and other Federal agencies and should be considered de facto risk areas. Included among these risk areas are: (1) The election process; (2) benefits and beneficiary protections; (3) quality assurance; (4) premiums and cost sharing; (5) solvency, licensure and other State regulatory issues; (6) claims processing; and (7) appeals and grievance procedures. Given the detailed nature of the rules and regulations, we have not attempted in this document to identify each and every policy that should be established by a Medicare+Choice organization. Rather, based on a review OIG audits, investigations and evaluations, we have identified the following areas of particular concern to OIG that the Medicare+Choice organization should consider in developing its written policies and procedures:[24]

- Marketing materials and personnel;
- Selective marketing and enrollment;
- Disenrollment;
- Underutilization and quality of care;
- Data collection and submission processes;
- Anti-kickback statute and other inducements; and
- Anti-dumping statute.

As note above, the list is not all-encompassing and the Medicare+Choice organization should conduct additional surveys and statistical analysis specifically tailored to the organization's beneficiary population and organizational structure.[25]

The following sections provide specific guidance regarding the types of policies that should be implemented by Medicare+Choice organizations.

a. Marketing Materials and Personnel

While each Medicare+Choice organization must comply with all of HCFA's detailed requirements relating to marketing their plans,[26] OIG is particularly concerned that organizations have policies regarding: (1) the completeness and accuracy of the marketing materials; and (2) marketing personnel.

Accurate and useful information is crucial to the success of the Medicare+Choice program. OIG is very concerned that Medicare+Choice organizations correctly and completely describe plan information in any marketing materials or other materials distributed to individuals once enrolled in the plan. Medicare+Choice organizations that misrepresent or falsify information submitted to HCFA, individuals or entities are subject to civil monetary penalties (CMPs).[27]

The submission of inaccurate or misleading information is of particular concern in light of the recent study conducted by the General Accounting Office (GAO) that examined 16 managed care organizations and found that all organizations had distributed materials containing inaccurate or incomplete benefit information.[28] It should be noted that HCFA had reviewed and approved the materials from all the organizations in the GAO study. Given this finding, Medicare+Choice organizations should take special care to ensure that all marketing materials are accurate, notwithstanding whether the materials have been approved by HCFA.[29]

HCFA considers marketing materials to include any material used by a Medicare+Choice organization to contact a Medicare beneficiary. As such, marketing materials go beyond the public's general conception of marketing materials and include general circulation brochures, leaflets, newspapers, magazines, television, radio, billboards, yellow pages, the Internet, slides and charts, and leaflets for distribution by providers. Such materials also include membership communication materials such as membership rules, subscriber agreements, or confirmation of enrollment.[30] Accordingly,

Security Act, 42 U.S.C. 1320a–7a and 42 U.S.C. 395w–27(g). *See also* 42 CFR 422.1–422.312.

[22] ''Recurrence of misconduct similar to that which an organization has previously committed casts doubt on whether it took all reasonable steps to prevent such misconduct'' and is a significant factor in the assessment of whether a compliance program is effective. *See* United States Sentencing Commission Guidelines, *Guidelines Manual,* 8A1.2, Application Note 3(7)(ii).

[23] Medicare+Choice organizations should regularly access the HCFA managed care website for updates on operational policies and procedures. Operational Policy Letters can be located on HCFA's website at http://www.hcfa.gov/medicare/mgd-ops.htm.

[24] Medicare+Choice organizations may also want to consult the OIG's Work Plan when conducting the risk assessment. The OIG Work Plan details the various projects the OIG currently intends to address in the fiscal year. It should be noted that the priorities in the Work Plan are subject to modification and revision as the year progresses and the Work Plan does not represent a complete or final list of areas of concern to the OIG. The Work Plan is currently available on the Internet at http://www.dhhs.gov/progorg/oig.

[25] Although many of these areas apply specifically to Medicare+Choice organizations, many of the areas identified below have analogous issues in non-Medicare organizations. Medicare+Choice organizations that provide private managed care products should establish additional policies and procedures for risk areas that apply specifically to those areas. Some overlap with Medicare+Choice policies will likely occur, however Medicare+Choice organizations should segregate any policies and procedures for which HCFA has instituted specific reporting requirements for the Medicare population.

[26] Medicare+Choice organizations should ensure that they conform to fair marketing standards as set forth in the statute, the Medicare Managed Care National Marketing Guide (Marketing Guide)(which can be located on the HCFA Managed Care website at http://www.hcfa.gov/medicare/mgd-ops.htm) and all HCFA Operational Policy Letters affecting marketing matters.

[27] 42 U.S.C. 1395w–27(g).

[28] ''Medicare+Choice: New Standards Could Improve Accuracy and Usefulness of Plan Literature.'' (GAO/HEHS–99–92)(April 1999).

[29] Medicare+Choice organizations may not distribute marketing materials or election forms unless they are approved by HCFA. 42 CFR 422.80.

[30] 42 CFR 422.80(b).

Medicare+Choice organizations should carefully scrutinize all of these materials for completeness, accuracy and compliance with HCFA rules.

In verifying that marketing materials meet all HCFA requirements, Medicare+Choice organizations should ensure that the materials contain an adequate written description of rules, procedures, basic benefits and services, and an explanation of the grievance and appeals process.[31] Of particular concern to HCFA and OIG is that the concept of ''lock-in'' is clearly explained in all marketing material. Many Medicare beneficiaries are unfamiliar with the notion that managed care may limit their health care provider choices. Describing the process of selecting a primary care physician and the limitations that this places on a Medicare+Choice enrollee's choice of provider will significantly reduce the unmet expectations of Medicare beneficiaries.

Another important concept to include in the marketing materials is the fact that the beneficiary may be terminated from enrollment in the plan due to the decision of the Medicare+Choice organization not to renew its contract with HCFA, or due to HCFA's decision to refuse to renew the contract.[32] This termination can affect the enrollee's [33] eligibility for supplemental insurance and other benefits.

Second, in light of the critical role that marketing personnel play in representing the plan to Medicare enrollees, the Medicare+Choice organization must take all appropriate steps to ensure that marketing personnel are presenting clear, complete and accurate information to potential enrollees. To that end, OIG strongly encourages Medicare+Choice organizations to employ their own marketing personnel, as opposed to contracting these responsibilities to outside entities.[34] This provides the Medicare+Choice organization the necessary control to ensure that these individuals meet all HCFA guidelines. Similarly, it safeguards Medicare beneficiaries from practices that could seriously endanger their access to health care to which they are entitled, and their ability to acquire accurate and complete information regarding their health care options.

Medicare+Choice organizations should also be aware that OIG and HCFA strongly discourage the use of physicians as marketing agents for several reasons: (1) physicians are usually not fully aware of membership plan benefits and costs; (2) physicians may not be the best source of membership information about their patients; (3) when a physician acts outside his or her traditional role as care provider, the physician's patients may be confused as to when the physician is acting as an agent of the plan, and when the physician is acting to further the interests of the patient; and (4) a physician's knowledge of a patient's health status increases the potential for discriminating in favor of Medicare beneficiaries with positive health status when acting as a marketing agent.[35] Therefore, the organization should develop procedures to prevent the use of physicians in this way.

b. Selective Marketing and Enrollment

OIG is very concerned about the practice known as ''cherry-picking,'' or selective marketing,[36] in which Medicare+Choice organizations discriminate in the marketing and enrollment process based upon an enrollee's degree of risk for costly or prolonged treatment.[37] Except for individuals who have been medically determined to have end-stage renal disease, a Medicare+Choice organization may not deny, limit or condition the coverage or furnishing of benefits to individuals eligible to enroll in a Medicare+Choice plan offered by the organization on the basis of any factor that is related to health status, including, but not limited to, the following: (1) Medical condition (including mental illness); (2) claims experience; (3) receipt of health care; (4) medical history; (5) genetic information; (6) evidence of insurability; and (7) disability.[38] Engaging in practices that would reasonably be expected to have the effect of denying or discouraging enrollment by eligible individuals whose medical condition or history indicates the need for substantial future medical services subjects the Medicare+Choice organization to a CMP.[39]

Certain types of practices clearly fall into the category of cherry-picking and Medicare+Choice organizations should implement policies to prohibit such practices. For example, organizations should prohibit employees from conducting medical screening, *i.e.*, asking the beneficiary medical questions prior to enrollment.[40] In a 1996 survey, the OIG found that such screening for health status at application was reported by 18 percent of beneficiaries. While this represented a reduction from the 1993 level of 43 percent, it still represents a potentially serious problem.[41]

Another way in which Medicare+Choice organizations may inappropriately target healthier beneficiaries is by marketing their plans in places where healthy enrollees would be more likely to be present, such as at health and exercise clubs, or in areas that are difficult to access for people with disabilities (*e.g.*, upper floors of buildings that do not have elevators).[42] Similarly, organizations may inappropriately provide inducements to potential enrollees in a way that would encourage younger, healthier beneficiaries to enroll in the plan. For example, the offering of free gym memberships or kayaking or other sporting lessons would appeal to a healthy class of enrollees and discriminate against those who would not be interested in such activities.[43]

[31] 42 CFR 422.80(c).

[32] 42 CFR 422.80(c)(3).

[33] Periodic on-site visits of the Medicare+Choice organization's operations, bulletins with compliance updates and reminders, distribution of audiotapes or videotapes on different risk areas, lectures at management and employee meetings, circulation of recent health care articles covering fraud and abuse and innovative changes to compliance training are various examples of approaches and techniques the compliance officer can employ for the purpose of ensuring continued interest in the compliance program and the Medicare+Choice organization's commitment to its principles and policies.

