CBE ID

0176

Title

Improvement in Management of Oral Medications

Project

Advanced Illness and Post-Acute Care

Endorsement Status

Endorsed with Conditions

E&M Committee Rationale/Justification

When this measure comes back for maintenance, the committee would like to see:

- The developer explore, with their technical expert panel (TEP), combining the four improvement measures (CBE #0167, CBE #0174, CBE #0175, and CBE #0176) into a composite score, with the ability to identify individual scores for each of the four areas of improvement.

Is Under Review

No

Next Maintenance Cycle

Spring 2029

Previous Endorsement Cycle

Spring 2024

Steward

Centers for Medicare & Medicaid Services

1.0 New or Maintenance

Maintenance

1.3 Electronic Clinical Quality Measure (eCQM)

No

1.6 Measure Description

Percentage of home health episodes of care during which the patient improved in ability to take their medicines correctly, by mouth. This is a rate/proportion measure targeted at elderly individuals with multiple chronic conditions during home health quality of care episodes.

1.7 Composite Measure

No

1.7 Measure Type

Outcome

1.8 Level of Analysis

Facility

1.9 Care Setting

Home Health

1.10 Measure Rationale

The patient's ability to independently manage oral medications reliably and safely is an important patient safety factor, impacting the effectiveness of the patient's treatment regimen and health-related outcomes. Patients need certain abilities to successfully manage their oral medications and may have difficulty safely taking their oral medications and/or may need help from another person or other assistance (e.g., from a drug diary or dispensing device) to accomplish this activity safely. High-quality care for Improvement in Oral Medication Management includes successful collaboration between provider and patient, reconciliation of all medications across the continuum of care, and meaningful education efforts. Home health care staff can evaluate patients' needs for, and can teach them how to use, devices to assist with taking the correct medication dose at the correct time. Developing and improving abilities related to management of oral medications contributes to quality of life and can allow patients to live as long as possible in their own environment. Improvement in this measure will contribute to the overall general health of the patient with impaired ability to manage oral medications and is an indicator of effective, high-value home health care.

1.11 Measure Webpage

https://www.cms.gov/medicare/quality/home-health/home-health-quality-measures

1.13 Data Dictionary

Attached

1.14 Numerator

The number of home health episodes of care where the value recorded on the discharge assessment indicates less impairment in taking oral medications at discharge than at start (or resumption) of care.

1.14a Numerator Details

The number of home health episodes of care from the denominator in which the value recorded for the OASIS item M2020 ("Management of Oral Medications") on the discharge assessment is numerically less than the value recorded on the start (or resumption) of care assessment, indicating less impairment at discharge compared to start/resumption of care.

1.15 Denominator

Number of home health episodes of care ending with a discharge during the reporting period, other than those covered by generic or measure-specific exclusions.

1.15a Denominator Details

Home health quality episodes ending with a discharge from the agency during the reporting period (M0100[2]=09), except for those meeting the exclusion criteria.

1.15b Denominator Exclusions

Home health quality episodes for which the patient, at start/resumption of care, was able to take oral medications correctly without assistance or supervision (M2020[1] = 00) or patient has no oral medications prescribed (M2020[1] = (NA,'^',') or M2020[2] = (NA)) or the patient was nonresponsive (M1700[1] = 04 or M1710[1] = NA or M1720[1] = NA) or the episode is covered by the generic exclusions (see following section).

1.15c Denominator Exclusions Details

Home health episodes of care for which (1) at start/resumption of care OASIS item M2020 = 0, indicating the patient was able to take the correct oral medication(s) and proper dosage(s) at the correct time; or (2) at start/resumption of care, OASIS item M1700 "Cognitive Functioning" is 4, or M1710 "When Confused" is NA, or M1720 "When Anxious" is NA, indicating the patient is non-responsive; or (3) the patient did not have a discharge assessment because the episode of care ended in transfer to inpatient facility or death at home; or patient has no oral medications prescribed (M2020[1] = (NA,'^',') or M2020[2] = (NA)), or (5) the episode is covered by one or more of the generic exclusions:

1. Pediatric home health patients (less than 18 years of age).
2. Home health patients receiving maternity care only.
3. Home health patients receiving non-skilled care only.
4. Home health patients for which neither Medicare nor Medicaid are a payment source.
5. The episode of care does not end during the reporting period.
6. If the home health agency sample includes fewer than 20 episodes after all other patient-level exclusions are applied, or if the agency has been in operation less than six months, then the data is suppressed from public reporting on Home Health Compare.
7. Hospice exclusion: Episodes of care that end in a non-institutional hospice on or after January 1, 2023 are excluded: M2420 "Discharge Disposition" is 3 and M0100 "Reason For Assessment" is 9.

