DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–246]

Agency Information Collection Activities: Proposed Collection; Comment Request

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

Type of Information Request: Extension of Currently Approved Collection.

Title of Information Collection: HEDIS 3.0 (Health Plan Data and Information Set) CAHPS (Consumer Assessment of Health Plans Study) Survey and Supporting Regulations 42 CFR 417.470, 417.126.

Form Number: HCFAR–246 (OMB approval #: 0938–0732).

Use: This collection effort (CAHPS) will be used to hold the Medicare managed care industry accountable for the quality of care they are delivering. This requirement will allow HCFA to obtain the information necessary for the proper oversight of the program. It is critical to HCFA's mission that we collect and disseminate information that will help beneficiaries choose among plans, contribute to the improved quality of care through identification of quality improvement opportunities, and assist HCFA in carrying out its responsibilities.

Frequency: Annually.

Affected Public: Businesses or other for profit, Individuals or Households.

Number of Respondents: 150,240.

Total Annual Responses: 150,240.

Total Annual Hours Requested: 49,579

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, E-mail your request, including your address and phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Attention: John Rudolph, Room N2–14–26 7500, Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: July 27, 1998.

John P. Burke III,

HCFA Reports Clearance Officer, Division of HCFA Enterprise Standards, Security and Standards Group, Health Care Financing Administration.

[FR Doc. 98–21109 Filed 8–6–98; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Solicitation of Information and Recommendations for Developing OIG Compliance Program Guidance for the Durable Medical Equipment Industry

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

ACTION: Notice.

SUMMARY: This **Federal Register** notice seeks the input and recommendations of interested parties into the OIG's development of a compliance program guidance for the durable medical equipment (DME) industry, its providers and suppliers. Many providers and provider organizations have expressed an interest in better protecting their operations from fraud and abuse. Previously, the OIG has developed compliance program guidances for hospitals, clinical laboratories and home health agencies. In order to provide clear and meaningful guidance to those segments of the health care industry involved in the supply and distribution of DME, we are soliciting comments, recommendations and other suggestions from concerned parties and organizations on how best to develop compliance program guidance and reduce fraud and abuse within the DME industry.

DATES: To assure consideration, comments must be delivered to the address provided below by no later than 5 p.m. on September 21, 1998.

ADDRESSES: Please mail or deliver your written comments, recommendations and suggestions to the following address:

Office of Inspector General, Department of Health and Human Services, Attention: OIG–3–CPG, Room 5246, Cohen Building, 330 Independence Avenue, SW, Washington, DC 20201.

We do not accept comments by facsimile (FAX) transmission. In commenting, please refer to file code OIG–3–CPG. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 5541 of the Office of Inspector General at 330 Independence Avenue, SW, Washington, DC, on Monday through Friday of each week from 8:00 a.m. to 4:30 p.m.

FOR FURTHER INFORMATION CONTACT: Christine Saxonis, Office of Counsel to the Inspector General, (202) 619–2078, or Joel Schaer, Office of Counsel to the Inspector General, (202) 619–0089.

SUPPLEMENTARY INFORMATION: The creation of compliance program guidance has become a major initiative of the OIG in its effort to engage the private health care community in addressing and fighting fraud and abuse. Recently, the OIG has developed and issued compliance program guidance directed at various segments of the health care industry.[1] This guidance is designed to provide clear direction and assistance to specific sections of the health care industry that are interested in reducing and eliminating fraud and abuse within their organizations.

The guidances represent the OIG's suggestions on how providers can best establish internal controls and monitoring to correct and prevent fraudulent activities. The contents of the guidances should not be viewed as mandatory for providers or as an exclusive discussion of the advisable elements of a compliance program.

In an effort to formalize the process by which the OIG receives public comments in connection with compliance program guidances, we are seeking, through this **Federal Register** notice, formal input from all interested parties as the OIG begins developing compliance program guidance directed at the DME industry, its providers and suppliers. The OIG will give consideration to all comments, recommendations and suggestions

[1] 62 FR 9435 (March 3, 1997) for clinical laboratories and 63 FR 8987 (February 23, 1998) for hospitals. The guidances can also be found on the OIG web site at http:/www.dhhs.gov/progorg/oig.

submitted and received by the time frame indicated above.

