3 rd Collection
Supporting Statement for the Paperwork Reduction Act Submission,
Medicare and Medicaid Programs: Use of OASIS as Part of the
CoPs for Home Health Agencies (CMS-3007-F)
and Supporting Regulations in 42 CFR 484.55, 484.205, 484.245 and 484.250
CMS-R-0245 (OMB Control #: 0938-0760)

A. Background

This request is for OMB approval to continue to require home health agencies (HHAs) to use the Outcome and Assessment Information Set (OASIS) data collection instrument as part of the comprehensive assessment. In addition, to implement the OASIS changes proposed in the Home Health Prospective Payment System Refinement and Rate Update for Calendar Year 2008 (CMS-1541-PFC), which are currently approved in 42 CFR 484.55, 484.205, and 484.250, a few items in the OASIS will need to be modified, deleted, or added. The current approval expires on August 31, 2007. OASIS is a requirement for one of the Conditions of Participation (CoP) that HHAs must meet in order to participate in the Medicare program. Specifically, the CoP at § 484.55 requires that each patient receive from an HHA a patient-specific, comprehensive assessment that identifies a patient's continuing need for home care and meets the patient's medical, nursing, rehabilitative, social and discharge planning needs. In addition, the regulation requires that as part of the comprehensive assessment, HHAs use a standard core assessment data set, the OASIS, to evaluate, non-maternity patients. The data collected using OASIS is used for three main purposes: assessing and improving the quality of care provided by an HHA, submitting and paying claims for Medicare home health services, and surveying the HHAs in accordance with Section 1891 of the Social Security Act (the Act).

Home health services are covered for the elderly and disabled under the Hospital Insurance (Part A) and Supplemental Medical Insurance (Part B) benefits of the Medicare program, and are described in section 1861(m) of the Act (42 U.S.C. 1395x). These services must be furnished by, or under arrangement with, an HHA that participates in the Medicare program, and be provided on a visiting basis in the beneficiary's home. Home health services may include care furnished by or under the supervision of a registered nurse, physical therapist, speech-language pathologist, or occupational therapist; medical social services under the direction of a physician; part-time or intermittent home health aide services; medical supplies (other than drugs and biologicals) and durable medical equipment; services of interns and residents if the HHA is owned by, or affiliated with, a hospital that has an approved medical education program; and/or services at hospitals, SNFs, or rehabilitation centers when they involve equipment too cumbersome to bring to the home.

OASIS is designed to be collected at defined time points from the start of care to discharge. Previously, OMB approved the following forms which designate specific

OASIS items collected on the four schedules as follows: Start-of-Care Version Form CMS-R245A, Follow-Up Version Form CMS-R245B, Transfer Version Form CMS-245C, and Discharge Version Form CMS-245D.

HHAs are required to incorporate and blend the OASIS into their own assessment process and to eliminate items on their assessment that are similar to those in OASIS. To maximize agencies' flexibility we have not prescribed how an agency is to accomplish the blending of assessments.

Since the implementation of OASIS, we have provided satellite broadcast training sessions; given numerous presentations at industry trade association meetings; distributed free software, which includes the data set and manuals on how to collect and report the data; provided updates and website information; established Educational Coordinators in all States and a help desk with a toll-free number; and provided periodic week-long conferences. As of July 19, 1999 all HHAs have collected and encoded OASIS data. Prior to 1999 OASIS had been tested in a national Outcome-Based Quality Improvement demonstration involving 50 home health agencies of all sizes, and in a single-State demonstration project involving 22 agencies, which showed that the quality of care could be significantly improved. OASIS had also been used in the national Medicare home health prospective payment demonstration, which included 90 agencies in five States. Since OASIS is structured in a checklist format, home health clinicians who use it spend less of the total evaluation time writing out a narrative response of their assessment findings and can spend more time with patients.

The use of OASIS as an assessment tool has helped make documenting home health patient information more consistent. Incorporating OASIS instrument into the patient assessment has meant that HHAs generally collect data in a more consistent manner than in the past. In the past, HHAs documented their findings in a variety of ways, often with narrative summaries. In contrast, OASIS now involves a set of standardized questions to be completed by choosing from a list of responses that substitute for most of the narrative.