[34] It should be noted that Medicare+Choice organizations have ultimate responsibility for the acts and omissions of its marketing agents. See 42 CFR 422.502(i).

[35] *See* Marketing Guide, Chapter IV.

[36] OIG is also concerned about a similar problem, known as ''gerrymandering,'' which is an attempt to eliminate certain high dollar risk areas from the Medicare+Choice organization's service area. Medicare+Choice organizations should be sure to have policies in place to prohibit such practices.

[37] Although the Medicare+Choice program has attempted to alleviate many of the selective marketing practices through the use of risk adjustment, the phase-in period for risk-adjustment virtually assures that this will remain a troubling issue at least through 2004.

[38] *See* 42 U.S.C. 1395w–22(b)(1); 42 CFR 422.110.

[39] 42 U.S.C. 1857(g)(1)(D).

[40] This screening can be done in a number of ways, such as by using cards or coupons requesting medical and other information as part of a survey to potential enrollees.

[41] ''Beneficiary Perspectives of Medicare Risk HMOs 1996.'' (OEI–06–95–00430) (March 1998).

[42] In fact, Medicare+Choice organizations are required to allocate part of their resources to marketing to the Medicare population with disabilities and beneficiaries aged 65 and over. 42 CFR 422.80(e)(2)(i).

[43] The statute prohibits the provision of cash or other monetary rebates as an inducement for enrollment in the plan. *See* 42 U.S.C. 1395w–21(h)(4)(A). However, HCFA allows Medicare+Choice organizations to give Medicare beneficiaries nominal value gifts, provided that the plan offers these gifts whether or not the beneficiary enrolls in the plan. HCFA defines nominal value as an item having little or no resale value (generally, less than $10), which cannot be readily converted into cash. *See* Marketing Guide, Chapter II. The use of inducements is also discussed in Section II.B.2.f.—Anti-kickback and Other Inducements.

Other examples of cherry-picking would be: (1) attempts to give enrollment priority to newly eligible Medicare beneficiaries (who are theoretically younger and healthier); (2) the tracking of costs incurred by enrollees who were enrolled in different settings (*e.g.*, at the health fair, or at a health club), which could be used to target healthier enrollees in the future; or (3) re-enrollment campaigns targeting past plan subscribers who had low medical costs. There are many other subtle ways in which a Medicare+Choice organization may try to enroll healthy patient populations and the organization should implement policies to prohibit such practices.

c. Disenrollment

In general, Medicare+Choice organizations are prohibited from disenrolling, or requesting or encouraging (either by action or inaction) an individual to disenroll from any plan it offers.[44] If a Medicare+Choice organization acts to expel or refuses to reenroll an individual in violation of the statute, a civil monetary penalty can be imposed on the organization.[45] OIG is particularly concerned about disenrollment in light of its recent review, which revealed that there was a problem with disenrollment of beneficiaries just prior to receiving expensive inpatient services.[46]

In this review, OIG found that Medicare paid for inpatient hospital services amounting to $224 million in fee-for-service (FFS) payments within three months of beneficiaries' disenrollment from six risk plans during 1991 through 1996. Had these beneficiaries not disenrolled, Medicare would have paid the HMOs $20 million in monthly capitation payments. Had the beneficiaries remained in the HMOs, Medicare would have saved $204 million in expenditures. Included in the Medicare FFS payments were $41 million for beneficiaries who disenrolled, had FFS procedures performed, and then reenrolled into another or the same managed care plan.

While this study did not identify the reasons for the disenrollment as part of this review, one partial explanation of the review is that some managed care plans may be encouraging sicker beneficiaries to disenroll as a way to avert their own costs at a high cost to the Medicare system.

Each Medicare+Choice organization must implement policies to ensure that inappropriate disenrollment does not occur. Such policies should include clarification of when it is appropriate for medical personnel to discuss the concept of disenrollment. Generally speaking, OIG believes it would be inappropriate for medical personnel to initiate discussion of disenrollment or to promote disenrollment except in the rare circumstance where the Medicare+Choice organization cannot provide the covered medical items or services needed by the patient.

d. Underutilization and Quality of Care

Medicare+Choice organizations must ensure that all covered services are available and accessible to all enrollees.[47] OIG views the inappropriate withholding or delay of services, known as underutilization or ''stinting,'' as a serious concern.[48] Examples of practices that can lead to underutilization and poor quality include the failure to employ or contract with sufficient institutional and individual providers to accommodate all enrollees, the failure to provide geographically reachable services to enrollees, the delay in approving or failure to approve referrals for covered services, the establishment of utilization review procedures that are so burdensome that an enrollee could not reasonably be expected to fulfill the requirements, and the categorical denial of payment of claims.

There are a wide variety of policies that a Medicare+Choice organization should implement to be sure it is providing all medically necessary services to its enrollees. The regulations and guidelines that implement the Medicare+Choice program contain numerous provisions that deal with this issue. While we have not attempted to develop a comprehensive list in this document, we would like to highlight three types of policies that Medicare+Choice organizations should develop that may help address underutilization and quality of care.

First, Medicare+Choice organizations should have policies that prohibit interference with health care professionals' advice to enrollees. Also known as the ''gag rule,'' this prohibition extends to advice regarding the patient's health status, medical care, and treatment options, the risks, benefits and consequences of treatment or non-treatment, or the opportunity for the individual to refuse treatment and to express preferences about future treatment options.[49] Failure to comply with this requirement can lead to sanctions.[50]

Second, Medicare+Choice organizations should be sure, to the extent that they utilize physician incentive plans (PIPs) in their payment arrangements with individual physicians or physician groups, that they comply with all applicable regulations. The PIPs raise utilization concerns because they are defined as ''any compensation arrangement that may directly or indirectly have the effect of reducing or limiting services provided to plan enrollees.'' [51] Any PIP operated by a Medicare+Choice organization must comply with the following requirements. First, it may make no payments to physicians (such as offerings of monetary value, including, but not limited to, stock options or waivers of debt [52]) to reduce or limit medically necessary services. Second, if the PIP puts a physician or physician group at ''substantial financial risk'' [53] for referral services, the Medicare+Choice organization must: (1) survey current and previously enrolled members to assess access to and satisfaction with the quality of services; and (2) assure that there is adequate and appropriate stop-loss protection.[54] Finally, Medicare+Choice organizations must disclose certain information regarding their PIPs. These disclosure requirements apply to direct contracting arrangements, as well as subcontracting arrangements.[55]

In general, Medicare+Choice organizations should take all necessary steps to ensure that they comply with the Guidance on Disclosure of Physician Incentive Plan, the Guidance on Surveys required by the Physician Incentive Plan Regulation and the Physician Incentive Plan Regulation Requirements.[56]

---

[44] Medicare+Choice organizations are entitled to disenroll individuals under certain circumstances, *e.g.*, failure to pay premiums or engagement in disruptive behavior. 42 CFR 422.74.

[45] 42 U.S.C. 1857(g)(1)(C).

[46] ''Review of Inpatient Services Performed on Beneficiaries After Disenrolling from Medicare Managed Care.'' (A–07098–01256) (May 1999).

[47] 42 U.S.C. 1395w–22.

[48] Medicare+Choice organizations can be subject to sanction for failing substantially to provide medically necessary items and services that are required to be provided, if the failure has adversely affected (or has the substantial likelihood of adversely affecting) the individual. 42 U.S.C. 1395w–27(g)(1)(A).

[49] 42 U.S.C. 1395w–22(j)(3), 42 C.F.R. § 422.206.

[50] 42 U.S.C. 1395w–27(g)(1)(F).

[51] *See* 42 CFR 422.208.

[52] *See* 42 U.S.C. 1395w–22(j)(4); 42 CFR 422.208.

[53] ''Substantial financial risk'' threshold is set at 25 percent of potential payments for covered services, regardless of the frequency of assessment (*i.e.*, collection) or distribution of payments. *See* 42 CFR 422.208.

[54] *See* 42 CFR 422.208(c).

[55] *See* 42 CFR 422.210(a).

[56] These documents can be found on the HCFA managed care website at http://www.hcfa.gov/medicare/mgd-ops.htm. Disclosure forms can be located at HCFA's website at http://www.hcfa.gov/medicare/physincp/pip-info.htm. Medicare+Choice organizations may elect paperless PIP disclosure.

Finally, OIG is aware of cases in which beneficiaries have received covered services from individuals that were not appropriately licensed. Given the serious quality of care implications of this type of practice, OIG is particularly concerned that Medicare+Choice organizations have procedures for the selection of providers, including criteria for the credentialing of providers. This process should include an application, verification of information and a site visit, where applicable.[57] The information that must be verified includes that the individual has a valid license to practice, clinical privileges in good standing and appropriate educational qualifications.

e. Data Collection and Submission Processes

The regulations implementing the Medicare+Choice program contain numerous requirements relating to the data collection and submission process, ranging from a requirement for an effective system for receiving, controlling, and processing election forms[58] to requirements for the timely submission of disenrollment notices.[59] These requirements cover the gamut of requirements with which a Medicare+Choice organization must comply and are too detailed to enumerate in this document. Medicare+Choice organizations should establish a policy that all required submissions to HCFA be accurate, timely and complete and that all appropriate reporting requirements are met.[60]

OIG is particularly concerned that Medicare+Choice organizations submit accurate information when that data determines the amount of payment received from HCFA. The regulations require that when a Medicare+Choice organization requests payment under the contract, the CEO or CFO must certify the accuracy, completeness and truthfulness of relevant data, including enrollment data, encounter data, and information provided as part of an adjusted community rate (ACR) proposal.[61] When a Medicare+Choice organization submits this type of data to HCFA, it is making a ''claim'' for capitation payment in the amount dictated by the data submitted, or in the case of the ACR submission, a ''claim'' to retain the portion of the capitation amount that is under the ACR amount, rather than providing additional benefits. When a Medicare+Choice organization is claiming payment (or the right to retain payment) based upon information submitted to HCFA, it must take responsibility for having taken reasonable steps to assure the accuracy of this information. The attestation forms developed by HCFA for this purpose require certification that the information submitted is true and accurate based on best knowledge, information, and belief.

