

SUPPORTING STATEMENT
FOR THE CMS-1572
HOME HEALTH AGENCY SURVEY AND DEFICIENCIES REPORT
AND CMS-1515
HOME HEALTH FUNCTIONAL ASSESSMENT INSTRUMENT
AND SUPPORTING REGULATIONS IN 42 CFR 488.26 and 442.30

A. BACKGROUND

This is a request for a 3-year extension of approval for the form CMS-1572, Home Health Agency Survey and Deficiencies Report and the form CMS-1515, Home Health Functional Assessment Instrument.

The survey forms are required to determine compliance with requirements for home health agencies (HHAs) (42 CFR Part 484), which were published as a Final Rule on July 18, 1991. These regulations are based on provisions of the Omnibus Budget Reconciliation Act of 1990 (OBRA-90). Implementation of these regulations and the statute require surveyors to focus on the actual delivery of care and the results of that care when making certification decisions. The survey process and forms are intended to ensure and strengthen patient health and safety, to enhance quality of care by emphasizing outcomes rather than process, to implement OBRA-87, and to achieve more effective compliance with Federal requirements.

State survey agencies use these forms to gather and record necessary data to support their decisions relating to a facility's compliance with the Federal conditions of participation and, therefore, eligibility to receive Medicare and Medicaid payments. In addition, the State agencies use the survey forms to report this information to the Federal Government. The survey forms and survey process have been designed to ensure consistency in the review and enforcement of the Federal requirements. The survey forms summarize data relative to provider characteristics, the patient population, and special needs of the patient populations. The forms also help to ensure surveyor consistency in the application of the requirements and serve as coding documents to facilitate data reduction (keypunching) and input and retrieval into the Online Survey Certification and Reporting (OSCAR) System at the State and at the Centers for Medicare and Medicaid Services (CMS) central and regional offices. Finally, these forms serve as an aid to help surveyors structure and record key observation data for subsequent reference and/or retrieval and are designed to result in an objective compliance decision. These forms are used in conjunction with the regulation text, interpretive guidelines and survey probes. In addition, Federal surveyors use these forms when conducting Federal monitoring surveys of HHAs.

In the Medicare and Medicaid programs, CMS is responsible for developing conditions of participation that facilities must meet to become eligible to receive Federal payments. State survey agencies conduct on-site surveys to ensure that facilities are in compliance with these requirements. The revised HHA conditions of participation and other requirements mandated by OBRA-87 represent a significant change in the survey and certification process by focusing on actual care as opposed to process-oriented requirements. The survey forms reflect this fundamental change and direct surveyors to observe and monitor the provision of care in the home setting. Surveyors use the survey forms to assist and direct them in evaluating important information relating to the quality of services provided in the home setting. Moreover, these forms represent a deficiency-based approach to evaluating and reporting compliance.

The HHA Survey and Deficiencies Report form (CMS-1572) has five parts. Each part has its own form designation. The first two parts of the form summarize: data relative to provider characteristics; description of the client population served; special needs represented by that population; and essential characteristics of the survey conducted. This part of the form provides comprehensive descriptive information about the provider, the clients served by the provider, and the survey team. Several data elements on this part of the form are necessary to compare specific characteristics about HHAs and their clients with other Medicare and Medicaid providers.

The third part contains instructions to the surveyor. The fourth part of the form is to be used in conjunction with the regulation text, interpretive guidelines, and a functional assessment instrument mandated by OBRA-87 to ensure that HHAs provide quality care. It includes basic information on noncompliance. Surveyors are no longer required to annotate on the survey form compliance or noncompliance for each individual data tag. Only deficiencies are cited on this survey form. Surveyors record all deficiencies found during the survey on the fourth part of the form. They then sign the form, certifying their review of the Federal requirements.

The Home Health Functional Assessment Instrument (CMS-1515) contains five modules, a calendar worksheet, and complementary instructions. The assessment instrument was mandated by OBRA-87 and is used in conjunction with selecting a case-mix, stratified sample of individuals furnished items and services by the agency and subsequently reviewing these individuals' clinical records and plans of care. Each module of the assessment instrument has a separate form designation.

B. JUSTIFICATION

1. Need and Legal Basis

Section 1864 of the Social Security Act (the Act) requires the Secretary to enter into agreements with States to survey providers and certify compliance or noncompliance with Medicare conditions of participation. Section 1902(a)(33)(B) of the Act requires the State Medicaid agency to contract with the State survey agency sued by Medicare to determine whether providers meet the requirements for participation in the Medicaid program.