In 2002, CMS introduced the "reduced-burden" OASIS that was a product of the Secretary's Regulatory Reform Advisory Committee to help guide HHS' broader efforts to streamline unnecessarily burdensome or inefficient regulations that interfere with the quality of health care. The Advisory Committee studied OASIS and recommended deleting those items and assessments not used for payment, quality measurement or survey purposes in an effort to ease paperwork burden on HHAs and their clinicians. This resulted in a burden reduction of 28% and the revised OASIS was implemented in December 2002.

Section 704 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) temporarily suspended OASIS collection for non-Medicare/non-Medicaid

patients until the outcome of an OASIS Study is presented to Congress. We expect this study will provide answers to questions related to burden, the value of the data to large and small HHAs, and will guide members of Congress and policy makers in the collection of non-Medicare/non-Medicaid OASIS data. The Secretary's Advisory Committee also made recommendations regarding the OASIS & OBQI Change and Evolution Program (OCEP). . .

This information collection was approved until June 2006. The terms of clearance of the current approval specified that on resubmission, CMS would provide OMB with an update on the progress of carrying out the recommendations of the OASIS and OBQI Change and Evolution Program.

Update on Recommendations of OASIS and OBQI Change and Evolution Program

CMS Response to Terms of Clearance:

1. The OBQI Change and Evolution Program (OCEP) recommended the relaxation of the assessment locking requirements and indicated the policy change should be announced as soon as possible. CMS-3006-F: Reporting Outcome and Assessment Information Set (OASIS) as Part of the CoPs for Home Health Agencies was published December 23, 2005 and took effect June 21, 2006.and removed the requirement for locking and requires the submission of records 30 days after completion. This will permit home health agencies to receive OASIS outcome reports 30 days or sooner.. Previously, HHAs were required to submit their data within 7 days.

2. CMS has evaluated the balance of the OCEP recommendations; and the Medicare Payment Advisory Commission (MEDPAC) is currently working to identify all necessary core items for a discharge assessment tool for Medicare beneficiaries across all post acute care (PanPAC) settings. As such, the items assessing activities of daily living and the instrumental activities of daily living identified by the OASIS OCEP will most likely be included in the new PanPAC tool. . Since the PAC assessment tool is supported by Congress and the Administrator of CMS, CMS has begun working with MEDPAC to produce the PanPAC instrument, which will most likely include the recommendations set forth by OBQI OCEP.

B. Justification

1. Need and Legal Basis

Section 1861(o) of the Act (42 U.S.C. 1395x) specifies certain requirements that a home health agency must meet in order to participate in the Medicare program. (Regulations

at 42 CFR 440.70(d) specify that HHAs participating in the Medicaid program must also meet the Medicare CoP.) In particular, section 1861(o)(6) of the Act requires that an HHA must meet the CoP specified in section 1891(a) of the Act and such other CoP as the Secretary finds necessary in the interest of the health and safety of its patients.

Section 1891(a) of the Act establishes specific requirements for HHAs in several areas, including patient rights, home health aide training and competency, and compliance with applicable Federal, State, and local laws. Section 1891(b) of the Act, states that the Secretary is responsible for assuring that the CoPs, and their enforcement, are adequate to protect the health and safety of individuals under the care of an HHA, and to promote the effective and efficient use of Medicare funds. To implement this requirement, State survey agencies generally conduct surveys of HHAs to determine whether they are complying with the CoPs. Section 1891(b) of the Act (42 U.S.C. 1395bbb) requires the Secretary to assure that the CoPs and their requirements adequately protect the health and safety of individuals under the care of a home health agency, and 1891(c)(2)(C)(i)(II) requires that a standard HHA survey shall include a survey of the quality of care and services furnished by the agency as measured by indicators of medical, nursing, and rehabilitative care. In accordance with section 1891(d)(1), we are required to monitor the quality of home health care with a "standardized, reproducible assessment instrument." Based on industry input, we selected the OASIS as the instrument to improve the quality of care and to comply with the law. The use of OASIS is a requirement that HHAs must meet to participate in the Medicare program (See 42 CFR § 484.55).