Table 1 (see supplemental attachment page 3) provides the episode counts by exclusion criterion for episodes of care that started and ended in CY 2022. In CY 2022, 1,817,918 episodes

of care were excluded from the denominator for *Improvement in Management of Oral Medications (#0176)* due to meeting at least one exclusion criterion. Approximately 94,000 episodes of care in CY 2022 ended in a discharge to non-institutional hospice. This exclusion criterion is only applicable to episodes of care ending on or after January 1, 2023 and is therefore not listed in **Table 1 (see supplemental attachment page 3).**

1.16 Type of Score

Rate/proportion

1.17 Measure Score Interpretation

Better performance = Higher score

1.18 Calculation of Measure Score

1. Define an episode of care (the unit of analysis): Data from matched pairs of OASIS assessments for each episode of care (start or resumption of care paired with a discharge or transfer to inpatient facility) are used to calculate individual patient outcome measures.

2. Identify target population: All quality episodes of care ending during a specified time interval (usually a period of twelve months), subject to generic and measure-specific exclusions. Cases meeting the target outcome are those where the patient indicates less impairment in taking oral medications correctly at discharge than at start (or resumption) of care: M2020_CRNT_MGMT_ORAL_MDCTN [2] < M2020_CRNT_MGMT_ORAL_MDCTN [1].

3. Aggregate the Data: The observed outcome measure value for each home health agency is calculated as the percentage of cases meeting the target population (denominator) criteria that meet the target outcome (numerator) criteria.

4. Risk Adjustment: The expected probability for a patient is calculated using the following formula:

$$P(x) = 1/(1+^{-(a+\Sigma b_i x_i)})$$

Where:

$P(x)$ = predicted probability of achieving outcome x

a = constant parameter listed in the model documentation

b_i = coefficient for risk factor i in the model documentation

x_i = value of risk factor i for this patient

Predicted probabilities for all patients included in the measure denominator are then averaged to derive an expected outcome value for the home health agency. This expected value is then used, together with the observed (unadjusted) outcome value and the expected value for the national population of patients for the same data collection period, to calculate a risk-adjusted outcome value for the home health agency. The formula for the adjusted value of the outcome measure is as follows:

$X(A_{ra}) = X(A_{obs}) + X(N_{exp}) - X(A_{exp})$

Where:

$X(A_{ra})$ = Agency risk-adjusted outcome measure value

$X(A_{obs})$ = Agency observed outcome measure value

$X(A_{exp})$ = Agency expected outcome measure value

$X(N_{exp})$ = National expected outcome measure value

If the result of this calculation is a value greater than 100%, the adjusted value is set to 100%. Similarly, if the result is a negative number the adjusted value is set to zero.

1.19 Measure Stratification Details

The measure is not stratified.

1.20 Types of Data Sources

Standardized Patient Assessments

1.25 Data Source Details

https://www.cms.gov/medicare/quality/home-health/oasis-data-sets

The reporting of quality data by home health agencies (HHAs) is mandated by Section 1895(b)(3)(B)(v)(II) of the Social Security Act (“the Act”). Outcome and Assessment Information Set (OASIS) reporting is mandated in the Medicare regulations at 42 C.F.R.§484.250(a), which requires HHAs to submit OASIS assessments to meet the quality reporting requirements of section 1895(b)(3)(B)(v) of the Act. It is important to note that to calculate quality measures from OASIS data, there must be a complete quality episode, which requires both a Start of Care (initial assessment) or Resumption of Care OASIS assessment and a Transfer or Discharge OASIS assessment.

1.26 Minimum Sample Size

Not Applicable.