The requirement that the CEO or CFO certify as to the accuracy, completeness and truthfulness of data, based on best knowledge, information and belief, does not constitute an absolute guarantee of accuracy. Rather, it creates a duty on the Medicare+Choice organization to put in place an information collection and reporting system reasonably designed to yield accurate information. Furthermore, the Medicare+Choice organization must conduct audits and spot checks of this system to verify whether it is yielding accurate information.

The knowing submission of false information to HCFA can lead to serious criminal or civil penalties.[62] Medicare+Choice organizations should be sure to implement policies so that the enrollment, encounter and ACR data submitted to HCFA is accurate, complete and truthful. While information from a variety of sources can affect this data, Medicare+Choice organizations should take note of two reports issued by the OIG that have found problems in two pieces of this data.

First, OIG recommends that Medicare+Choice organizations have policies and procedures in place that ensure that the administrative component of the ACR is calculated accurately.[63] As part of this process, Medicare+Choice organizations should have clearly defined criteria for claiming reimbursement for their administrative costs. These costs should not include any costs that are directly associated with furnishing patient care. All such costs should be allocated to the applicable operating component. The OIG has articulated serious concerns about the methodology used by managed care organizations in computing their administrative rate on the ACR proposal.[64] For example, computing an administrative rate based on the use of a medical utilization factor could generate a payment that is almost three times what would be charged on the commercial side. The OIG believes that the allocation of ''administration'' should be determined in accordance with the Medicare program's longstanding principle that Medicare only pay its applicable or fair share of needed costs.

Second, OIG recommends that Medicare+Choice organizations have adequate internal controls in place to ensure that the institutional status of beneficiaries is reported accurately.[65] A recent report issued by OIG estimated that risk-based HMOs received Medicare overpayments of $22.2 million for beneficiaries incorrectly classified as institutionalized.[66] The incorrect classification was largely due to deficiencies in the HMOs internal controls in two areas: (1) Verification of beneficiaries' institutional status; and (2) reporting of institutional beneficiaries to HCFA. The results were based on audits of eight statistically selected HMOs.

f. Anti-kickback Statute and Other Inducements

The anti-kickback statute provides criminal penalties for individuals or entities that knowingly and willfully offer, pay, solicit or receive remuneration to induce the referral of business reimbursable under a Federal health care program (including Medicare and Medicaid).[67] The anti-

The PIP Data Entry Software is available on the Internet at http://www.fu.com/HPMS.

[57] 42 CFR 422.204.

[58] 42 CFR 422.60(e).

[59] 42 CFR 422.66(b)(3)(i).

[60] On a related topic, Medicare+Choice organizations should also be sure that their computer systems are Year 2000 (Y2K) compliant. A May 1999 OIG report indicates that based on a survey of Medicare managed care organizations, only 22 percent were Y2K ready, with two-thirds of the remainder reporting that they will be ready by December 31, 1999. The majority of the respondents were unaware of the Y2K readiness of their subcontractors. ''Y2K Readiness of Managed Care Organizations.'' (OEI–005–98–00590) (May 1999).

[61] 42 CFR 422.502(l) and (m). *See* Contract for Year 2000, Attachments A, B and C.

[62] Falsification of documentation in any application for any benefit or payment under a Federal health care program is a Federal offense punishable by not more than $25,000 or imprisonment for 5 years, or both. *See* 42 U.S.C. 1320a–7b. In addition, a CMP can be imposed for the misrepresentation or falsification of information submitted to HCFA under Medicare+Choice. *See* 42 U.S.C. 1395w–27(g)(1)(E).

[63] The administrative component of the ACR covers any management, financial or other costs that are incurred by or allocated to a business unit for the management or administration of the business unit as a whole.

[64] *See e.g.,* ''Administrative Costs Submitted by Risk-Based Health Maintenance Organizations on the Adjusted Community Rate Proposals are Highly Inflated.'' (A–14–97–00202) (July 1998).

[65] This will remain a concern until risk adjustment is fully implemented.

[66] ''Review of Medicare Managed Care Payments for Beneficiaries with Institutional Status.'' (A–05–98–00046) (April 1999).

[67] 42 U.S.C. 1320a–7b(b). If it is determined that a party has violated the anti-kickback statute, the individual or entity can be excluded from participation in the Medicare and other Federal health care programs (as defined in 42 U.S.C.

Continued

kickback statute potentially applies to many managed care arrangements because a common strategy of these arrangements is to offer physicians, hospitals and other providers increased patient volume in return for substantial fee discounts. Because discounts to managed care organizations can constitute ''remuneration'' within the meaning of the anti-kickback statute, a number of health care providers have expressed concern that many relatively innocuous, or even beneficial, commercial managed care arrangements implicate the statute and may subject them to criminal prosecution and administrative sanctions.

The OIG recognizes that when managed care organizations are paid a capitated amount for all of the services they provide regardless of the dates, frequency or type of services, there is no incentive for them to overutilize. In any event, even if overutilization occurs, the Federal health care programs are not at risk for these increased costs. Accordingly, OIG will be issuing a safe harbor from the anti-kickback statute that will provide protection for certain financial arrangements between managed care organizations (including Medicare+Choice organizations offering coordinated care plans) and individuals or entities with whom they contract for the provision of health care items or services, where a Federal health care program pays such organizations on a capitated basis.[68]

In general, the safe harbor protects payments between managed care organizations (including Medicare+Choice organizations offering coordinated care plans) and individuals or entities with which it has direct contracts to provide or arrange for the provision of items or services.[69] While this is a broad exception, there are three important limitations.

The first significant limitation is that there is no protection if the financial arrangements under the managed care agreement are implicitly or explicitly part of a broader agreement to steer fee-for-service Federal health care program business to the entity giving the discount to induce the referral of managed care business. Specifically, we understand that most managed care organizations have multiple relationships with their contractors and subcontractors for the provision of services for various product lines, including non-federal HMOs, preferred provider organizations (PPOs) and point of service networks. Consequently, although neither a managed care organization receiving a capitated payment from a Federal health care program nor its contractors or subcontractors has an incentive to overutilize items or services or pass additional costs back to the Federal health care programs under the capitated arrangement, we are concerned that a managed care organization or contractor may offer (or be offered) a reduced rate for its items or services in the Federal capitated arrangement in order to have the opportunity to participate in other product lines that do not have stringent payment or utilization constraints. This practice is a form of a practice known as ''swapping;'' in the case of managed care arrangements, low capitation rates could be traded for access to additional fee-for-service lines of business. We are concerned when these discounts are in exchange for access to fee-for-service lines of business, where there is an incentive to overutilize services provided to Federal health care program beneficiaries.

For example, we would have concerns where an HMO with a Medicare risk contract under Medicare Part C also has an employer-sponsored PPO that includes retirees and requires participating providers to accept a low capitation rate for the Medicare HMO risk patients in exchange for access to the Medicare fee-for-service patients in the PPO. Although in such circumstances the cost to the Medicare program for the risk-based HMO beneficiaries will not be increased, there may be increased expenditures for Medicare beneficiaries in the PPO arrangement, because the providers may have an incentive to increase services to the Medicare enrollees in the PPO to offset the discounted rates to the Medicare HMO. Accordingly, such arrangements could violate the anti-kickback statute and should not be protected.

A second limitation on the regulatory safe harbor protection is that it only applies to remuneration for health care items and services and those items or services reasonably related to the provision of health care items and services. It does not cover marketing services or any services provided prior to a beneficiary's enrollment in a health plan.

Finally, the broad protection is limited to risk-based managed care plans that do not claim any payment from a Federal health care program other than the capitated amount set forth in the managed care organization's agreement with the Federal health care program. Where the managed care plan, its contractors or its subcontractors are permitted to seek additional payments from any of the Federal health care programs, the regulatory safe harbor protection is significantly more limited. For example, protection is not extended to arrangements with subcontractors when the contract under section 1876 of the Social Security Act is cost-based or where the prime contract is protected solely because the contracting entity is a Federally-qualified HMO. In the first instance, reimbursement from the Federal health care program is based on costs, and in the latter case, services for Medicare enrollees are reimbursed on a fee-for-services basis. In both instances, reimbursement will increase with utilization, thus providing the same incentive to overutilize as any fee-for-service payment methodology.

While the new safe harbor will provide protection from the anti-kickback statute for most arrangements between Medicare+Choice organizations and their contractors, Medicare+Choice organizations should also have policies in place that ensure that any incentives offered to beneficiaries and potential beneficiaries do not run afoul of the anti-kickback statute or the new civil monetary penalty relating to incentives to beneficiaries.[70] The CMP was enacted in section 231(h) of HIPAA (42 U.S.C. 320a–7a(a)(5)) and imposes sanctions against individuals or entities that offer remuneration to a program beneficiary that they know, or should know, will influence the beneficiary's decision to order or receive items or services from a particular provider, practitioner or

1320a–7b(f)). 42 U.S.C. 1320a–7(b)(7). In addition, there is an administrative CMP provision for violating the anti-kickback statute. 42 U.S.C. 1320a–7a(a)(7).