We recognize, however that the conditions of participation (42 CFR §484.200 - §484.265) that require submission also provide for exclusions from this requirement. Generally, the agencies excluded from the OASIS submission requirement do not receive Medicare payments as it either does not provide services to Medicare beneficiaries or the patients are not receiving Medicare-covered home health services. Under the Conditions of Participation, agencies are excluded form the OASIS reporting requirement on individual patients if:

- Those patients are receiving only non-skilled medical services,
- Neither Medicare not Medicaid is paying for home health care (patients receiving care under a Medicare or Medicaid Managed Care Plan are not excluded from the OASIS reporting requirement).
- Those patients are receiving pre-or post – partum services,
- Those patients are under the age of 18 years.

We believe that the rationale behind the exclusion of these agencies from submission of OASIS on patients which are excluded form OSIS submission as a Condition Of Participation (CoP) is equally applicable to HHAs for quality purposes. If an agency is not submitting OASIS for patients excluded from OASIS submission for purposes of a Condition of Participation we believe that the submission of OASIS quality measures for Medicare purposes is not necessary. There, we

~~propose~~believe that those agencies ~~f~~do not need to submit quality measure for DRA reporting purposes, for those patients who are excluded from OASIS submission as a Condition of Participation in the Medicare Home Health program.

Section 4603 of the Balanced Budget Act of 1997 (BBA) created section 1895(a) of the Act, which required the development of a prospective payment system (PPS) for HHAs beginning October 1, 2000. Specifically, section 1895(b)(4)(C) of the Act requires the Secretary to establish appropriate case-mix adjustment factors for home health services in a manner that explains a significant amount of the variation in cost among different units of services. Section 4601(d) of the BBA provided the statutory authority for the development of a case-mix system by requiring the Secretary to expand research on a PPS for HHAs under the Medicare program that ties prospective payments to a unit of service, including an intensive effort to develop a reliable case-mix adjuster that explains a significant amount of the variances in costs. Further, section 4601(e) of the BBA provides the authority for the submission of data for the case-mix system, effective for cost reporting periods beginning on or after October 1, 1997, by permitting the Secretary to require all HHAs to submit additional information necessary for the development of a reliable case-mix system. Regulations implementing these requirements are codified at 42 CFR 484 Subpart E. We have plans to eventually link beneficiary information across provider settings with other administrative data (for example, payment and utilization data). Beneficiaries may have very complex service delivery histories, moving among various services and benefits. If OASIS data are not collected, It would be difficult to track outcomes and facilitate administrative tasks involved with integrating the care of individuals in our data systems, including the Minimum Data Set (MDS) for nursing home residents.

Under the home health PPS, HHAs have an incentive to provide care more efficiently to maximize the payment they receive. Some have raised concern that the quality of care could suffer as agencies reduce the number of visits provided to patients. With the data, we will be able to support or refute anecdotal information, unsubstantiated opinion, or conjecture, facilitate consensus building, and develop more objective policy decisions. Most importantly, data provides a better opportunity to formulate effective quality driven home health policy in the future.

In accordance with the requirements of the Privacy Act of 1974, we published a notice in the Federal Register (64 FR 32992) on June 18, 1999 to announce to the public that we were establishing a new system of records (SOR) for the OASIS. The SOR was later modified in a Federal Register Notice (66 FR 66903) on December 27, 2001. The SOR contains data on the physical, mental, functional and psychological status of all HHA patients receiving home health services from HHAs participating in the Medicare and/or Medicaid programs. Information retained in the system for those individuals who have only non-Medicare/Medicaid payment sources is retained in a non-identifiable format. Information retrieved from the SOR was helpful to us as we developed, validated, and

refined the Medicare HHPPS. The information was also used to study and ensure the quality of care provided by HHAs, and to aid us in administering survey and certification activities for Medicare/Medicaid HHAs.

