Part III

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 409, 424, 431 et al.
Medicare Program; Home Health Prospective Payment System Rate Update for Calendar Year 2013, Hospice Quality Reporting Requirements, and Survey and Enforcement Requirements for Home Health Agencies; Proposed Rule
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 409, 424, 431, 484, 488, 489, and 498

[CMS–1358–P]

RIN 0938–AR18

Medicare Program; Home Health Prospective Payment System Rate Update for Calendar Year 2013, Hospice Quality Reporting Requirements, and Survey and Enforcement Requirements for Home Health Agencies

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would update the Home Health Prospective Payment System (HH PPS) rates, including the national standardized 60-day episode rates, the national per-visit rates, the low-utilization payment amount (LUPA), and outlier payments under the Medicare prospective payment system for home health agencies effective January 1, 2013. This rule also proposes requirements for the Hospice quality data reporting program. This proposed rule would also establish requirements for unannounced, standard and extended surveys of home health agencies (HHAs) and provide a number of alternative (or intermediate) sanctions that could be imposed if HHAs were out of compliance with Federal requirements. This proposed rule would set forth alternative sanctions that could be imposed instead of or in addition to termination of the HHAs’s participation in the Medicare program, which could remain in effect up to a maximum of 6 months, until the HHA achieved compliance with the HHA Conditions of Participation (CoPs), or until the HHA’s provider agreement was terminated.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on September 4, 2012.

ADDRESSES: In commenting, please refer to file code CMS–1358–P. Because of staff and resource limitations, we cannot accept comments by facsimile (Fax) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. Electronically. You may submit electronic comments on this regulation to http://www.regulations.gov. Follow the instructions under the “More Search Options” tab.

2. By regular mail. You may mail written comments to the following address only:

   Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1358–P, P.O. Box 8016, Baltimore, MD 21244–8016.

   Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments to the following address only:


4. By hand or courier. If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

   (Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)
   b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

   If you intend to deliver your comments to the Baltimore address, please call (410) 786–7195 in advance to schedule your arrival with one of our staff members.

   Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

   For information on viewing public comments, see the beginning of the SUPPLEMENTARY INFORMATION section.

   FOR FURTHER INFORMATION CONTACT:

Kristine Chu, (410) 786–8953, for information about the HH payment reform study and report.
Robin Dowell, (410) 786–0060, for information about HH and Hospice quality improvement and reporting.
Kim Evans, (410) 786–0009, for information about HH therapy policies.
Mollie Knight, (410) 786–7948, for information about the HH market basket.
Hillary Loeffler, (410) 786–0456, for information about the HH PPS.
Lori Teichman, (410) 786–6684, for information about HHCAHPS.
Pattie Gholson, (410) 786–8965, for information about HHCAHPS.
Patricia Sevast, (410) 786–8135 and Peggye Wilkerson, 410–786–4857, for information about HHCAHPS.
Kim Evans, (410) 786–7948, for information about the HH market basket.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: http://www.regulations.gov. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. EST. To schedule an appointment to view public comments, phone 1–800–743–3951.

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to update providers of any changes to our current plans through the following forums: the ICD–10 Home Health section of the CMS Web site, the Home Health, Hospice and DME Open Door Forums, and provider outreach sessions for ICD–10.

In December 2008, we updated and released Attachment D: Selection and Assignment of OASIS Diagnoses to promote accurate selection and assignment of the patient’s diagnosis (https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/OASIS Attachment_D_Guidance.html). This guidance was designed to ensure that providers limited the number of diagnoses assigned to M1024. In addition, Attachment D reminded HHA clinicians/coders to comply with ICD–9–CM coding guidelines when assigning primary and secondary diagnoses to the OASIS items M1020 and M1022. Analysis conducted by our HH PPS Grouper maintenance contractor revealed that many HHAs do not comply with these guidelines. The analysis demonstrated that HHAs are not limiting the number of diagnoses assigned to M1024 and continue to not comply with ICD–9–CM coding guidelines. We have reviewed the diagnosis codes identified in the HH PPS Grouper and confirmed that the only codes that cannot be reported as a primary or secondary diagnosis code (M1020 and M1022) are the fracture codes (V-code). As a result, we are proposing two enhancements for the HH PPS Grouper, which we believe will encourage compliance with coding guidelines.