We anticipate that the DME guidance will contain the seven elements that we consider necessary for a comprehensive compliance program. These seven elements have been discussed in our previous guidances and include:

- The development of written policies and procedures;
- The designation of a compliance officer and other appropriate bodies;
- The development and implementation of effective training and education;
- The development and maintenance of effective lines of communication;
- The enforcement of standards through well-publicized disciplinary guidelines;
- The use of audits and other evaluation techniques to monitor compliance; and
- The development of procedures to respond to detected offenses and to initiate corrective action.

We would appreciate specific comments, recommendations and suggestions on (1) risk areas for the DME industry, and (2) aspects of the seven elements contained in previous guidances that may need to be modified to reflect the unique characteristics of the DME industry. Detailed justifications and empirical data supporting suggestions would be appreciated. We are also hopeful that any comments, recommendations and input be submitted in a format that addresses the above topics in a concise manner, rather than in the form of comprehensive draft guidance that mirrors previous guidance.

Dated: July 28, 1998.

June Gibbs Brown,

Inspector General.

[FR Doc. 98–20965 Filed 8–6–98; 8:45 am]

BILLING CODE 4150–04–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Publication of the OIG Compliance Program Guidance for Home Health Agencies

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

ACTION: Notice.

SUMMARY: This **Federal Register** notice sets forth the recently issued Compliance Program Guidance for Home Health Agencies developed by the Office of Inspector General (OIG) in cooperation with, and with input from, several provider groups and industry representatives. Many home health care providers have expressed interest in better protecting their operations from fraud and abuse through the adoption of a voluntary compliance program. The OIG has previously developed and published compliance program guidances focused on the clinical laboratory and hospital industries (62 FR 9435, March 3, 1997 and 63 FR 8987, February 23, 1998, respectively). We believe that the development of this compliance program guidance for the home health industry will continue as a positive step towards promoting a higher level of ethical and lawful conduct throughout the entire health care community.

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

SUPPLEMENTARY INFORMATION: The creation of compliance program guidances has become a major initiative of the OIG in its efforts to engage the health care community in combating fraud and abuse. In formulating compliance guidances, the OIG has worked closely with the Health Care Financing Administration, the Department of Justice and various sectors of the health care industry to provide clear guidance to those segments of the industry that are interested in reducing fraud and abuse within their organizations. The first of these compliance program guidances focused on clinical laboratories and was published in the **Federal Register** on March 3, 1997 (62 FR 9435). Building on basic elements of the first issuance, the second compliance program guidance developed by the OIG focused on the hospital industry and was published in the **Federal Register** on February 23, 1998 (63 FR 8987). The development of these types of compliance program guidance is based on our belief that a health care provider can use internal controls to more efficiently monitor adherence to applicable statutes, regulations and program requirements.

The OIG has identified seven fundamental elements to an effective compliance program. They are:

- 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;
- Enforcing standards through well-publicized disciplinary guidelines;
- Conducting internal monitoring and auditing; and
- Responding promptly to detected offenses and developing corrective action.

Using these seven basic elements, the OIG has identified specific areas of home health operations that, based on prior Government enforcement efforts, have proven to be vulnerable to fraud and abuse. The development of this Compliance Program Guidance for Home Health Agencies has been further enhanced by input from various home health trade associations and others with expertise in the home health industry. Regardless of a home health agency's size and structure—whether large or small, urban or rural, for-profit or non-profit—the OIG believes that every home health agency can and should strive to accomplish the objectives and principles underlying all of the compliance policies and procedures set forth in this accompanying guidance. Like the previously-issued compliance guidances for hospitals and clinical laboratories, adoption of the Compliance Program Guidance for Home Health Agencies set forth below will be voluntary.

A reprint of the OIG's Compliance Program Guidance for Home Health Agencies follows.

Office of Inspector General's Compliance Program Guidance for Home Health Agencies

I. Introduction

The Office of Inspector General (OIG) of the Department of Health and Human Services (HHS) continues in its efforts to promote voluntarily developed and implemented compliance programs for the health care industry. The following compliance program guidance is intended to assist home health agencies [1] and their agents and subproviders (referred to collectively in this document as ''home health agencies'') develop effective internal controls that promote adherence to applicable Federal and State law, and the program requirements of Federal, State, and private health plans.[2] The adoption and implementation of voluntary compliance programs significantly advance the prevention of fraud, abuse, and waste in these health care plans while at the same time further the fundamental mission of all

[1] The term ''home health agency'' is applied in this document as defined in section 1861(o) of the Social Security Act, 42 U.S.C. 1395x(o).

[2] This Compliance Program Guidance for Home Health Agencies is not intended to address issues specific to suppliers of durable medical equipment, infusion therapy, and other services typically provided in the home setting.