In the SOR notice, we outlined how the data is collected and described the entities to who we allow access. In response to public comment, we only disclose the minimum personal data necessary to achieve the purpose of OASIS. Also in that notice, we outlined how information is maintained in the system, and how it is disclosed. In general, disclosure of the information from the system of records will be approved only for the minimum information necessary to accomplish the purpose of the disclosure as first determined by CMS. In the SOR we explain the limitations on "routine uses" of data under the Privacy Act, so that personally-identifiable data will only be used where statistical information is not sufficient. Under the SOR, we limit the "routine uses" of data to other Federal and State agencies that contribute to the accuracy of CMS's health insurance operations including payment, treatment and coverage, and/or support State agencies in the evaluations and monitoring of care provided by HHAs.

2. Information Users

- HHAs: HHAs use the patient-specific information and continue to conduct patient assessment, care planning, quality assessment, and program improvement activities. HHAs are able to examine their specific care domains and types of patients. They also compare present performance to past performance with national performance norms. The quality indicators have been compiled, evaluated, and are available for use. Agency profiles are used in the survey process to compare the HHA's results with past performance. Individual HHAs use the outcome reports to evaluate the effectiveness of care provided to specific types of patients and, in the context of investigating processes of care, to individual patients. They also use the data from outcome reports to continuously monitor quality improvement outcomes over time, and to objectively assess their own strengths and weaknesses in the clinical services they provide. These outcome reports inform the HHA of the care-related areas, activities, and/or behaviors that result in effective patient care, and alert them to needed improvements. Such information is essential to HHAs in initiating quality improvement strategies. They also serve to improve HHAs' financial planning and marketing strategies.

- State agencies/CMS: The availability of performance data enables State survey agencies and CMS to identify opportunities for improvement in the HHA, and to evaluate more effectively the HHA's own quality assessment and performance improvement program. CMS and State agency surveyors use the reports off-site in a pre-survey protocol to target areas of concern for the on-site survey. The

surveyors look at how the HHA uses OASIS data internally, and uses the information to more effectively target survey activities.

- Accrediting Bodies: Upon specific request, national accrediting organizations such as the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) and the Community Health Accreditation Program (CHAP) are able to access the information only for the facilities they accredit, and that participate in the Medicare program by virtue of their accreditation (deemed) status. CMS provides OASIS information to these national accrediting bodies to enable them to target potential or identified problems during the organization's accreditation review of that facility.

- Beneficiaries/Consumers: In the fall of 2003, CMS had a national roll out of Home Health Compare, which consists of 11 quality measures available to consumers on www.Medicare.gov. This was the first effort to allow consumers and beneficiaries to compare outcomes among home health agencies in their area. As with the nursing home quality initiative, the home health agency initiative uses quality measures to assist consumers in making informed decisions when choosing a home health agency; to monitor the care their home health agency is providing; and to stimulate home health agencies to further improve quality.

3. Improved Information Technology

OASIS is designed to yield outcome measures to determine the quality of care for patients receiving home health services. CMS has developed a database where outcome reports are generated for use in quality assessment and performance improvement program activities. CMS also utilizes the interdependencies among the quality and payment data generated from the OASIS information. Using the same data elements for quality monitoring and payment allows CMS to ensure that HHAs are not maximizing profits at the expense of beneficiary outcomes while realizing the efficiency of using a single data source.

4. Duplication

The OASIS is required to be used by all HHAs. It does not duplicate any other collection data sets. It is a standardized assessment that is required to be integrated in the HHA's current patient data collection process since July 1999. For prospective payment, the case-mix methodology is used by all Medicare-approved HHAs. It uses elements that are currently collected as part of the condition of participation at § 484.55 that requires a standardized assessment to be integrated into the HHA's current patient data collection and care planning processes. Specifically, to avoid duplication, HHAs

must incorporate and blend the OASIS into their own assessment process and eliminate items on their assessment that are similar to items on the OASIS.