We propose to restrict M1024 to only permit fracture (V-code) diagnoses codes which according to ICD–9–CM coding guidelines cannot be reported in a home health setting as a primary or secondary diagnosis. To further ensure compliance with proper coding guidelines, we propose to pair the fracture codes (V-code) with appropriate diagnosis codes and only when these pairings appear in the primary and payment diagnosis fields will the grouper award points. Currently, when a code from the Diabetes, Skin 1 or Neuro 1 group is submitted in the primary diagnosis position (M1020) the diagnosis code may score additional points. In situations where ICD–9 coding guidelines have required a V-code to be submitted in the M1020 position, HHAs have been instructed to report the etiology code in the payment diagnosis field (M1024) and receive equivalent scoring. Specifically, we are proposing a revision in HHRG logic to permit equivalent scoring when the Diabetes, Skin 1 or Neuro 1 codes are submitted immediately following the V-code in the M1020 position without requiring utilization of the payment diagnosis field. These grouper enhancements will enforce appropriate use of our payment diagnosis field based upon the guidance issued in Attachment D (putting us in a much more favorable position to eventually retire the payment diagnosis field) until we move to ICD–10 where there is no longer an issue with fracture codes, and ensure ICD–9 and ICD–10 coding guidelines are followed to assist in the eventual transition of grouping the claim, versus OASIS, to determine the appropriate HIPPS code for payment.

IV. Quality Reporting for Hospices

A. Background and Statutory Authority

Section 3004 of the Affordable Care Act amends the Act to authorize a quality reporting program for hospices. As added by section 3004 (c), new section 1814(i)(5)(A)(i) of the Act requires that beginning with FY 2014 and each subsequent FY, the Secretary shall reduce the market basket update by 2 percentage points for any hospice that does not comply with the quality data submission requirements with respect to that fiscal year. Depending on the amount of the annual update for a particular year, a reduction of 2 percentage points could result in the annual market basket update being less than 0.0 percent for a FY and may result in payment rates that are less than payment rates for the preceding FY. Any reduction based on failure to comply with the reporting requirements, as required by section 1814(i)(5)(B) of the Act, would apply only for the particular FY involved. Any such reduction will not be cumulative and will not be taken into account in computing the payment amount for subsequent FYs.

Section 1814(i)(5)(C) of the Act requires that each hospice submit data to the Secretary on quality measures specified by the Secretary. Such data must be submitted in a form and manner, and at a time specified by the Secretary. Any measures selected by the Secretary must have been endorsed by the NQF, which holds a contract regarding performance measurement with the Secretary under section 1890(a) of the Act. This contract is currently held by the National Quality Forum (NQF). However, section 1814(i)(5)(D)(iii) of the Act provides that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the consensus-based entity, the Secretary may specify a measure(s) that is(are) not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus-based organization identified by the Secretary. Under section 1814(i)(5)(D)(iii) of the Act, the Secretary must publish selected measures that will be applicable with respect to FY 2014 no later than October 1, 2012.

B. Public Availability of Data Submitted

Under section 1814(i)(5)(E) of the Act, the Secretary is required to establish procedures for making any quality data submitted by hospices available to the public. Such procedures will ensure that a hospice will have the opportunity to review the data regarding the hospice’s respective program before it is made public. In addition, under section 1814(i)(5)(E) of the Act, the Secretary is authorized to report quality measures that relate to services furnished by a hospice on the CMS Web site. We recognize that public reporting of quality data is a vital component of a robust quality reporting program and are fully committed to developing the necessary systems for public reporting of hospice quality data. We also recognize it is essential that the data we make available to the public be meaningful data and that comparing performance between hospices requires that measures be constructed from data collected in a standardized and uniform manner. The development and implementation of a standardized data set for hospices must precede public reporting of hospice quality measures. We will announce the timeline for public reporting of data in future rulemaking.

C. Quality Measures for Hospice Quality Reporting Program and Data Submission Requirements for Payment Year FY 2014

1. Quality Measures Required for Payment Year 2014

In the Hospice Wage Index for Fiscal Year 2012 Final Rule (76 FR 47302, 47320 (August 4, 2011)), to meet the quality reporting requirements for hospices for the FY 2014 payment determination as set forth in section 1814(i)(5) of the Act, we finalized the requirement that hospices report two measures:

- An NQF-endorsed measure that is related to pain management, NQF #0209: The percentage of patients who report being uncomfortable because of pain on the initial assessment (after admission to hospice services) who report pain was brought to a comfortable
level within 48 hours. The data collection period for this measure is October 1, 2012 through December 31, 2012, and the data submission deadline is April 1, 2013. The data for this measure are collected at the patient level, but are reported in the aggregate for all patients cared for within the reporting period, regardless of payor.