2.1 Attach Logic Model

0176_Logic Model.pdf

2.2 Evidence of Measure Importance

A patient's ability to independently manage oral medications reliably and safely is an important safety factor and can lead to improved management of chronic and acute illness, and the reduction of medication errors (Sheehan, et al, 2018). Conversely, the inability to manage oral medication can lead to adverse health outcomes and unnecessary hospitalization (Khezrian, et al, 2020; Sokol, et al, 2005; World Health Organization, 2019). Post-acute care patients often struggle to obtain medications, understand their safe administration, and techniques related to safe self-management (Mortelmans, et al, 2021; Tomlinson, et al, 2020). All these problems contribute to medication errors, which are the third leading cause of death in the USA (Makary & Daniel, 2016). In order to safely manage medications, patients and their caregivers need support and education (Kairuz, et al, 2008). Home health care staff can evaluate patients' needs and can teach them how to use devices to assist with taking the correct medication dose at the correct time. High-quality care in Improvement in Oral Medication Management includes successful collaboration between provider and patient, reconciliation of all medications across the continuum of care, and meaningful education efforts. Research has shown that when patients and families receive this type of support, it leads to improved medication adherence and better clinical outcomes (Lyngstad, et al, 2013; Dineen-Griffin, et al, 2019; Yang, et al, 2022). The appropriate management of medications is essential to assure the efficacy of treatment regimens among patients, and the safe administration of medications.

Dineen-Griffin, S., Garcia-Cardenas, V., Williams, K., & Benrimoj, S. I. (2019). Helping patients help themselves: a systematic review of self-management support strategies in primary health care practice. *PloS one*, *14*(8), e0220116.

Kairuz, T., Bye, L., Birdsall, R., Deng, T., Man, L., Ross, A., ... & Tautolo, E. (2008). Identifying compliance issues with prescription medicines among older people. *Drugs & aging*, *25*(2), 153-162.

Khezrian, M., McNeil, C.J., Murray, A.D., Myint, P.K., (2020). An overview of prevalence, determinants and health outcomes of polypharmacy. Ther. Adv. Drug Saf. 11, 1–10. https://doi.org/10.1177/2042098620933741

Lyngstad, M., Melby, L., Grimsmo, A., & Hellesø, R. (2013). Toward increased patient safety? Electronic communication of medication information between nurses in home health care and general practitioners. *Home Health Care Management & Practice*, *25*(5), 203-211.

Makary, M. A., & Daniel, M. (2016). Medical error—the third leading cause of death in the US. *Bmj*, *353*.

Mortelmans, L., De Baetselier, E., Goossens, E., Dilles, T. (2021). What happens after hospital discharge? Deficiencies in medication management encountered by geriatric patients with polypharmacy. Int. J. Environ. Res. Public Health 18 (13), 7031. https://doi.org/10.3390/ijerph18137031.

Sheehan, O. C., Kharrazi, H., Carl, K. J., Leff, B., Wolff, J. L., Roth, D. L., ... & Boyd, C. M. (2018). Helping older adults improve their medication experience (HOME) by addressing medication regimen complexity in home healthcare. *Home healthcare now*, *36*(1), 10-19.

Sokol, M.C., McGuigan, K.A., Verbrugge, R.R., Epstein, R.S. (2005). Impact of medication adherence on hospitalization risk and healthcare cost. Med. Care 43 (6), 521–530. https://doi.org/10.1097/01.mlr.0000163641.86870.af.

Tomlinson, J., Silcock, J., Smith, H., Karban, K., Fylan, B. (2020). Post-discharge medicines management: the experiences, perceptions and roles of older people and their family carers. Health Expect. 23 (6), 1603–1613. https://doi.org/10.1111/hex.13145.

World Health Organization (2019). Medication safety in polypharmacy: technical report. https://apps.who.int/iris/handle/10665/325454

Yang C, Lee DTF, Wang X, Chair SY. (2022) Effects of a nurse-led medication self-management intervention on medication adherence and health outcomes in older people with multimorbidity: A randomised controlled trial. Int J Nurs Stud. 2022 Oct;134:104314. doi: 10.1016/j.ijnurstu.2022.104314. Epub 2022 Jun 22. PMID: 35849886.

2.4 Performance Gap

Improvement in Management of Oral Medications (#0176) is calculated using CMS's Home Health Quality Reporting Program's assessment tool, the Outcome and Assessment Information Set (OASIS). All components of the measure are defined using data from the OASIS, including the numerator, denominator, exclusions, and risk factors. The measure is risk adjusted to account for patient characteristics at the start of care or resumption of care (SOC/ROC). The denominator consists of unique quality episodes, i.e. a SOC/ROC assessment paired with an end of care (EOC) assessment.

While all the data used to report results in this form are derived from the OASIS, the periods used to generate results vary. Trends are presented from the calendar year 2019 (CY 2019) to CY 2022. We restrict descriptive characteristics, reliability, and validity to CY 2022, the most recent calendar year of data currently available. The results generated for risk adjustment use CY 2021 data, the data used during the most recent maintenance reevaluation and risk adjustment update.