5. Small Business Impact

CMS previously took steps to reduce OASIS-driven burden. For example, we provide a hotline for troubleshooting purposes and free software to HHAs. This software, containing all of the OASIS data time points, is available at no charge, and can be downloaded from our website. There is also a training page on the website, along with an OASIS Q&A mailbox. Additionally, the entire OASIS User's Manual is available on our website at no cost to HHAs. CMS has also provided training through its OASIS contractors either directly or via satellite.

6. Less Frequent Collection

We continue to believe that if data collection occurs less frequently than the four specified time points, as stated in § 484.55, the ability to make proper Medicare payments and to evaluate the quality of care provided by HHAs to Medicare and Medicaid beneficiaries will be compromised. The modifications we are making to the OASIS will not affect HHA assessment activity or patient care planning.

7. Special Circumstances Leading to Information Collection

There are no special circumstances.

8. Federal Register Notice/Outside Consultation

Attached is the 60-day Federal Register notice that published on February 2, 2007.

In addition to the Secretary's Advisory Committee on Regulatory Reform, a CMS Technical Evaluation Panel composed of home health agency professionals; experts in quality measurement, payment indicators and systems; and a beneficiary representative provide advice on OASIS policy.

9. Payments or Gifts to Respondents

There are no payments or gifts to respondents.

10. Confidentiality

We pledge confidentiality of patient-specific data in accordance with the Privacy Act of 1974 (5 U.S.C. 552a). We do not pledge confidentiality of aggregate data.

11. Sensitive Questions

There are no sensitive questions.

12/13. Burden Estimates (Hours and Wages)/Estimate of Total Annual Cost Burden Summary:

At the time of the OASIS implementation, there was a one-time start-up cost for HHAs in the first year. After the first year of OASIS implementation, existing HHAs experience an ongoing cost of reporting the gathered information to the State or OASIS contractor. We continue to acknowledge that the time frames required by § 484.55 serve as a strong performance expectation for HHAs. In identifying standardized data elements that fit within the HHA's overall comprehensive assessment responsibilities, the OASIS includes only information necessary to measure outcomes of care for quality indicators and for HHAs to continue to receive payment through the prospective payment system. Therefore, we require that HHAs use the current version of the OASIS as specified in §484.55(e). We believe this requirement is necessary to continue to build a valid, reliable, comparable data set of outcomes.

OASIS items have undergone rigorous validity and reliability testing so that trained individuals can have confidence in incorporating the data items as part of their comprehensive assessment of patients. When used correctly, and if HHA staff conduct assessments accurately and use the measurement criteria specified for each item, OASIS has become one of the most important tools of the HHA's quality assessment and performance improvement efforts. HHAs can use the data set as the foundation for valid and reliable information for patient assessment, care planning, and service delivery while at the same time, building a strong and effective quality assessment and performance improvement program.

Burden Estimates

Since the implementation of the OASIS, many HHAs have conducted their own time studies. Although minimal, we acknowledge that there is a small burden associated with the on-going use of OASIS when collecting OASIS information as part of the comprehensive assessment, and collecting the information for PPS. Our estimates of time, cost, average HHA size, and staff salaries are calculated based on information from the industry, consultation with the University of Colorado, assistance with statistical information from our contractors at Stepwise Systems, and recommendations from the Secretary's Advisory Committee on Regulatory Reform.

Currently, there are about 8277 HHAs participating in the Medicare program. For years 2004 and 2005 there was a total of 11,622,052 and 12,333,150 OASIS submissions respectfully ((11,622,052 + 12,333,150)/ 2= 11,977,601 average number of OASIS).

Therefore we estimate that on average, each HHA will submit 1,447 assessments on an annual basis. We believe each assessment will require 45 minutes to complete. We define an average sized HHA as having 18 clinicians with an average salary of $ 28.00 per clinician.
11,977,601 total responses ÷ 8,277 HHAs = 1,447 responses/HHA

(.75 hours/response) x 1,447 responses/HHA = 1,085 hours/HHA

(11,977,601 responses) x (.75 hours/response) = 8,983,201 total hours

Training: Training clinicians in newly certified HHAs, and new staff in existing HHAs on the use of OASIS is an ongoing process. We continue to estimate 8 hours associated with OASIS training per facility on an annual basis, . Therefore, the estimated total staff training hours is 67,616.