[68] This safe harbor was developed in accordance with section 216 of HIPAA and section 14 of the Medicare and Medicaid Patient and Program Protection Act of 1987 (Pub. L. 100–93) through a negotiated rulemaking process that began in the spring of 1997. For a more detailed description of the negotiated rulemaking, see the Committee Statement of the Negotiated Rulemaking Committee on the Shared Risk Exception (January 22, 1998), which can be found on the Internet at http://www.dhhs.gov/progorg/oig.

[69] In addition, arrangements between direct contractors and all subcontractors or successive tiers of subcontractors are protected, as long as the arrangement is for the provision of health care items or services that are covered by the arrangement between the direct contractor and the managed care organization and the arrangement meets the requirements applicable to arrangements between the direct contractor and the managed care organization.

[70] Our concerns regarding the use of inducements in a manner that leads to enrollment of only healthy beneficiaries, such as offering memberships to exercise clubs for purposes of patient screening, is discussed above in Section II.B.2.b.-Selective Marketing and Enrollment.

supplier reimbursable by Medicare or the State health care programs.

Pending the publication of the final rule implementing this CMP, we can provide the following guidance. It is our view that organizations that provide incentives to Federal health care program beneficiaries to enroll in a *plan* are not offering remuneration to induce the enrollees to use a *particular provider, practitioner or supplier.* Accordingly, we anticipate that organizations that provide incentives to enroll in a plan will not be subject to sanctions under this provision. However, incentives provided by organizations to induce a beneficiary to use a particular provider, practitioner or supplier once the beneficiary has enrolled in a plan are within the purview of this CMP and are prohibited if they do not meet an exception. For example, incentives given to beneficiaries by a particular physician group within the physician panel of a Medicare+Choice organization to encourage the beneficiary to use that physician group over another physician in the panel would be prohibited.

g. Anti-Dumping

The OIG and HCFA believe that there may be special concerns regarding the provision of emergency services to enrollees of Medicare+Choice plans. The anti-dumping statute [71] imposes specific obligations on Medicare-participating hospitals that offer emergency services to individuals presenting themselves at the hospital seeking possible emergency treatment. While the obligations under the anti-dumping statute prohibit a hospital from inquiring into the patient's method of payment or insurance status, it has come to our attention that many hospitals routinely seek authorization from a Medicare+Choice enrollee's primary care physician or from the Medicare+Choice organization when a Medicare+Choice enrollee requests emergency services. The OIG and HCFA are cognizant that many managed care organizations require their enrollees to seek prior authorization for some medical services, including emergency services and that there are circumstances when patients should be informed of their potential financial liability. However, both the OIG and HCFA have concerns that a Medicare+Choice enrollee may be unduly influenced by hospital personnel to leave the hospital without obtaining necessary care.[72]

It is the view of OIG and HCFA that the anti-dumping statute requires that notwithstanding the terms of any managed care contractual arrangements, the provisions of the anti-dumping statute govern the obligations of hospitals to screen and provide stabilizing treatment to any patient presenting at an emergency facility. No contract between a hospital and managed care organization can excuse the hospital from the anti-dumping statute obligations. Once a Medicare+Choice enrollee comes to the hospital that offers emergency services, the law requires that the hospital must provide the services required under the anti-dumping statute without regard to the patient's insurance status or any prior authorization of such insurance. All Medicare+Choice organizations should have policies in place to ensure that these requirements are met.

Medicare+Choice organizations should be particularly careful of these requirements in the event that they participate in the so-called ''dual staffing'' of emergency departments. Dual staffing refers to the situation where hospitals have entered into arrangements allowing a managed care organization to station its own physicians in the hospital's emergency department for the purpose of screening and treating managed care enrollees. Implementation of dual staffing raises some concerns under the anti-dumping statute, particularly where different procedures and protocols have been established for each staff.

3. Retention of Records and Information Systems

Medicare+Choice organizations' compliance programs should provide for the implementation of a records retention system. This system should establish policies and procedures regarding the creation, distribution, retention, storage, retrieval and destruction of documents. The three types of documents developed under this system should include: (1) All records and documentation required by either Federal or State law and the program requirements of Federal and State health plans; (2) records listing the persons responsible for implementing each part of the compliance plan; and (3) all records necessary to protect the integrity of the Medicare+Choice organization's compliance process and confirm the effectiveness of the program. The documentation necessary to satisfy the third requirement includes: evidence of adequate employee training; reports from the Medicare+Choice organization's hotline; results of any investigation conducted as a consequence of a hotline call; modifications to the compliance program; self-disclosure; all written notifications to providers regarding compliance activities; [73] and the results of the Medicare+Choice organization's auditing and monitoring efforts.

In light of the increasing reliance on electronic data interchange by the health care industry, Medicare+Choice organizations should take particular care in establishing procedures for maintaining the integrity of its data collection systems. This should include procedures for regularly backing-up data (either by diskette, restricted system or tape) collected in connection with all aspects of the Medicare+Choice program requirements.

4. Compliance as an Element of a Performance Plan

Compliance programs should require that the promotion of, and adherence to, the elements of the compliance program be a factor in evaluating the performance of all employees. Employees should be periodically trained in new compliance policies and procedures. Policies should require that managers:

- Discuss with all supervised employees and relevant contractors the compliance policies and legal requirements applicable to their function;
- Inform all supervised personnel that strict compliance with these policies and requirements is a condition of employment; and
- Disclose to all supervised personnel that the Medicare+Choice organization will take disciplinary action up to and including termination for violation of these policies or requirements.

In addition to making performance of these duties an element in evaluations, the compliance officer or company management should include a policy that managers and supervisors will be sanctioned for failure to instruct adequately their subordinates or for failure to detect noncompliance with applicable policies and legal requirements, where reasonable diligence on the part of the manager or supervisor should have led to the discovery of any problems or violations.

[71] *See* 42 U.S.C. 1395dd. A separate provision prohibits Medicare+Choice organizations requiring enrollees to obtain prior authorization for emergency services. *See* 42 U.S.C. 1395w–22(d)(1)(E).

[72] OIG and HCFA have issued a proposed Special Advisory Bulletin on this topic. *See* 63 FR. 67486 (12/7/98).

[73] This should include notifications regarding quality of care issues; confusing or inaccurate encounter data; and termination of the contract.

B. Designation of a Compliance Officer and a Compliance Committee

1. Compliance Officer

Every Medicare+Choice organization should designate a compliance officer to serve as the focal point for compliance activities. This responsibility may be the individual's sole duty or added to other management responsibilities, depending upon the size and resources of the Medicare+Choice organization and the complexity of the task.

Designating a compliance officer with the appropriate authority is critical to the success of the program, necessitating the appointment of a high-level official in the Medicare+Choice organization with direct access to the company's governing body, the CEO and all other senior management and legal counsel.[74] While it is important that the compliance officer have appropriate authority, we are not suggesting that the compliance officer should have programmatic responsibility for the various aspects of the Medicare+Choice program. For example, the compliance officer should have full authority to stop the submission of data that he or she believes is problematic until such time as the issue in question has been resolved. In addition, the compliance officer should be copied on the results of all internal audit reports and work closely with key managers to identify aberrant trends in the areas that require certification. The compliance officer must have the authority to review all documents and other information that are relevant to compliance activities, including, but not limited to, beneficiary records (where appropriate) and records concerning the marketing efforts of the facility and the Medicare+Choice organization arrangements with other parties, including employees, professionals on staff, relevant independent contractors, suppliers, agents, supplemental staffing entities and physicians. This policy enables the compliance officer to review contracts and obligations (seeking the advice of legal counsel, where appropriate) that may contain referral and payment provisions that could violate statutory or regulatory requirements.

Coordination and communication are the key functions of the compliance officer with regard to planning, implementing and monitoring the compliance program. With this in mind, the OIG recommends the Medicare+Choice organization's compliance officer closely coordinate compliance functions with providers' compliance officers.

The compliance officer should have sufficient funding and staff to fully perform his or her responsibilities. These duties should include:

- Overseeing and monitoring the implementation of the compliance program;[75]
- Reporting on a regular basis to the Medicare+Choice organization's governing body, CEO and compliance committee on the progress of implementation and assisting these components in establishing methods to improve the Medicare+Choice organization's efficiency and quality of services and to reduce the Medicare+Choice organization's vulnerability to fraud, abuse and waste;
- Periodically revising the program in light of changes in the organization's needs and in the law and policies and procedures of Government and private payor health plans;
- Reviewing employees' certifications stating that they have received, read and understood the standards of conduct;
- Developing, coordinating and participating in a multifaceted educational and training program that focuses on the elements of the compliance program and seeks to ensure that all appropriate employees and management are knowledgeable of, and comply with, pertinent Federal and State standards;
- Coordinating personnel issues with the Medicare+Choice organization's human resources/personnel office (or its equivalent) to ensure that providers and employees do not appear in the List of Excluded Individuals/Entities and the GSA list of debarred contractors;[76]
- Assisting the Medicare+Choice organization's management in coordinating internal compliance review and monitoring activities, including annual or periodic reviews of departments;
- Independently investigating and acting on matters related to compliance, including the flexibility to design and coordinate internal investigations (*e.g.*, responding to reports of problems or suspected violations) and any resulting corrective action with all departments, providers and sub-providers, agents and, if appropriate, independent contractors;
- Developing policies and programs that encourage managers and employees to report suspected fraud and other improprieties without fear of retaliation; and
- Continuing the momentum of the compliance program and the accomplishment of its objectives long after the initial years of implementation.