Section 1861(o) of the Act describes Home Health Care with respect to the Medicare program. 42 CFR Part 484.10 – CFR Part 484.52 sets forth the Health and Safety Conditions of Participation (CoPs) that all Home Health Agencies must meet to participate in Medicare. State survey agencies, as well as accreditation agencies, are used by CMS to determine if the CoPs are met.

2. Information Users

CMS uses the information collected as the basis for certification decisions affecting continued participation of HHAs in the Medicare and Medicaid programs. The information is used by CMS regional offices, which have the delegated authority to certify Medicare facilities for participation, and by State Medicaid agencies, which have comparable authority under Medicaid. The information on the CMS-1572 is coded for entry into the OSCAR system. These data are analyzed by the regional offices and by the CMS central office components for program evaluation and monitoring purposes. This information is also available to the public upon request.

3. Improved Information Technology

The coded information on the HHA survey form provides essential data on HHAs and facility performance. This improves the OSCAR database as a means of monitoring and evaluating the survey and certification activities. Also, the standardized format provides for consistent reporting by State survey agencies, and the data are keyed on-site into laptop computers by the surveyors.

4. Duplication

These forms are used for surveying HHAs and do not duplicate any other collection instruments. The forms address specific requirements for

participation in the Medicare and Medicaid programs, and use of these forms is required under the contracts with the State agencies.

5. Small Business

These information collection requirements do not affect small businesses.

6. Less Frequent Collection

The 1996 budget bill amended Section 1819(c)(2)(A) of the Act in order to provide flexibility in the standard survey cycle for HHAs. The law now states that standard surveys will occur not later than 36 months after the previous standard survey, and that the Secretary shall establish a frequency for surveys within this 36-month interval commensurate with the need to assure the delivery of quality home health services.

7. Special Circumstances

There are no special circumstances.

8. Federal Register/Outside Consultation

We published a notice with a 60-day Federal Register notice with comment period on August 28, 2009.

These forms are modeled after forms used for Intermediate Care Facilities for the Mentally Retarded and Skilled Nursing Facilities and Nursing Facilities. We worked closely with a wide spectrum of public and private organizations in development of the forms and worksheets for Intermediate Care Facilities for the Mentally Retarded and Skilled Nursing Facilities and Nursing Facilities. The assessment instrument was developed under contract with a private consulting firm.

9. Payment/Gifts to Respondent

There are no payment/gifts to respondent.

10. Confidentiality

We do not pledge confidentiality.

11. Sensitive Questions

There are no questions of a sensitive nature associated with these forms.

12. Burden Estimate (Total Hrs. & Wage)

The HHA survey report form portion of the CMS-1572 is completed by the State agency surveyor based on the results of the investigation of the HHA's compliance with each individual Condition of Participation. The survey report form is used in conjunction with the Home Health Functional Assessment Instrument (FAI), CMS-1515, which documents information about the HHA identified through a review of the clinical records of HHA patients as well as visits to the homes of selected Medicare/Medicaid patients. The surveyor compiles all information collected through this process pertaining to the provider's compliance with the health and safety conditions and summarizes this on the survey report form. In relation to each regulatory standard or singularly surveyable item, the surveyor determines if the standard is met. In 2008, we determined there were 10,078 agencies and the number of surveys completed was 4028 standard and 1586 complaint for a total of 5614.

We estimate that the burden on the HHA for the form CMS-1572 will be no more than 15 minutes, which will be the time it will take the HHA's representative to make any information necessary available to the surveyor (including the identification of patients to be interviewed for the CMS 1515).

5614	Providers surveyed annually	x
.25	Hour per HHA survey report form, CMS-1572,	=
1403.5	Hours of respondent burden	

Plus,
The burden on the patients, incurred because of the surveyor's need to complete the CMS-1515, will be no more than 15 minutes each, and there will be an average of six interviews per HHA.

5614	Providers surveyed annually	x
6	Patients	x
.25	Hours	=
8421	Respondent burden	

The total hours of respondent burden for the CMS-1572 and the CMS-1515 equals 9824.5 hours of respondent burden annually.

13. Capital Costs

There are no capital costs associated with this collection.

14. Costs to Federal Government

All costs associated with this form are incurred by the Federal Government in the normal course of business; therefore, there are no additional costs to the Federal Government.

15. Changes in Burden/Program Changes

There are no program changes. The slight increase in burden is due to a change in our calculation.

16. Publication and Tabulation Dates

There are no publication and tabulation dates.

17. Expiration Date

CMS does not want to display the expiration date. The forms are used on a continuing basis, and to discard surplus every 3 years (or fewer), would not be economically sound.

18. Certification Statement

There are no exceptions to the certification statement.

C. Collections of Information Employing Statistical Methods

There are no statistical methods employed in the information collected.