- A structural measure that is not endorsed by NQF: Participation in a Quality Assurance and Performance Improvement (QAPI) program that includes at least three quality indicators related to pain management. Specifically, hospice programs are required to report whether or not they have a QAPI program that addresses at least three indicators related to pain management. The data collection period for this measure is October 1, 2012 through December 31, 2012, and the data submission deadline is January 31, 2013. Hospices are not asked to report the level of performance on these patient care related indicators. The information being gathered will be used by CMS to ascertain the breadth and content of existing hospice QAPI programs. This stakeholder input will help inform future measure development.

Hospice programs will be evaluated for purposes of the quality reporting program based on whether or not they respond, not on how they respond or on performance level. No additional measures are required for payment year FY 2014.

2. Data Submission Requirements for Payment Year 2014

We will provide a Hospice Data Submission Form to be completed using a web-based data entry site. Training for use of this Web-based data submission form will be provided to hospices through webinars and other downloadable materials before the data submission date. Though similar to the data entry site utilized during the hospice voluntary reporting period, the site will be changed to accommodate the addition of the NQF #0209 measure, as well as to simplify the data entry requirements for the structural measure. Hospices will be asked to provide identifying information, and then complete the web-based data entry for the required measures. For hospices that cannot complete the web-based data entry, a downloadable data entry form will be available upon request.

The data submission form as well as details regarding education and resources related to the data collection and data submission for both the NQF #0209 measure and the structural measure will be provided on the CMS Web site at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/

D. Quality Measures for Hospice Quality Reporting Program for Payment Year FY 2015 and Beyond

1. Quality Measures Required for Payment Year FY 2015 and Subsequent Years

To meet the quality reporting requirements for hospices for the FY 2015 payment determination and each subsequent year, as set forth in section 1814(i)(5) of the Act, we propose that hospices report the following:

- The NQF-endorsed measure that is related to pain management, NQF #0209: The percentage of patients who report being uncomfortable because of pain on the initial assessment (after admission to hospice services) who report pain was brought to a comfortable level within 48 hours.

- The structural measure: Participation in a Quality Assurance and Performance Improvement (QAPI) Program that Includes at Least Three Quality Indicators Related to Patient Care. Specifically, hospice programs would report whether or not they have a QAPI program that addresses at least three indicators related to patient care.

We are not extending the requirement that hospices provide a list of their patient care indicators. We invite comment on the proposed selection of measures.

2. Data Submission Requirements for Payment Year FY 2015

As previously noted, in the Hospice Wage Index for Fiscal Year 2012 Final Rule, we finalized the following:

- All hospice quality reporting periods subsequent to that for Payment Year FY 2014 be based on a calendar year rather than a calendar quarter. For example, January 1, 2013 through December 31, 2013 will be the data collection period used for determination of the hospice market basket update for each hospice in FY 2015, etc.; and

- Hospices submit data in the fiscal year prior to the payment determination. For FY 2015 and beyond, the data submission deadline will be April 1 of each year. For example, April 1, 2014 will be the data submission deadline used for determination of the hospice market basket update for each hospice in FY 2015, etc.

E. Additional Measures Under Consideration and Standardization of Data Collection

While initially we will build a foundation for quality reporting by requiring hospices to report one NQF-endorsed measure and one structural measure, we seek to achieve a comprehensive set of quality measures to be available for widespread use for quality improvement and also informed decision making. The provision of quality care to hospice patients and families is of utmost importance to CMS. For annual payment determinations beyond FY 2015, we will be asking hospices to submit an expanded set of quality measures to be available for widespread use for quality improvement and also informed decision making. The provision of quality care to hospice patients and families is of utmost importance to CMS. For annual payment determinations beyond FY 2015, we are considering an expansion of the required measures to include some additional measures endorsed by NQF. The measures of particular interest are NQF numbers 1634, 1637, 1638, 1639, and 0208 and can be found by searching the NQF site at www.qualityforum.org. We welcome comments on whether all, some, any, or none of these measures should be considered for future rulemaking. A potential timeline and titles of future measures under consideration are included below.