2. Compliance Committee

The OIG recommends that a compliance committee be established to advise the compliance officer and assist in the implementation of the compliance program.[77] When assembling a team of people to serve as the Medicare+Choice organization's compliance committee, the company should include individuals with a variety of skills.[78] The OIG strongly recommends that the compliance officer manage the compliance committee. Once a managed care organization chooses the people that will accept the responsibilities vested in members of the compliance committee, the organization must train these individuals on the policies and procedures of the compliance program.

The committee's responsibilities should include:

- Analyzing the organization's regulatory environment, the legal requirements with which it must comply and specific risk areas;
- Assessing existing policies and procedures that address these areas for possible incorporation into the compliance program;
- Working with appropriate departments, as well as affiliated providers, to develop standards of

[74] The OIG believes that it is not advisable for the compliance function to be subordinate to the Medicare+Choice organization's general counsel, comptroller or similar company financial officer. Free-standing compliance functions help to ensure independent legal reviews and financial analyses of the institution's compliance activities. By separating the compliance function from the key management positions of general counsel or CFO (where the size and structure of the organization make this a feasible option), a system of checks and balances is established to more effectively achieve the compliance program's goals.

[75] For multi-site Medicare+Choice organizations, the OIG encourages coordination with each facility owned by the Medicare+Choice organization through the use of compliance liaisons at each site.

[76] *See* note 94.

[77] The compliance committee benefits from having the perspectives of individuals with varying responsibilities in the organization, such as operations, finance, audit, human resources, utilization review, medicine, claims processing, information systems, legal, marketing, enrollment and disenrollment as well as employees and managers of key operating units. These individuals should have the requisite seniority and comprehensive experience within their respective departments to implement any necessary changes in the company's policies and procedures.

[78] A Medicare+Choice organization should expect its compliance committee members and compliance officer to demonstrate high integrity, good judgment, assertiveness and an approachable demeanor, while eliciting the respect and trust of employees of the organization. The compliance committee members should also have significant professional experience in working with quality assurance, enrollment, marketing, clinical records and auditing principles.

conduct and policies and procedures that promote allegiance to the organization's compliance program;

- Recommending and monitoring, in conjunction with the relevant departments, the development of internal systems and controls to carry out the organization's standards, policies and procedures as part of its daily operations;
- Determining the appropriate strategy/approach to promote compliance with the program and detection of any potential violations, such as through hotlines and other fraud reporting mechanisms;
- Developing a system to solicit, evaluate and respond to complaints and problems; and
- Monitoring internal and external audits and investigations for the purpose of identifying troublesome issues and deficient areas experienced by the Medicare+Choice organization and implementing corrective and preventive action.

The committee may also address other functions as the compliance concept becomes part of the overall operating structure and daily routine.

C. Conducting Effective Training and Education

The proper education and training of corporate officers, managers, employees and the continual retraining of current personnel at all levels are significant elements of an effective compliance program. Where feasible, the Medicare+Choice organization should afford outside contractors and its provider clients the opportunity to participate in the organization's compliance training and educational programs. The contractors and provider clients should be encouraged to develop their own compliance programs that complement the Medicare+Choice organization's compliance program.

1. Formal Training Programs

In order to ensure the appropriate information is being disseminated to the correct individuals, the Medicare+Choice organization training program should include both a general session and specialized sessions on specific risk areas. All employees should attend the general session on compliance. Employees whose job responsibilities implicate specific risk areas (*e.g.*, marketing or capitated reimbursement rules) should attend the specialized sessions.

The OIG recommends attendance and participation at training programs be made a condition of continued employment and that failure to comply with training requirements should result in disciplinary action, including possible termination, when such failure is serious. The Medicare+Choice organization should retain adequate records of its training of employees, including attendance logs and material distributed at training sessions. New employees should be targeted for training early in their employment, and to the extent that they perform complicated tasks with greater organizational legal exposure, should be monitored closely until all training is completed.

a. General Sessions

As part of their compliance programs, Medicare+Choice organizations should require all affected employees to attend annual training that emphasizes the organization's commitment to compliance with all Federal and State statutes and requirements, and the policies of private payors. This training should highlight the organization's compliance program, summarize fraud and abuse statutes and regulations, Federal and State health care program requirements, documentation requirements for data submission and marketing practices that reflect current legal and program standards.

As part of the initial training, the standards of conduct should be distributed to all employees. Every employee, as well as contracted consultants, should be required to sign and date a statement that reflects the employee's knowledge of, and commitment to the standards of conduct. This attestation should be retained in the employee's personnel file. For contracted consultants, the attestation should become part of the contract and remain in the file that contains such documentation. To ensure that employees continuously meet the expected high standards set forth in the code of conduct, any employee handbook delineating or expanding upon these standards of conduct should be regularly updated as applicable statutes, regulations and Federal health care program requirements are modified.[79] Medicare+Choice organizations should provide an additional attestation in the modified standards that stipulates the employee's knowledge of, and commitment to, the modifications.

[79] While the OIG recognizes that not all standards, policies and procedures need to be communicated to all employees, it believes that the bulk of the standards that relate to complying with fraud and abuse laws and other ethical areas should be addressed and made part of all employees' training.

b. Specialized Training

Because Medicare+Choice organizations are responsible for compliance in all of the risk areas mentioned in section II.A. above, the OIG recommends Medicare+Choice organizations require individuals who are involved in the risk areas to receive specialized training. For example, marketing employees should receive training on the marketing, enrollment, disenrollment and anti-kickback policies. All employees who work with beneficiaries or providers regarding medical services should receive appropriate training on the risks associated with under-utilization. Those employees who are involved in developing enrollment, encounter and ACR data should receive training on HCFA policies in these areas. Clarifying and emphasizing these areas of concern through training and educational programs are particularly relevant to a Medicare+Choice organization's marketing and financial personnel, in that the pressure to meet business goals may render these employees particularly vulnerable to engaging in prohibited practices.

The OIG recommends Medicare+Choice organizations' compliance programs address the need for periodic professional education courses for personnel. Such courses would be in addition to the internal training sessions provided by the organization. For example, the Medicare+Choice organization should ensure that data submission personnel receive annual professional training on the updated policies, requirements and directives for the current year.

c. Format of the Training Program

The OIG suggests all relevant levels of personnel be made part of various educational and training programs of the Medicare+Choice organization. Employees should be required to have a minimum number of educational hours per year, as appropriate, as part of their employment responsibilities. A variety of teaching methods, such as interactive training and training in several different languages (including the translation of standards of conducts and other materials), particularly where a Medicare+Choice organization has a culturally diverse staff, should be implemented so that all affected employees are knowledgeable about the institution's standards of conduct and procedures for alerting senior management to problems and concerns. In addition, the materials should be written at appropriate reading levels for targeted employees. All training

materials should be designed to take into account the skills, knowledge and experience of the individual trainees. Post-training tests can be used to assess the success of training provided and employee comprehension of the billing company's policies and procedures.

2. Informal and Ongoing Compliance Training

It is essential that compliance issues remain at the forefront of the Medicare+Choice organization's priorities. The organization must demonstrate its commitment by continuing to disseminate the compliance message. One effective mechanism to achieve this goal is to publish a monthly compliance newsletter. This would allow the Medicare+Choice organization to address specific examples of problems the company encountered during its ongoing audits and risk analysis, while reinforcing the company's firm commitment to the general principles of compliance and ethical conduct. The newsletter could also include the risk areas identified in current OIG publications or investigations. Finally, the Medicare+Choice organization could use the newsletter as a mechanism to address areas of ambiguity in the marketing, utilization review and data submission process, and to notify employees of significant legal or regulatory developments. The Medicare+Choice organization should maintain its newsletters in a central location to document the guidance offered and provide new employees with access to guidance previously provided. Other written materials, such as posters, fliers or articles in other company publications, could also be used to disseminate the compliance message.

Another effective method of maintaining the presence of the compliance message is to maintain a website devoted to compliance issues. This could be linked to the homepage of the organization. Many organizations have chosen to maintain these sites internally on the Intranet to alleviate any confidentiality concerns. The Intranet (or Internet) also facilitates the use of hypertext links that allow the organization to maintain a centralized source on statutory, regulatory and other program guidance disseminated by HCFA,[80] the OIG, the Department of Justice and the Congress. These links, along with any other webpages that the Medicare+Choice organization deems pertinent and useful can be assembled on a single site that can, by hypertext link, provide access to all of these useful resources.

D. Developing Effective Lines of Communication

An open line of communication between the compliance officer and Medicare+Choice organization personnel, as well as among the organization, health care providers and enrollees, is critical to the successful implementation of a compliance program and the reduction of any potential for fraud, abuse and waste. Each organization should have in place both a mechanism for the reporting of improper conduct, as well a mechanism for more routine types of communication among the compliance officer and relevant groups.

