

(See, e.g., *Heckler v. Chaney*, 470 U.S. 821 (1985); *Schering v. Heckler*, 779 F.2d 683 (D.C. Cir. 1985).) It is also consistent with the *Pearson* decision, which described several circumstances in which FDA might be justified in banning certain health claims outright—e.g., where consumer health and safety are threatened, or where FDA can demonstrate that a health claim would be misleading even if qualified (see *Pearson*, 164 F.3d at 650, 657–60). For example, the court said that FDA could prohibit a health claim where the evidence in support of the claim is outweighed by evidence against the claim, either quantitatively or qualitatively (164 F.3d at 659 & n.10). The agency is adopting this modified process on an interim basis to minimize any burden on speech pending consumer research and rulemaking to complete the implementation of the *Pearson* decision.

3. Timing of FDA's Decisions on Health Claims for Dietary Supplements

FDA will complete its reconsideration of the four *Pearson* claims and issue a final decision on each of the claims within 190 days after the close of the comment period seeking scientific data on the claims, i.e., by October 10, 2000. For new health claim petitions for dietary supplements, FDA will continue to follow the applicable deadlines in § 101.70(j), as with past health claim petitions.

Dated: October 2, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–10011]

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: New Collection;

Title of Information Collection: Stages of Change Survey for Informed Choice in the Medicare Population;

Form No.: HCFA–10011 (OMB# 0938–NEW);

Use: This is a survey of Medicare beneficiaries in the first step in the application the Transtheoretical Model (the “stage model”) to informed choice in the Medicare population. The Transtheoretical Model has been applied and proven effective in facilitating behavior change in a wide range of health behaviors including smoking cessation, mammography screening, and safe sex. This work will yield psychometrically sound and externally valid measures of beneficiaries' readiness to make informed choices about health plans, and provide information to HCFA to assist with its national educational campaign to inform beneficiaries about their choices. Stages of Change measures will be administered to 560 Medicare beneficiaries and initial enrollees. This survey research will yield psychometrically sound measures of beneficiaries' readiness to make informed choices about health plans, and provide information to guide HCFA's National Medicare Education Program (NMEP);

Frequency: Other: One-time survey;
Affected Public: Individuals or Households;

Number of Respondents: 560;

Total Annual Responses: 560;

Total Annual Hours: 327.

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: Melissa Musotto, HCFA–10011, Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: September 26, 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–9044]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, OHHS.

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:* Provider Reimbursement Manual, Part 1—Chapter 27, Section 2721, 2722 and 2725, Request for Exception to ESRD Composite Rates and Supporting Regulations in 42 CFR 413.170 and 413.184; *Form No.:* HCFA–9044 (OMB# 0938–0296); *Use:* Sections 2721, 2722 and 2525 of the Provider Reimbursement Manual describe the information ESRD facilities must submit