

expressed concern about the use of the individual BE approach.

FDA acknowledged the public concerns about the use of the individual BE approach when the final guidance entitled "BA and BE Studies for Orally Administered Drug Products—General Considerations" (65 FR 64449, October 27, 2000) was issued. In that guidance, FDA recommends the continued use of the average BE approach for both replicated and nonreplicated studies. However, that guidance states that sponsors have the option to choose another approach, e.g., an individual BE approach for highly variable drugs. The final statistical guidance being made available today provides recommendations on how to use this approach if it is chosen.

This statistical guidance is one of a set of core guidances being developed to provide recommendations on how to meet the provisions of part 320. Taken together, these guidances are designed to address the studies that should be provided to document product quality BA/BE for all drug products regulated by CDER in accordance with the provisions of part 320.

This guidance is being issued consistent with FDA's good guidance practices regulation (65 FR 56468, September 19, 2000). This Level 1 guidance document represents the agency's current thinking on the statistical approaches used in BA and BE studies. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such an approach satisfies the requirements of the applicable statutes, regulations, or both.

Interested persons may, at any time, submit written comments on the 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 guidance and received comments are available for public examination in the Documents Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 24, 2001.

**Ann M. Witt,**

*Acting Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration

[Document Identifier: HCFA-10030]

#### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Health Care Financing Administration, DHHS.

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 this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

*Type of Information Collection Request:* New Collection; *Title of Information Collection:* National Medicare Practitioner and Provider Survey; *Form No.:* HCFA-10030 (OMB# 0938-NEW); *Use:* 1. Health Care Financing Administration (HCFA) Program Safeguard Provider Education Project (Contract # 500-99-0013, Task Order 00001)—New

HCFA is conducting a national assessment of Medicare practitioner and provider (hereinafter referred to collectively as providers) educational needs. The purpose of the needs

assessment is to obtain information about the education or training related to Medicare claims submission that is required by providers to increase their rate of correct first-time submission of Medicare claims. Specifically, the needs assessment survey will seek information about: (1) What providers need to know about accurate claims submission, and (2) what they believe would be the best methods for obtaining that information.

Responses will be gathered from a random sample of fee-for-service providers representing both Medicare Part A (hospital-based outpatient clinics, emergency rooms, and ambulatory surgery units; home health care agencies; and skilled nursing facilities) and Medicare Part B (physician and non-physician) providers. The information gathered by the needs assessment survey will allow HCFA to develop effective education and training tools and resources that address identified provider needs and focus on the topics that providers indicated were most important for improving accuracy of claims submissions.

The needs assessment survey will be administered one time only. It will be mailed to 9,000 individual and organizational providers nationwide that render Medicare services. HCFA anticipates receiving approximately 7,200 responses. As an alternative to completing the paper survey, respondents will have the option of completing the survey electronically using a computer with an Internet connection. A toll-free telephone line will be available to respondents who have questions or need help completing the survey. HCFA is collaborating with national and State medical societies and organizations to make providers aware of the survey and the importance of their participation in the needs assessment process. Publicity about the survey prior to its dissemination, along with a follow-up mail reminder and conduct of follow-up phone calls to respondents after its dissemination, will increase the survey response rate. Burden estimates are as follows:

Respondents	Estimated Number of respondents	Number of responses per respondent	Average burden/response (in hours)
Survey .....	7,200	1	1/2

*Total Burden:* 3,600 hours (at ½ hour each).

*Total Cost to Respondents:* \$396,000 (\$55 per respondent at an estimated \$110 hourly salary).

As a part of the Medicare Integrity Program (MIP), HCFA is seeking to increase the incidence of correct Medicare claims submitted by health care providers. Reduction of incorrect claims will reduce the administrative costs associated with review, return, and correction of claims prior to reimbursement and will increase the ability to make timely payments to providers. By making effective education and training resources available, HCFA will help providers improve their correct submission rates. Results of this survey will provide a sound foundation for the development of those resources.;

*Frequency:* Other: One-time only;  
*Affected Public:* Business or other for-profit; *Number of Respondents:* 9,000; *Total Annual Responses:* 9,000; *Total Annual Hours:* 3,600.

To obtain copies of the supporting statement and any related forms 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, phone number, OMB number, and HCFA document identifier, to [MKlein@hcfa.gov](mailto:MKlein@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: Dawn Willingham, HCFA-10030, Room N2-14-26, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: January 23, 2001.

**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-855]

#### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Health Care Financing Administration, DHHS.

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 this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

*Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicare Federal Health Care Programs Provider/Supplier Enrollment Application; *Form No.:* HCFA-855 (OMB# 0938-0685); *Use:* This information is needed to enroll providers and suppliers into the Medicare program by identifying them, pricing and paying their claims, and verifying their qualifications and eligibility to participate in Medicare; *Frequency:* Initial enrollment/recertification and Every three years; *Affected Public:* Business or other for-profit, Individuals or Households, and Not-for-profit institutions; *Number of Respondents:* 1,300,000; *Total Annual Responses:* 604,000; *Total Annual Hours:* 792,000. To obtain copies of the supporting statement and any related forms 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, phone number, OMB number, and HCFA document identifier, to [Paperwork@hcfa.gov](mailto: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, Information Technology Investment Management Group, Division of HCFA Enterprise Standards, Attention: Julie Brown, Room N2-14-26, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: January 24, 2001.

**John P. Burke III,**

*HCFA Reports Clearance Officer, HCFA Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration

[Document Identifier: HCFA-10017]

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

**AGENCY:** Health Care Financing Administration, DHHS.

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 this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

*Type of Information Collection Request:* New; *Title of Information Collection:* Follow-Up of Medicare+Choice Disenrollees Receiving Fee-for-Service Inpatient Hospital Care; *Form No.:* HCFA-10017 (OMB# 0938-NEW); *Use:* This study will survey Medicare beneficiaries who had a fee-for-service hospital stay after choosing to leave a Medicare+Choice health plan. The purpose is to gather information about their reasons for