1. Hotline or Other System for Reports of Potential Misconduct

Each Medicare+Choice organization should have in place a hotline or other mechanism[81] through which employees, enrollees or other parties can report potential violations of the organization's compliance policies or of Federal or State health care program requirements. In any event, several independent reporting paths should be created for an employee to report fraud, waste or abuse so that such reports cannot be diverted by supervisors or other personnel. If the organization establishes a hotline, the telephone number should be made readily available to all employees, enrollees and independent contractors, by circulating the number on wallet cards or conspicuously posting the telephone number in common work areas.[82]

Matters reported through the hotline or other communication sources that suggest violations of compliance policies, Federal and State health care program requirements, regulations or statutes should be documented and investigated promptly to determine their veracity. A log should be maintained by the compliance officer that records such calls, including the nature of any investigation and its results.[83] Such information should be included in reports to the governing body, the CEO and compliance committee.

Employees, enrollees and providers should be permitted to report matters on a confidential basis. To encourage such reporting, written confidentiality and non-retaliation policies should be developed and distributed to all employees, enrollees and providers to encourage communication and the reporting of incidents of potential fraud.[84] While the Medicare+Choice organization should always strive to maintain the confidentiality of the reporter's identity, the policies should explicitly communicate that there may be a point where the individual's identity may become known or may have to be revealed.

The OIG recognizes that assertions of fraud and abuse by those who may have participated in illegal conduct or committed other malfeasance raise numerous complex legal and management issues that should be examined on a case-by-case basis. The compliance officer should work closely with legal counsel to obtain guidance on these issues.

2. Routine Communication/Access to the Compliance Officer

While it is crucial that Medicare+Choice organizations have effective systems in place for the reporting of suspected misconduct, it is equally important that the compliance officer foster more routine communication both among its employees and among its health care providers and enrollees.

With respect to its own employees, the OIG encourages the establishment of procedures for personnel to seek clarification from the compliance officer or members of the compliance committee in the event of any confusion or question regarding a company policy, practice or procedure. Questions and responses should be documented and dated and, if appropriate, shared with other staff so that standards, policies, practices and procedures can be updated and improved to reflect any

[80] HCFA's Medicare+Choice webpage is located at http://www.hcfa.gov/medicare/mgdcar1.htm.

[81] The OIG recognizes that it may not be financially feasible for a small Medicare+Choice organization to maintain a telephone hotline dedicated to receiving calls solely on compliance issues. These companies may explore alternative methods, e.g., contracting with an independent source to provide hotline services or establishing a written method of confidential disclosure.

[82] Medicare+Choice organizations should also post in a prominent, available area the HHS-OIG Hotline telephone number, 1–800–447–8477 (1–800–HHS–TIPS), in addition to any organization's hotline number that may be posted.

[83] To efficiently and accurately fulfill such an obligation, the Medicare+Choice organization should create an intake form for all compliance issues identified through reporting mechanisms. The form could include information concerning the date the potential problem was reported, the internal investigative methods utilized, the results of any investigation, any corrective action implemented, any disciplinary measures imposed and any overpayments and monies returned.

[84] The OIG believes that whistleblowers should be protected against retaliation, a concept embodied in the provisions of the False Claims Act. See 31 U.S.C. 3730(h). In many cases, employees sue their employers under the False Claims Act's qui tam provisions out of frustration because of the company's failure to take action when a questionable, fraudulent or abusive situation was brought to the attention of senior corporate officials.

necessary changes or clarifications. The compliance officer may want to solicit employee input in developing these communication and reporting systems. The methods discussed above relating to ongoing training and education are an integral part of this communication.[85]

The communication and coordination function of the compliance program serves an even more critical role in the context of the managed care environment because the managed care entity serves as an intermediary between the health care provider and the enrollee.[86] In fact, the raison d'étre of a managed care organization is to coordinate the care of its enrollees. As with providers, communications with beneficiaries and communications with HCFA (and its designees) must demonstrate the highest level of integrity, honesty and judgment. The Medicare+Choice organization should implement methods to encourage communication among its enrollees and providers. For example, a Medicare+Choice organization should communicate the results of audits, disenrollment surveys, utilization data and quality of care determinations to its contracting suppliers and providers in order to facilitate open discussion regarding appropriate health care delivery.

E. Auditing and Monitoring

An ongoing evaluation process is critical to a successful compliance program. The OIG believes an effective program should incorporate thorough monitoring of its implementation and regular reporting to senior company officers.[87] Compliance reports created by this ongoing monitoring, including reports of suspected noncompliance, should be maintained by the compliance officer and reviewed with the Medicare+Choice organization's senior management and the compliance committee. The extent and frequency of the audit function may vary depending on factors such as the size of the company, the resources available to the company, the company's prior history of noncompliance and the risk factors that are prevalent in a particular organization.

Although many monitoring techniques are available, one effective tool to promote and ensure compliance is the performance of regular, periodic compliance audits by internal or external auditors who have expertise in Federal and State health care statutes, regulations and Federal health care program requirements. The audits should focus on the Medicare+Choice organization's programs or divisions, including external relationships with third-party contractors, specifically those with substantive exposure to Government enforcement actions. The audits should be sure to cover the range of programmatic requirements of the Medicare+Choice program. In particular, the audits should focus on the risk areas identified earlier in this document, especially the data and information which affects payments by Medicare. Finally, the Medicare+Choice organization should focus on any areas of specific concern identified within that organization and those that may have been identified by any outside agency, whether Federal or State.

Monitoring techniques may include sampling protocols that permit the compliance officer to identify and review variations from an established baseline.[88] Significant variations from the baseline should trigger a reasonable inquiry to determine the cause of the deviation. If the inquiry determines that the deviation occurred for legitimate, explainable reasons, the compliance officer or manager may want to limit any corrective action or take no action. If it is determined that the deviation was caused by improper procedures, misunderstanding of rules, including fraud and systemic problems, the Medicare+Choice organization should take prompt steps to correct the problem.[89] Any overpayments discovered as a result of such deviations should be reported promptly to HCFA (or its designees), with appropriate documentation and a thorough explanation of the reason for the overpayment.[90]

An effective compliance program should also incorporate periodic (at a minimum, annual) reviews of whether the program's compliance elements have been satisfied, *e.g.*, whether there has been appropriate dissemination of the program's standards, training, ongoing educational programs and disciplinary actions.[91] This process will verify actual conformance by all departments with the compliance program. Such reviews may support a determination that appropriate records have been created and maintained to document the implementation of an effective program.

The reviewers involved in any audits should:

- Possess the qualifications and experience necessary to adequately identify potential issues with the subject matter to be reviewed;
- Be independent of line management;
- Have access to existing audit and health care resources, relevant personnel and all relevant areas of operation;
- Resent written evaluative reports on compliance activities to the CEO, governing body members of the compliance committee and its provider clients on a regular basis, but not less than annually; and
- Specifically identify areas where corrective actions are needed.

In the Medicare+Choice context, a variety of different methods will be necessary to adequately monitor and evaluate the ongoing operations of the Medicare+Choice organization. In general, OIG recommends the use of techniques such as on-site visits, questionnaires (for providers, enrollees and employees), and trend analyses, to name just several.[92] Because the

[85] In addition to methods of communication used by current employees, an effective employee exit interview program could be designed to solicit information from departing employees regarding potential misconduct and suspected violations of the Medicare+Choice organization's policy and procedures.

[86] An ''enrollee'' is defined in this compliance program guidance as any Medicare+Choice eligible individual who has elected a Medicare+Choice plan offered by a Medicare+Choice organizations. See 42 CFR 422.2.

[87] Even when a facility is owned by a larger corporate entity, the regular auditing and monitoring of the compliance activities of an individual facility must be a key feature in any annual review. Appropriate reports on audit findings should be periodically provided and explained to a parent-organization's senior staff and officers.

[88] The OIG recommends that when a compliance program is established in a Medicare+Choice organization, the compliance officer, with the assistance of department managers, take a ''snapshot'' of the organization's operations from a compliance perspective. This assessment can be undertaken by outside consultants, law or accounting firms, or internal staff, with authoritative knowledge of health care compliance requirements. This ''snapshot,'' often used as part of bench marking analysis, becomes a baseline for the compliance officer and other managers to judge the Medicare+Choice organization's progress in reducing or eliminating potential areas of vulnerability. Medicare+Choice organizations should track statistical data on utilization review and quality data based on customer satisfaction and renewal data. This will facilitate identification of problem areas and elimination of potential areas of abusive or fraudulent conduct.

[89] Prompt steps to correct the problem include contacting the appropriate provider in situations where the provider's actions contributed to the problem.

[90] In addition, when appropriate, as referenced in section G.2, below, reports of fraud or systemic problems should also be made to the appropriate governmental authority.

[91] One way to assess the knowledge, awareness and perceptions of the Medicare+Choice organization's staff is through the use of a validated survey instrument (*e.g.*, employee questionnaires, interviews or focus groups).

[92] Medicare+Choice organizations may want to consult HCFA's Contractor Performance Monitoring System Manual to get additional ideas for monitoring methods. In addition, organizations may

Continued

auditing and monitoring function is very different and much more complex in the managed care context than in any other segment of the health care industry, we have provided additional guidance on the methods to be used in evaluating selected risk areas.

1. Marketing/Enrollment/Disenrollment

Developing a system for evaluating the compliance of the marketing, enrollment and disenrollment functions of a Medicare+Choice organization requires innovative techniques. Each Medicare+Choice organization will have to develop an individualized method as to how to obtain this data. Some of the methods that the OIG suggests include: the use of secret shoppers; surveying current enrollees;[93] and conducting exit interviews with former enrollees (particularly those that disenrolled just prior to obtaining an expensive service) on their experience with the Medicare+Choice marketing and enrollment process. Once this data is collected, it must be maintained in a format that can be accessed readily.