(8277current HHAs) + (175 projected HHAs) = 8452 HHAs

(8452 total HHAs) x (8 hours training time per HHA) = 67,616 hours

The total annual burden of completing assessments and training is 9,050,817 hours.

8,983,201 hours + 67,616 hours = 9,050,817 hours

14. Estimate of Annualized Cost to the Federal Government

There are no costs to the Federal government.

15. Program or Burden Changes

With regards to program changes, for the purposes of payment, in order for the OASIS to have the information necessary to allow the grouper to price-out the claim, we need~~propose~~ to make the following changes to the OASIS to capture whether an episode is an early or later episode. There are six basic categories of ~~proposed~~ changes to the OASIS (See Table 1 of PRA Package for more detail) for purposes of payment:

1) Items to be added to the OASIS
    a. M0110
2) Items to be deleted and replaced by a new items
    a. M0245 replaced by M0246
    b. M0825 replaced by M0826
3) Change format and instruction to accommodate changes to payment diagnosis

   a. M0230/M0240
4) Changes to OASIS items due to replacement of M0825 with M0826
   a. M0810: change reference to M0825 to refer to M0826
5) Add to recertification (follow-up) and "other" follow-up OASIS
   a. M0470
   b. M0474
   c. M0520
   d. M0800
6) Delete from recertification (follow-up) and "other" follow-up OASIS
   a. M0175
   b. M0610

The creation of a new OASIS item (M0110) to capture whether a particular assessment, for the purposes of payment, is for an episode considered to be an early episode or a later episode in the patient's current sequence of adjacent Medicare home health payment episodes. As defined in Section II.A.1. of CMS-1541-P and implemented in CMS-1451-FC, we defined a sequence of adjacent episodes for a beneficiary as a series of claims with no more than 60 days without home care between the end of one episode, which is the 60th day (except for episodes that have been PEP-adjusted), and the beginning of the next episode. This definition holds true regardless of whether or not the same HHA provided care for the entire sequence of adjacent episodes. The HHA will chose from the options: "Early" for single episodes or the first episodes in a sequence of adjacent episodes, "Later" for third or later episodes, "UK" for unknown if the HHA is uncertain as to whether the episode is an early or later episode (grouper software will default to the definition of an "early" episode for the purposes of payment), and "NA" for Not Applicable (No Medicare case-mix group to be defined by this assessment).

In addition, for the purposes of payment, we ~~propose to~~ are makeing changes to the OASIS in order to enable agencies to report secondary case mix diagnosis codes. Thesе ~~proposed~~ changes clarify how to appropriately fill out OASIS items M0230 and M0240, using ICD-9-CM sequencing requirements if multiple coding is indicated for any diagnosis. Specifically, the addition of secondary diagnoses to the case-mix system requires that the OASIS allow for reporting of instances in which a V-code is coded in place of a case-mix diagnosis, other than the primary diagnosis, for OASIS item M0230 or M0240, then the new optional OASIS item (M0246) may be completed. A case-mix diagnosis is a diagnosis that determines the HH PPS case-mix group. Currently, the OASIS allows for reporting of instances of displacement involving primary diagnosis only (M0245). Consequently, because of the nature and significance of the changes needed, we are ~~proposing to~~ deleteing the OASIS item M0245 and replaceing it with a new OASIS item (M0246).

