

substance, (3) testing for photosensitivity (photoirritation and photoallergy), (4) testing for the enhancement of UV-associated skin carcinogenesis (direct photochemical carcinogenicity or indirect effects in skin), (5) reasons for a separate approach to testing nonphotosensitizing drugs for long-term photosafety, and (6) current needs for assay development.

This Level 1 draft guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). The draft guidance represents the agency's current thinking on testing for photosafety. 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 approach satisfies the requirements of the applicable statutes, regulations, or both.

Interested persons may, on or before April 10, 2000, submit to the Dockets Management Branch (address above) written comments on the draft guidance. 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 The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 29, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA-R-0209 and HCFA-R-0245]

Agency Information Collection Activities: Submission for OMB Review; 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.

1. Type of Information Collection Request: Revision of a currently approved collection.

Title of Information Collection: Medicare and Medicaid Programs: Reporting Outcome and Assessment Information Set (OASIS) Data as Part of the Conditions of Participation for Home Health Agencies (HCFA-3006-IFC) and Supporting Regulations in 42 CFR 484.11 and 484.20.

Form No.: HCFA-R-0209 (OMB# 0938-0761).

Use: The information collection requirements contained in the HCFA-3006 regulation state that HHAs must report data from the OASIS data set as a condition of participation for HHAs. Specifically, the above named rule provides guidelines for HHAs for the electronic transmission of the OASIS data set as well as responsibilities of the State agency or OASIS contractor in collecting and transmitting this information to HCFA. These requirements are necessary to establish a prospective payment system for HHAs and to achieve broad-based, measurable improvement in the quality of care furnished through Federal programs.

Frequency: As determined by HHA and monthly.

Affected Public: Business or other for profit, Not for profit institutions, Federal Government, and State, Local, or Tribal Government.

Number of Respondents: 8,200.

Total Annual Responses: 8,200.

Total Annual Hours: 996,368.

2. Type of Information Collection Request: Revision of a currently approved collection.

Title of Information Collection: Medicare and Medicaid Programs: Use of Outcome and Assessment Information Set (OASIS) as Part of the Conditions of Participation for Home Health Agencies (HCFA-3007-F) and Supporting Regulations in 42 CFR 484.55.

Form No.: HCFA-R-0245 (OMB# 0938-0760).

Use: These information collection requirements revise the existing conditions of participation that home health agencies (HHAs) must meet to participate in the Medicare program.

Specifically, this final rule requires that each patient receive from the HHA a patient-specific, comprehensive assessment that identifies the patient's need for home care and that meets the patient's medical, nursing, rehabilitative, social and discharge planning needs. In addition, this final rule requires that as part of the comprehensive assessment, HHAs use a standard core assessment data set, the OASIS, when evaluating adult, non-maternity patients. These changes are an integral part of the Administration's efforts to achieve broad-based improvements in the quality of care furnished through Federal programs and in the measurement of that care.

Frequency: Upon patient assessment.

Affected Public: Business or other for profit, Not for profit institutions, Federal Government, and State, Local, or Tribal Government.

Number of Respondents: 8,200.

Total Annual Responses: 8,200.

Total Annual Hours: 967,600.

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 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: November 29, 1999.

John Parmigiani,

Acting 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

[HCFA-9005-N]

Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—Second Quarter, 1999

AGENCY: Health Care Financing Administration (HCFA), HHS.