In an effort to integrate the monitoring function with its training function, Medicare+Choice organizations may wish to test their marketing staff on their knowledge of the company's policies and procedures, as well as the Federal and State statutes that govern the marketing process. This assessment can be developed to take on many formats. Many companies have customized interactive software to test employees' knowledge of relevant policies and procedures. It may also be formulated in the traditional written version.

Methods used to monitor marketing agents include the analysis of disenrollment data to identify marketing agents with high and low percentages of member disenrollments within a set number of days (*e.g.*, 90 days). In addition, Medicare+Choice organizations may want to establish enrollment verification systems requiring that a different individual from the sales agent meet with beneficiaries who have applied for enrollment to ensure that they understand restrictions of the plan, such as the lock-in provision.

Finally, it is essential for all marketing materials to be reviewed by the general counsel's office to ensure that they do not mislead, confuse or misrepresent any aspect of the plan. Similarly, they should also be examined by the claims processing department and utilization review office for consistency with the policies, procedures and practices of these departments.

2. Underutilization and Quality of Care

Procedures for tracking and reporting utilization review data are vital to the success of any compliance endeavor. Medicare+Choice organizations should periodically review the service areas that are part of the Medicare+Choice organization to ensure that enrollees are receiving adequate access to care. In reviewing service areas, Medicare+Choice organizations should collect data on the number of primary care physicians in the service area, the number and type of specialists in the service area, the waiting time for appointments, the telephone access to the Medicare+Choice organization and the problems associated with the coordination of care. All of this data should be maintained in a database in a format that can be used to generate statistical data and analysis.

Medicare+Choice organizations should ensure that there are adequate systems in place to monitor underutilization and inappropriate denials. Such procedures include collecting data on utilization patterns and detecting aberrant patterns. This data should be checked against utilization rates in the industry. This function could be performed by a medical affairs department that is responsible for regular review of claims, the payment system, encounter data and medical record review to assess the degree to which care is under (or over) utilized.

Similarly, the Medicare+Choice organization should survey its enrollees on utilization patterns and whether they felt they were subjected to inadequate health care services or inappropriate denials. Such survey results should be reviewed and investigated, when appropriate. Generally, these may be skewed in favor of the Medicare+Choice organization if the enrollees are current members. Presumably, if an enrollee was truly dissatisfied with the Medicare+Choice organization's attitude toward enrollee rights, the enrollee would have disenrolled from the plan. As a result, a Medicare+Choice organization should evaluate both current enrollee satisfaction surveys and exit interview surveys of former enrollees.

Medicare+Choice organizations have a good source of information regarding utilization issues, simply by tracking the type of appeals and grievances they receive from beneficiaries. This information should be tracked in a database that can be easily accessed by type of grievance or appeal and results.

3. Data Collection and Submission Processes

Given the importance of the enrollment, encounter and ACR data, the Medicare+Choice organization should develop ways to audit this information to assure its accuracy. For example, encounter data should be sampled periodically to determine its accuracy and reliability. As a part of that process, Medicare+Choice organizations must detail in their contractual relationships with providers the access that they will need to the provider's medical record documentation.

4. Anti-Kickback and Other Inducements

Medicare+Choice organizations should periodically review their contractual documents and discussions with providers to ensure that ''swapping'' is not occurring, which would cause such relationships to fall outside the applicable safe harbor. In addition, contracts with marketing personnel should be reviewed by legal counsel to be sure they do not violate applicable statutes and regulations.

F. Enforcing Standards Through Well-Publicized Disciplinary Guidelines and Policies Regarding Dealings With Ineligible Persons

The OIG recommends that all Medicare +Choice organizations' compliance programs include several key policies in the area of personnel/human resources. The first deals with the establishment and consistent application of appropriate disciplinary policies to deal with improper conduct and the second deals with the employment of certain ineligible individuals.

1. Consistent Enforcement of Disciplinary Policies

An effective compliance program should include guidance regarding disciplinary action for all employees who have failed to comply with the Medicare+Choice organization's standards of conduct, policies and procedures, Federal health care program requirements, or Federal and State laws, or those who have otherwise engaged in wrongdoing. It is vital to publish and disseminate the range of possible disciplinary actions for improper

---

want to consult the OAS website for information on conducting audits, including information on statistical sampling (RAT–STATS). *See* note 10.

[93] It should be noted, while this method may be less expensive, it may not provide unbiased data, particularly in the area of selective marketing. In fact, in the selective marketing area, the data may be skewed significantly in favor of the Medicare+Choice organization.

conduct and to educate officers and other staff regarding these standards. Employees should be advised that disciplinary action may be appropriate where a responsible employee's failure to detect a violation is attributable to his or her negligence or reckless conduct. The sanctions could range from oral warnings to suspension, termination or other sanctions, as appropriate. While each situation must be considered on a case-by-case basis to determine the appropriate sanction, intentional or reckless noncompliance should subject transgressors to significant sanctions.

The written standards of conduct should elaborate on the procedures for handling disciplinary problems and identify who will be responsible for taking appropriate action. For example, while disciplinary actions can be handled by department managers, others may have to be resolved by a more senior official of the organization. Personnel should be advised by the organization that disciplinary action will be taken on a fair and equitable basis, that is, all levels of employees should be subject to similar disciplinary action for the commission of similar offenses. Managers and supervisors should be held accountable to implement the disciplinary policy consistently so that the policy will have the required deterrent effect.

2. Employment of and Contracting With Ineligible Persons

All Medicare+Choice organizations should use care when delegating substantial discretionary authority to make decisions that may involve compliance with the law or compliance oversight. In particular, the organization should ensure that it does not delegate such responsibilities to individuals or entities that it knows, or should have known, have a propensity to engage in inappropriate or improper conduct. Pursuant to the compliance program, Medicare+Choice organization's policies should prohibit the employment of or contracting with individuals or entities who have been recently convicted of a criminal offense related to health care or who are listed as debarred, excluded or otherwise ineligible for participation in Federal health care programs. The policies should require the Medicare+Choice organization to utilize Government resources to determine whether such individuals or entities are debarred or excluded. These resources should be used for both potential employees (as part of the employment application process, which should also include a reasonable and prudent background investigation), and should be used to periodically check existing employees and contractors.

Lists of debarred and excluded individuals and entities are currently maintained by both the OIG and the General Services Administration.[94] By approximately January 2000, the Healthcare Integrity Protection Data Bank (HIPDB) will be available to Medicare+Choice organizations (for a nominal fee) to use in conducting these checks on employees and contractors.[95] The HIPDB is an electronic data collection program that will collect, store and disseminate reports on practitioners, providers and suppliers that have been the subject of health care related final adverse actions in criminal, civil and administrative proceedings. The final adverse actions to be reported to the HIPDB include criminal convictions or civil judgments related to the delivery of health care, actions by Federal or State agencies responsible for licensing or certification of health care providers, suppliers and practitioners, and exclusions from Federal or State health care programs.

Pending the resolution of any known criminal charges or proposed debarment or exclusion, the OIG recommends that such individuals should be removed from direct responsibility for, or involvement in, any Federal health care program.[96] Similarly, with regard to current employees or independent contractors, if resolution of the matter results in conviction, debarment or exclusion, then the Medicare+Choice organization should remove the individual from direct responsibility for, or involvement with, the organization's business operations related to Federal health care programs. In addition, they should remove such person from any position for which the person's salary or other items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds, at least until such time as the person is reinstated into participation in the Federal health care programs.

G. Responding to Detected Offenses and Developing Corrective Action Initiatives

Violations of the Medicare+Choice organization's compliance program, failures to comply with applicable Federal or State law, rules and program instructions and other types of misconduct threaten a Medicare+Choice organization's status as a reliable, honest and trustworthy company. Detected but uncorrected misconduct can seriously endanger the mission, reputation and legal status of the organization. Consequently, upon reports or reasonable indications of suspected noncompliance, it is important that the chief compliance officer or other management officials promptly investigate the conduct in question to determine whether a material violation of applicable law, rule or program instruction or the requirements of the compliance program has occurred, and if so, take steps to correct the problem.[97] As appropriate, such steps may include an immediate referral to criminal and/or civil law enforcement authorities, a corrective action plan, a report to the Government,[98] and the notification to the provider of any discrepancies or overpayments, if applicable.

The Medicare+Choice organization should document its efforts to comply with applicable statutes, regulations and Federal health care program requirements. For example, where a Medicare+Choice organization, in its efforts to comply with a particular statute, regulation or program requirement, requests advice from a Government agency charged with administering a Federal health care program, the Medicare+Choice organization should document and retain a record of the request and any written or oral response. This step is extremely important if the Medicare+Choice organization intends to rely on that response to guide it in future decisions, actions or appeals. A log of oral inquiries between the Medicare+Choice organization and third parties will help the organization document its attempts at compliance. In

[94] OIG's List of Excluded Individuals/Entities is available on the Internet at http://www.dhhs.gov/progorg/oig and the General Services Administration list of debarred contractors is available on the Internet at http://www.arnet.gov/epls.

[95] See 42 U.S.C. 1320a–7e.

[96] Prospective employees who have been officially reinstated into the Medicare and Medicaid programs by the OIG may be considered for employment upon proof of such reinstatement.

