

demonstration projects under which competitive acquisition areas are established for contract award purposes for the furnishing of Part B items and services, except for physician's services. The demonstration currently operating in Polk County, Florida and the demonstration planned for San Antonio, Texas involve competitive bidding of categories of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). The new set of products to be offered for competitive bidding in San Antonio are: Oxygen equipment and supplies, hospital beds, non-customized orthotic devices, manual wheelchairs and accessories, and nebulizer inhalation drugs. Under the law, suppliers can receive payments from Medicare for items and services covered by the demonstration only if their bids are competitive in terms of quality and price. Each demonstration project may be conducted in up to three metropolitan areas for a three year period. Authority for the demonstration expires on December 31, 2002.

There are eight forms that are required for this demonstration. Form A will be used by the bidding supplier to provide information about the characteristics of the company. Form B will be used by the bidding supplier to provide specific information about the prices it bids for specific product categories, and to provide information about the attributes of the supplier in relation to the specific product category. Form C will be used by HCFA or its agents to obtain information on site regarding the bidding supplier. Form D will be used by HCFA or its agents to obtain financial references on the bidding supplier from banks and other financial sources. Form E will be used by HCFA or its agents to obtain information about the bidding suppliers from referral sources such as home health agencies and hospital discharge planners. Form F will be used to obtain information about the suppliers' financial status and to assure that they have sufficient fiscal resources to operate in a competitive environment where the prices being paid for some products are less than what have been customarily paid. It is required only from suppliers whose bids are in the competitive range. Form G will be used for nursing homes to identify their suppliers of products and services who have not been awarded Demonstration Supplier status for services to beneficiaries in their home. This is to permit payment to those suppliers for products and services furnished to nursing homes. Form H will be used to monitor the performance of Demonstration Suppliers to assure their

adherence to the quality standards established for the project.

The competitive bidding demonstration for DMEPOS has the following objectives:

- Test the policies and implementation methods of competitive bidding to determine whether or not it should be expanded as a Medicare Program.
- Reduce the price that Medicare pays for medical equipment and supplies.
- Limit beneficiary out-of-pocket expenditures for copayments.
- Assure beneficiary access to high quality medical equipment and supplies.
- Prevent business transactions with suppliers who engage in fraudulent practices.

Frequency: On occasion;

Affected Public: Business or other for-profit, and not-for-profit institutions;

Number of Respondents: 5,100;

Total Annual Responses: 1,700;

Total Annual Hours: 12,420.

(2) *Type of Information Collection*

Request: Revision of a currently approved collection;

Title of Information Collection: End-Stage Renal Disease (ESRD) Network Business Proposal Forms and Supporting Regulations in 42 CFR 405.2110 and 405.2112;

Form No.: HCFA-684A-I (OMB# 0938-0658);

Use: The submission of business proposal information by current ESRD networks and other bidders, according to the business proposal instructions, meets HCFA's need for meaningful, consistent, and verifiable data when evaluating contract proposals;

Frequency: Other: Every 3 years;

Affected Public: Not-for-profit institutions;

Number of Respondents: 18;

Total Annual Responses: 36;

Total Annual Hours: 1,080.

(3) *Type of Information Collection*

Request: Extension of a currently approved collection;

Title of Information Collection: End-Stage Renal Disease (ESRD) Network Semi-Annual Cost Report Forms and Supporting Regulations in 42 CFR 405.2110 and 405.2112;

Form No.: HCFA-685 (OMB# 0938-0657);

Use: Submission of semi-annual cost reports allow HCFA to review, compare, and project ESRD network costs. The reports are used as an early warning system to determine whether the networks are in danger of exceeding the total cost of the contract. Additionally, HCFA can analyze line item costs to identify any significant aberrations;

Frequency: Semi-annually;
Affected Public: Not-for-profit institutions;

Number of Respondents: 18;

Total Annual Responses: 36;

Total Annual Hours: 108.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, access HCFA's Web Site Address at <http://www.hcfa.gov/regs/prdact95.htm>, or 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 30 days of this notice directly to the OMB Desk Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: September 20, 2000.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA-730/182 & HCFA-R-77]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposal for the collection of information. 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.

