(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.*

[FR Doc. 00–25702 Filed 10–3–00; 4:29 pm]

**BILLING CODE 4160–01–F**

## 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.*

[FR Doc. 00–25761 Filed 10–5–00; 8:45 am]

**BILLING CODE 4120–03–P**

## 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

in justifying an exception request to their composite rate for outpatient dialysis services.; *Frequency:* On occasion; *Affected Public:* Business or other for-profit, Not-for-profit institutions and Federal Government; *Number of Respondents:* 291; *Total Annual Responses:* 291; *Total Annual Hours:* 14,000.

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, 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–9044 Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: September 28, 2000.

**John P. Burke III,**

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

[FR Doc. 00–25762 Filed 10–5–00; 8:45 am]

**BILLING CODE 4120–03–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration

**[Document Identifiers: HCFA–R–296 (OMB # 0938–0781)]**

### Notice of Extension of Emergency Office of Management and Budget Clearance of Agency Information Collection Activities

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

The Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing this Notice to inform the public that the Office of Management and Budget (OMB) has approved our request for an extension of the OMB clearance on model advance beneficiary notices (ABNs), for which we first requested emergency clearance by **Federal Register** notice dated September 22, 1999 (HCFA–R–296, OMB # 0938–0781). Clearance of these model ABNs (referred to as HHABNs) for use by home health agencies (HHAs) has been extended through January 31, 2001. These model notices, together with the instructions in Program Memorandum Transmittals A–99–52 and A–99–54, remain in effect following the implementation of the prospective payment system (PPS) for home health agencies on October 1, 2000. HCFA also has published a **Federal Register** notice on September 26, 2000, 65 FR 57821, seeking emergency OMB clearance, pursuant to the Paperwork Reduction Act, of a revised uniform Home Health Advance Beneficiary Notice (HHABN), which we expect to make mandatory in January 2001.

*Use:* The purpose of this Notice is to clarify, for Medicare beneficiaries, for HHAs, and for other interested members of the public that existing requirements regarding notice and demand bills, as set forth in Program Memorandum Transmittals A–99–52 and A–99–54, and as reflected in the model notices for which OMB has extended the emergency clearance, remain in effect following the implementation of the prospective payment system for HHAs on October 1, 2000. Thus, in accordance with the instructions in PMs A–99–52 and A–99–54, HHAs continue to be responsible for providing proper ABNs and for submitting demand bills to Regional Home Health Intermediaries (RHHIs) when requested to do so by a beneficiary or by a person acting on the beneficiary's behalf. Moreover, the transition to PPS does not change HHAs' responsibility to follow ABN and demand bill procedures for plans of care in which the physician's order spans the transition.

HHAs must give a Medicare beneficiary a proper ABN before reducing or terminating home health care the beneficiary already is receiving, if the physician's order for such care would still continue the care, and an HHA believes that the services do not meet Medicare coverage criteria. In instances where care has not yet been initiated and an HHA believes services ordered by the physician do not meet Medicare coverage criteria, it must also provide a proper ABN. Currently, HHAs may use the model HHABNs designed by HCFA (Form No. HCFA–R–0296) or forms of the HHA's own design to meet the beneficiary notification requirement.

*Continued Use of Demand Billing Procedures and Meaning of ''Prompt'' Submission Under HHA PPS*

With respect to the instructions regarding demand bills in Transmittals A–99–52 and A–99–54, we want to emphasize that the demand bill process remains in effect following the implementation of HHA PPS, and must be used by HHAs to ensure continuation of beneficiary rights to obtain an official Medicare initial determination. Beginning in June, HCFA has been assessing the operational feasibility and impact of options for integrating the initial determination process into HHA PPS. In the HHA PPS final rule published on July 3, 2000, we stated, in response to public comment, that HCFA was reviewing demand billing procedures to determine whether they must be modified to account for the differences between HHA reasonable cost billing and HHA PPS. 65 FR 41128, 41169 (July 3, 2000) (Medicare Program; Prospective Payment System for Home Health Agencies, Final Rule). As a result of our assessment of the feasibility of various options, HCFA decided to continue to use the demand bill process as the mechanism by which Medicare beneficiaries obtain an official Medicare initial determination when an HHA believes, under HHA PPS, that Medicare will not, or will no longer, cover services ordered by a physician.

When a beneficiary agrees to be fully and personally responsible for payment for the services if Medicare decides the services are not covered, and has requested that a claim be submitted to Medicare, HHAs must ''promptly'' submit a claim to the RHHI and report, on the claim submitted, condition code 20 (demand-beneficiary requested billing) to indicate the beneficiary believes the services are covered (*see* PM A–99–52 sec. I–2A). Under HHA PPS, HHAs may submit only one claim for payment at the end of each episode of care. *See* 65 FR at 41141. Thus, under HHA PPS, ''prompt submission'' of a claim with the demand bill code requires that the claim (*i.e.,* the demand bill) be submitted at the end of the episode in question, at the same time the claim for final payment for the episode is submitted. Pursuant to the HHA PPS Final Rule, where an HHA has received a ''request for anticipated payment'' (RAP) for an episode, the RAP will be canceled and recovered unless the claim for the episode (with the condition code 20 to indicate that the claim is a demand bill when requested by the beneficiary in the circumstances described in PM A–99–52) is submitted within the greater of 60 days from the end of the episode or 60 days from the issuance of the anticipated payment. 65 FR at 41141.

*Future Plans*

As noted above, on September 26, 2000, HCFA published a **Federal**