[97] Instances of non-compliance must be determined on a case-by-case basis. The existence, or amount, of a *monetary* loss to a health care program is not solely determinative of whether or not the conduct should be investigated and reported to governmental authorities. In fact, there may be instances where there is no readily identifiable monetary loss at all, but corrective action and reporting are still necessary to protect the integrity of the applicable program and its beneficiaries.

[98] The OIG currently maintains a provider self-disclosure protocol that encourages providers to report suspected fraud. The concept of self-disclosure is premised on a recognition that the Government alone cannot protect the integrity of the Medicare and other Federal health care programs. Health care providers must be willing to police themselves, correct underlying problems and work with the Government to resolve these matters. The self-disclosure protocol can be located on the OIG's website at http://www.dhhs.gov/progorg/oig.

addition, the Medicare+Choice organization should maintain records relevant to the issue of whether its reliance was ''reasonable,'' and whether it exercised due diligence in developing procedures to implement the advice.

1. Violations and Investigations

Depending upon the nature of the alleged violations, an internal investigation will probably include interviews and a review of relevant documents. Medicare+Choice organizations should consider engaging outside counsel, auditors or health care experts to assist in an investigation. Records of the investigation should contain documentation of the alleged violation, a description of the investigative process (including the objectivity of the investigators and methodologies utilized), copies of interview notes and key documents, a log of the witnesses interviewed and the documents reviewed, the results of the investigation, e.g., any disciplinary action taken and any corrective action implemented. Although any action taken as the result of an investigation will necessarily vary depending upon the Medicare+Choice organization and the situation, Medicare+Choice organizations should strive for some consistency by utilizing sound practices and disciplinary protocols. Further, after a reasonable period, the compliance officer should review the circumstances that formed the basis for the investigation to determine whether similar problems have been uncovered or modifications of the compliance program are necessary to prevent and detect other inappropriate conduct or violations.

If an investigation of an alleged violation is undertaken and the compliance officer believes the integrity of the investigation may be at stake because of the presence of employees under investigation, those subjects should be removed from their current work activity until the investigation is completed (unless an internal or Government-led undercover operation known to the Medicare+Choice organization is in effect). In addition, the compliance officer should take appropriate steps to secure or prevent the destruction of documents or other evidence relevant to the investigation. If the Medicare+Choice organization determines disciplinary action is warranted, it should be prompt and imposed in accordance with the organization's written standards of disciplinary action.

2. Reporting

If the compliance officer, compliance committee or a management official discovers credible evidence of misconduct from any source and, after reasonable inquiry, has reason to believe that the misconduct may violate criminal, civil or administrative law,[99] then the Medicare+Choice organization should report the existence of misconduct promptly to the appropriate Government authority [100] within a reasonable period, but not more than 60 days after determining that there is credible evidence of a violation. Prompt reporting will demonstrate the Medicare+Choice organization's good faith and willingness to work with governmental authorities to correct and remedy the problem. In addition, reporting such conduct will be considered a mitigating factor by the OIG in determining administrative sanctions (e.g., penalties, assessments and exclusion), if the reporting company becomes the target of an OIG investigation.[101]

3. Reporting Procedure

When reporting misconduct to the Government, a Medicare+Choice organization should provide all evidence relevant to the alleged violation of applicable Federal or State law(s) and any potential cost impact. The compliance officer, with guidance from the governmental authorities, could be requested to continue to investigate the reported violation. Once the investigation is completed, the compliance officer should be required to notify the appropriate governmental authority of the outcome of the investigation, including a description of the impact of the alleged violation on the operation of the applicable health care programs or their beneficiaries. If the investigation ultimately reveals criminal, civil or administrative violations have occurred, the appropriate Federal and State officials [102] should be notified immediately.

4. Corrective Actions

As previously stated, Medicare+Choice organizations should take appropriate corrective action, including prompt identification of any overpayment, repayment of the overpayment, modification to policies or manuals and the imposition of proper disciplinary action, if applicable. Failure to notify authorities of an overpayment within a reasonable period of time could be interpreted as an intentional attempt to conceal the overpayment from the Government, thereby establishing an independent basis for a criminal violation with respect to the Medicare+Choice organization, as well as any individuals who may have been involved.[103] For this reason, Medicare+Choice compliance programs should ensure that overpayments are identified quickly and promptly return overpayments obtained from Medicare or other Federal health care programs.[104]

---

[99] When making the determination of credible misconduct, the Medicare+Choice organization should consider, among other statutes, 18 U.S.C. 669 [holding an individual(s) criminally liable for knowingly and willfully embezzling, stealing or otherwise converting to the use of any person other than the rightful owner or intentionally misapplying any of the monies, funds * * * premiums, credits, property or assets of a health care benefit program] and 18 U.S.C. 2 [establishing criminal liability for an individual(s) who commits an offense against the United States or aids, abets, counsels, commands, induces or procures its commission as punishable as the principle]. In making this determination, the Medicare+Choice organization should also consider the civil False Claims Act, 31 U.S.C. 3729, which imposes treble damages and penalties on those (including subcontractors) who knowingly submit false claims for Federal funds, or cause their submission, or who knowingly prepare false records or statements to get such false claims paid. Under the civil False Claims Act, ''knowingly'' means that a person ''has actual knowledge of the information, acts in deliberate ignorance of the truth or falsity of the information, or acts in reckless disregard of the truth or falsity of the information, and no proof of specific intent to defraud is required.'' 31 U.S.C. 3729.

[100] Appropriate Federal and/or State authorities include the Office of Inspector General of the Department of Health and Human Services, the Criminal and Civil Divisions of the Department of Justice, the U.S. Attorneys in the relevant districts, and the other investigative arms for agencies administering the affected Federal or State health care programs, such as the State Medicaid Fraud Control Unit, the Defense Criminal Investigative Service, the Department of Veterans Affairs, the Office of Inspector General, U.S. Department of Labor (which has primary criminal jurisdiction over FECA, Black Lung and Longshore programs) and the Office of Inspector General, U.S. Office of Personnel Management (which has primary jurisdiction over the Federal Employees Health Benefit Program).

[101] The OIG has published criteria setting forth those factors that the OIG takes into consideration in determining whether it is appropriate to exclude a health care provider from program participation pursuant to 42 U.S.C. 1320a–7(b)(7) for violations of various fraud and abuse laws. See 62 FR 67392 (12/24/97).

[102] *See* note 100.

[103] *See* 42 U.S.C. 1320a–7b(a)(3).

[104] If a Medicare+Choice organization needs further guidance regarding normal repayment channels, the organization should consult with the CHPP. The CHPP may require certain information (*e.g.*, alleged violation or issue causing overpayment, description of overpayment, description of the internal investigative process with methodologies used to determine any overpayments, disciplinary actions taken and corrective actions taken) to be submitted with return of any overpayments, and that such repayment information be submitted to a specific department or individual in the carrier or intermediary's organization. Interest will be assessed, when appropriate. See 42 CFR 405.376.

III. Conclusion

Through this document, the OIG has attempted to provide a foundation for the development of effective and comprehensive Medicare+Choice compliance programs. These principles can also be used by entities to develop compliance programs applicable to other Federal and health care programs, as well as for their private lines of business. As previously stated, however, each program must be tailored to fit the needs and resources of an individual organization, depending upon its particular corporate structure, mission and employee composition. The statutes, regulations and guidelines of the Federal and State health insurance programs, as well as the policies and procedures of the private health plans, should be integrated into every Medicare+Choice organization's compliance program.

The OIG recognizes that the health care industry, which reaches millions of beneficiaries and expends about a trillion dollars annually, is constantly evolving. In no area of the industry is this more evident than in the growing area of managed care, particularly Medicare managed care. As a result, the time is right for Medicare+Choice organizations to implement strong, voluntary compliance programs. Compliance is a dynamic process that helps to ensure Medicare+Choice organizations are better able to fulfill their commitment to ethical behavior and to meet the changes and challenges being imposed upon them by the Congress and private insurers. It is OIG's hope that voluntarily created compliance programs will enable Medicare+Choice organizations to meet their goals of providing efficient and quality health care and at the same time, substantially reduce fraud, waste and abuse.

Dated: June 18, 1999.

June Gibbs Brown,

Inspector General.

[FR Doc. 99–16072 Filed 6–23–99; 8:45 am]

BILLING CODE 4150–04–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel, Spore in Ovarian Cancer

Date: June 27–29, 1999.

Time: 6:00 pm to 6:00 pm.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn—Silver Spring, 8777 Georgia Avenue, Silver Spring, MD 20910.

Contact Person: Martin H. Goldrosen, PhD., Scientific Review Administrator, Grants Review Branch, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, 6130 Executive Boulevard, Room 635 C, Rockville, MD 20852–7408, (301) 496–7930.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: June 18, 1999.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 99–16062 Filed 6–23–99; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel.

Date: July 13–14, 1999.

Time: 7:00 pm to 6:00 pm.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott Hotel, 5151 Pooks Hill Road, Bethesda, MD 20814.

Contact Person: Shan S. Wong, PhD, Scientific Review Administrator, Review Branch, DEA, NIDDK, Natcher Building, Room 6 AS 25, National Institutes of Health, Bethesda, MD, (301) 594–7797.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: June 16, 1999.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 99–16058 Filed 6–23–99; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental and Craniofacial Research; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., a amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Dental Research Special Emphasis Panel 99–37, Review of R01.

Date: June 24, 1999.

Time: 11:00 am to 12:30 pm.

Agenda: To review and evaluate grant applications.

Place: Natcher Building, Rm. 4AN44F, Bethesda, MD 20892 (Telephone Conference Call).