To support the standardized collection and calculation of quality measures specifically focused on hospice services, we believe the required data elements would potentially require a standardized assessment instrument. We are committed to developing a quality reporting program for hospices that utilizes standardized methods to collect data needed to calculate endorsed quality measures. To achieve this goal, we have been working on the initial development and testing of a hospice patient-level data item set. This patient level item set could be used by all hospices at some point in the future to collect and submit standardized data items about each patient admitted to hospice. These data could be used for calculating quality measures. Many of the items currently in testing are already standardized and included in assessments used by a variety of other providers. Other items have been developed specifically for the hospice care settings, and obtain information needed to calculate the hospice-appropriate quality measures that were endorsed by NQF in February 2012. We are considering a target date for implementation of a standardized hospice data item set as early as CY 2014, dependent on development and infrastructure logistics. We welcome comments on the potential implementation of a hospice patient-level data item set in CY 2014.
In developing the standardized data item set, we have included data items that will support the following endorsed measures:

- 1617 Patients Treated With an Opioid Who Are Given a Bowel Regimen
- 1634 Pain Screening
- 1637 Pain Assessment
- 1638 Dyspnea Treatment
- 1639 Dyspnea Screening

Starting with data collection in 2015, we envision these measures as possible measures that we would implement subject to future rulemaking. We welcome comments on the potential future implementation of these measures and the associated projected timeframe for implementation.

We are also considering future implementation of measures based on an experience of care survey such as the Family Evaluation of Hospice Care Survey (FEHC). The NQF endorsed measure # 0208 Family Evaluation of Hospice Care is such a measure. Implementation of an experience of care measure and the associated use of a specified survey could precede or follow the implementation of a standardized data set. We do not envision implementation of both a data set and an experience of care survey in the same year and would project implementation in succession in order to avoid excessive burden to hospices.

We solicit comment on the succession of implementation of these two potential requirements.

Summary Tables:

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**Target Date for Potential Future Implementation of Standardized Data Set**

Considering Hospice Standardized Data Item Set for implementation in CY 2014.

**Target Dates for Potential Implementation of Future Measures Under Consideration**


Considering NQF endorsed measures supported by a standardized data set:

- 1617 Patients Treated With an Opioid Who Are Given a Bowel Regimen
- 1634 Pain Screening
- 1637 Pain Assessment
- 1638 Dyspnea Treatment
- 1639 Dyspnea Screening

Considering NQF endorsed measure derived from the FEHC survey:

- 0208 Family Evaluation of Hospice Care

**V. Survey and Enforcement Requirements for Home Health Agencies**

**A. Background and Statutory Authority**

In the 1980s and 1990s, home health services became a rapidly growing segment of Medicare expenditures. During that time, Congress enacted several laws that dramatically expanded the authority of CMS in its administration of the home health benefit. The Omnibus Budget Reconciliation Act of 1987 (OBRA ’87) (Pub. L. 100–203, enacted on December 22, 1987) amended the Act to incorporate provisions that would create mechanisms to improve the quality of home health services as well as long-term care services. It also provided the Secretary with the authority to change the manner in which CMS regulated and carried out enforcement actions with respect to HHAs participating in the Medicare program. Changes in both the HHA and long-term care arenas required significant adjustments and increased workload for CMS in its operation and regulatory oversight of these programs.

The OBRA ’87 amendments mandated an outcome-oriented survey process for HHAs that would include “a survey of the quality of care and services furnished by the agency as measured by indicators of medical, nursing, and rehabilitative care,” as reflected in section 1891(c)(2)(C)(i)(II) of the Act. We responded to that mandate by creating an outcome-oriented survey process for HHAs that included specific procedures to be followed, including visits to patients in their homes. We also defined in our policies, although not in regulation, the different types of surveys to be used, including the standard, partial extended and extended surveys addressed in section 1891 of the Act. This proposed rule would codify these types of surveys in regulation.

To participate as an HHA in the Medicare program, an agency or organization must meet the definition of an HHA in section 1861(o) of the Act. Section 1861(o) of the Act defines an HHA as a public agency or private organization or a subdivision of such an agency or organization, which among other things, is primarily engaged in the provision of skilled nursing services and other therapeutic services, has policies established by a group of professional personnel, maintains clinical records, is licensed under State or local law, and meets the health and safety standards established by the Secretary. Additionally, section 1891(a) of the Act sets out specific participation requirements for HHAs. The regulations implementing sections 1861(o) and 1891(a) of the Act are known as health and safety standards, or CoPs, for HHAs and are codified in 42 CFR part 484.

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. Section 1861(m) of the Act defines the