(1) *Type of Information Collection Request:* New Collection;

Title of Information Collection: Employee Building Pass Application and File;

Form No.: HCFA-730 & 182 (OMB# 0938-NEW);

Use: The purpose of this system and the forms are to control United States Government Building Passes issued to all HCFA employees and non-HCFA employees who require continuous access to HCFA buildings in Baltimore and other HCFA and HHS buildings.;

Frequency: Other; as needed;
Affected Public: Federal Government, and business or other for-profit;
Number of Respondents: 150;
Total Annual Responses: 150;
Total Annual Hours: 37.50.

(2) *Type of Information Collection Request:* Extension of a currently approved collection;

Title of Information Collection: Limitation on Liability and Information Collection Requirements Referenced in 42 CFR 411.404, 411.406, and 411.408;

Form No.: HCFA-R-77 (OMB# 0938-0465);

Use: The Medicare program requires to provide written notification of noncovered services to beneficiaries by the providers, practitioners, and suppliers. The notification gives the beneficiary, provider, practitioner, or supplier knowledge that Medicare will not pay for items or services mentioned in the notification. After this notification, any future claim for the same or similar services will not be paid by the program and the affected parties will be liable for the noncovered services.;

Frequency: Other; as needed;
Affected Public: Individuals or households;

Number of Respondents: 890,826;
Total Annual Responses: 3,563,304;
Total Annual Hours: 296,942.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, access HCFA's Web Site Address at <http://www.hcfa.gov/regs/prdact95.htm>, or 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 30 days of this notice directly to the OMB Desk Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive

Office Building, Room 10235, Washington, D.C. 20503.

Dated: September 11, 2000.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

OIG Compliance Program for Individual and Small Group Physician Practices

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

ACTION: Notice.

SUMMARY: This **Federal Register** notice sets forth the recently issued Compliance Program Guidance for Individual and Small Group Physician Practices developed by the Office of Inspector General (OIG). The OIG has previously developed and published voluntary compliance program guidance focused on several other areas and aspects of the health care industry. We believe that the development and issuance of this voluntary compliance program guidance for individual and small group physician practices will serve as a positive step towards assisting providers in preventing the submission of erroneous claims or engaging in unlawful conduct involving the Federal health care programs.

FOR FURTHER INFORMATION CONTACT: Kimberly Brandt, Office of Counsel to the Inspector General, (202) 619-2078.

SUPPLEMENTARY INFORMATION:

Background

The creation of compliance program guidances is a major initiative of the OIG in its effort to engage the private health care community in preventing the submission of erroneous claims and in combating fraudulent conduct. In the past several years, the OIG has developed and issued compliance program guidances directed at a variety of segments in the health care industry. The development of these types of compliance program guidances is based on our belief that a health care provider can use internal controls to more efficiently monitor adherence to applicable statutes, regulations and program requirements.

Copies of these compliance program guidances can be found on the OIG web site at <http://www.hhs.gov/oig>.

Developing the Compliance Program Guidance for Individual and Small Group Physician Practices

On September 8, 1999, the OIG published a solicitation notice seeking information and recommendations for developing formal guidance for individual and small group physician practices (64 FR 48846). In response to that solicitation notice, the OIG received 83 comments from various outside sources. We carefully considered those comments, as well as previous OIG publications, such as other compliance program guidance and Special Fraud Alerts, in developing a guidance for individual and small group physician practices. In addition, we have consulted with the Health Care Financing Administration and the Department of Justice. In an effort to ensure that all parties had a reasonable opportunity to provide input into a final product, draft guidance for individual and small group physician practices was published in the **Federal Register** on June 12, 2000 (65 FR 36818) for further comments and recommendations.

Components of an Effective Compliance Program

This compliance program guidance for individual and small group physician practices contains seven components that provide a solid basis upon which a physician practice can create a voluntary compliance program:

- Conducting internal monitoring and auditing;
- Implementing compliance and practice standards;
- Designating a compliance officer or contact;
- Conducting appropriate training and education;
- Responding appropriately to detected offenses and developing corrective action;
- Developing open lines of communication; and
- Enforcing disciplinary standards through well-publicized guidelines.

Similar components have been contained in previous guidances issued by the OIG. However, unlike other guidances issued by OIG, this guidance for physicians does not suggest that physician practices implement all seven components of a full scale compliance program. Instead, the guidance emphasizes a step by step approach to follow in developing and implementing a voluntary compliance program. This change is in recognition of the financial and staffing resource constraints faced