

prejudice to a future filing (21 CFR 171.7).

Dated: September 27, 2000.

Alan M. Rulis,

*Director, Office of Premarket Approval,
Center for Food Safety and Applied Nutrition.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA-10006]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, HHS.

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: Extension of a currently approved collection; *Title of Information Collection:* TWWIIA Demonstration to Maintain Independence and Employment Grants; *Form No.:* HCFA-10006 (OMB# 0938-0799); *Use:* Section 204 of the Ticket to Work and Work Incentives Act provides for the establishment of grants for States that develop and implement demonstration programs designed to support working people with physical or mental impairments that without medical assistance will result in disability. State agencies will be applying for these grants; *Frequency:* Annually; *Affected Public:* State, local, or tribal gov't; *Number of Respondents:* 56; *Total Annual Responses:* 56; *Total Annual Hours:* 5,600.

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 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: Julie Brown, Room N2-14-26, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: October 4, 2000.

John P. Burke III,

Reports Clearance Officer, 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-10012]

Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

AGENCY: Health Care Financing Administration, HHS.

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.

We are, however, requesting an emergency review of the Information

collections referenced below. In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we have submitted to the Office of Management and Budget (OMB) the following requirements for emergency review. We are requesting an emergency review because the collection of this information is needed prior to the expiration of the normal time limits under OMB's regulations at 5 C.F.R., Part 1320. This collection of information will be used to test the effectiveness of three possible Medicare smoking cessation benefits and to make inferences that are generalizable to the Medicare program. Using a comparison trial with restricted randomization of study locales, this study will compare three variations in a potential Medicare smoking cessation benefit on smoking cessation and abstinence rates. Smoking cessation for seniors is currently receiving attention from Congress and the White House. Senator Graham (D-FL) has proposed a smoking cessation Medicare benefit, while the White House provides for a smoking cessation demonstration in the President's Plan to Modernize and Strengthen Medicare for the 21st Century. In response to this White House initiative, HCFA is launching this demonstration to test smoking cessation as a possible covered benefit under the Medicare program. If this information is not collected, public harm is likely to occur. Considerable evidence indicates that much greater improvement in health status could be accomplished if currently existing, effective and commonly available preventative practices and services were implemented more widely; therefore, this demonstration could help improve the health of the Medicare population.

HCFA is requesting OMB review and approval of this collection by October 31, 2000, with a 180-day approval period. Written comments and recommendations will be accepted from the public if received by the individuals designated below by October 27, 2000. During this 180-day period, we will publish a separate **Federal Register** notice announcing the initiation of an extensive 60-day agency review and public comment period on these requirements. We will submit the requirements for OMB review and an extension of this emergency approval.

Type of Information Collection Request: New Collection;

Title of Information Collection: Healthy Aging Smoking Cessation Demonstration;

Form No.: HCFA-10012 (OMB# 0938-NEW);