As discussed in CMS-1541-P and implemented in CMS-1541-FC, the ~~proposed~~ four equation model for the HH PPS, with multiple therapy thresholds and payment graduation between those thresholds, adds a certain amount of complexity to the HH PPS. Consequently, in order to group beneficiaries into case-mix groups in this ~~proposed~~ four equation model, for the purpose for payment, we ~~propose~~ are~~to~~ make changes to the OASIS to capture the projected number of total therapy visits for a given episode, as opposed to indicating if there is a projected need for ten or more therapy visits (current OASIS item M0825). With the projected total number of therapy visits, the grouper will be able to group that episode into the appropriate case-mix group for payment. We are~~propose to~~ delete OASIS item M0825 and replace it with a new OASIS item (M0826). The OASIS item will ask the following: "In the plan of care for the Medicare payment episode for which this assessment will define a case-mix group, what is the indicated need for therapy visits (total of reasonable and necessary physical, occupational, and speech-pathology visits combined)? The HHA will~~ould~~ provide the total number of projected therapy visits for that Medicare payment episode, unless not applicable (i.e. no case-mix group defined by this assessment). The HHA will~~ould~~ enter "000" if no therapy visits were projected for that particular episode. As a result of OASIS item M0826 replacing M0825, OASIS item M0810's skip instruction for the NA response needs to change its' reference from that of M0825 to M0826.

The ~~proposed~~ OASIS revisions also include incorporating previously revised instructions regarding diagnosis coding in items M0190, M0210, and M0230/M0240/M0246 (previously M0245). Previously, the instructions for these OASIS items were stated in shaded boxes when the last version of OASIS was issued (12/2002), and the shaded boxes provided the effective date, Oct. 1, 2003, for the those instructions. The instructions required that ICD-9-CM diagnoses be coded to the highest level of specificity. Instructions prior to 10/1/2003 had allowed the use of three-digit category codes. We are ~~proposing to~~ remove the shaded boxes containing those instructions that were effective Oct. 1, 2003, and incorporate those instructions directly into items M0190, M0210, and M0230/M0240/M0246.

In addition, due to ~~proposed~~ changes to the HH PPS, we are ~~proposing to~~ add OASIS items M0470, M0474, M0520, and M0800 and delete OASIS items M0175 and M0610 from the recertification (follow-up) and "other" follow-up assessments. OASIS items M0470, M0474, and M0520 are needed in recertification and follow-up assessments, due to our proposed change in the way we account for non-routine medical supplies (NRS) costs based on five severity groups. OASIS items M0175 and M0610, currently on the recertification and "other" follow-up assessments, are no longer needed on those assessments due to proposed changes in the case-mix model. For that same reason, we are also ~~proposing to~~ remove the reference to the follow-up assessment in the "NA" response for OASIS item M0175.

The burden associated with these ~~proposed~~ changes includes possible training of staff, the time and effort associated with downloading a new form and replacing previously pre-printed versions of the OASIS, and utilizing updated vendor software. However, CMS ~~will be~~is removing or modifying existing questions in the OASIS data set to accommodate the requirements referenced above. In addition, as a result of the ~~proposed~~ changes of CMS-1541-P~~F~~FC, ~~we expect that~~ the claims processing system ~~is expected to~~will automatically adjust the therapy visits, upward and downward on the final claim, according to the information on the final claim. Consequently, the HHA will no longer have to withdraw and resubmit a revised claim when the number of therapy visits delivered to the patient is higher than the level report on the RAP. Therefore, CMS believes the burden increase associated with these changes is negated by the removal or modification of several current data items. We have ~~are~~ soliciting public comment on each of these ~~proposed~~ changes for the information collection requirements (ICRs). For the purposes of soliciting public review and comment, we ~~have~~ placed a ~~current~~ draft of the ~~proposed~~ changes to the OASIS on the CMS Web site at:
http://www.cms.hhs.gov/PaperworkReductionActof1995/PRAL/list.asp#TopOfPage

The burden also changed due to a miscalculation that was found in a former submission. The calculations were corrected in this submission.

16. Publication and Tabulation Dates

There are no publication or tabulation dates.

17. Expiration Date

These information collection requirements do not lend themselves to an expiration date.

18. Certification Statement

There are no exceptions to the certification statement.

C. Collections of Information Employing Statistical Methods

These information collection requirements do not employ statistical methods.