Table 2 (see supplemental attachment page 9) presents performance for *Improvement in Management of Oral Medications (#0176)* from CY 2019 to CY 2022 among home health agencies that exceed the public reporting threshold of at least 20 quality episodes of care. Overall, mean performance has been trending upwards, with a low of 0.713 in CY 2019 and a high of 0.770 in CY 2022. The lower and upper bounds of the interquartile range have also increased with each year. Despite the steady increases year-over-year, there remains a performance gap for *Improvement in Management of Oral Medications (#0176)*. Fewer than 70 percent of quality episodes exhibit improvement among the lowest quartile of home health agencies, and between 20 and 25 percent of quality episodes fail to improve for the average home health agency (**see Tables 2 and 3 on supplemental attachment page 9**).

Aside from CY 2020, which was affected by the COVID public health emergency reporting requirements, roughly 4.2 million quality episodes are used to score the measure. The measure is publicly reported for over 7,000 home health agencies.

Table 3 (see supplemental attachment page 9) presents performance for *Improvement in Management of Oral Medications (#0176)* for CY 2022 by home health agency size among home health agencies that exceed the public reporting threshold. From bottom decile to top decile, the distribution in performance is tight with a minimum at Decile 1 of 0.639 and a maximum at Decile 9 of 0.849, a 0.21 difference in mean score. Smaller home health agencies perform worse on the measure, with Deciles 1 to 4 performing lower than the overall mean score and Deciles 5 to 10 performing higher.

Table 1. Performance Scores by Decile

Performance Gap

	Overall	Minimum	Decile_1	Decile_2	Decile_3	Decile_4	Decile_5	Decile_6	Decile_7	Decile_8	Decile_9	Decile_10	Maximum
Mean Performance Score	0.770	0.000	0.639	0.691	0.718	0.735	0.764	0.805	0.824	0.836	0.849	0.843	1.000
N of Entities	7,498		654	763	739	750	751	746	747	750	749	749	
N of Persons / Encounters / Episodes	4,247,370		20,480	36,075	55,085	84,116	126,528	189,978	286724	448,677	752,046	2,247,661	

2.6 Meaningfulness to Target Population

The public can comment on the home health quality reporting program when notice of proposed rulemaking is published as well as through the consensus-based entity (CBE) public commenting. No comments have been received in this time period regarding this measure. The target of this performance-based measure is the Medicare-certified home health agency. Functional status was confirmed as a domain of importance for quality measurement at a recent Technical Expert Panel (TEP).

3.1 Contributions Towards Closing Care Gaps

Across home health agencies, we compared *Improvement in Management of Oral Medications (#0176)* CY 2022 performance by subgroups for urbanicity/rurality, size, and share of quality episodes with non-white patients (**see Figure 4 on supplemental attachment page 25**).

We define urbanicity as home health agencies located within a Core-Based Statistical Area (CBSA) as defined by the Office of Management and Budget (OMB). Urban home health agencies on average performed slightly worse at 0.771 than rural home health agencies at 0.777.

We define large home health agencies as home health agencies with quality episode counts in the top quartile for CY 2022 and small home health agencies as being in the bottom quartile. Large home health agencies perform much better at 0.844 than small home health agencies at 0.676.

For “Highest Quartile Non-White” home health agencies, we use the M0140: Race/Ethnicity OASIS item to identify the patient’s race/ethnicity as non-white. Home health agencies in the lowest quartile share of quality episodes with non-white patients perform better at 0.789 than home health agencies in the highest quartile at 0.686.

The results, particularly for home health agency size and percentage of non-white patients, indicate a performance gap across home health agencies by subgroup. CMS is monitoring the persistence of these gaps and investigating next steps for addressing through reevaluated measure specifications or other policies
(see https://www.cms.gov/medicare/quality/home-health-quality-reporting-prog... for additional

resources).

4.1 Feasibility Assessment

This is a long-standing measure in the Home Health Quality Reporting Program. We have not identified any feasibility issues for this measure. The Outcome and Assessment Information Set (OASIS) items for this measure must be completed as part of the OASIS assessment. Responses to the questions are required for data submission to the CMS system. The OASIS burden estimates are reported through rulemaking.

4.3 Feasibility Informed Final Measure

OASIS data collection and submission are a requirement of the Medicare Home Health Conditions of Participation. Medication management assessment is conducted as part of usual clinical practice, and information on a patient's ability to manage their oral medications used to calculate this measure is recorded in the relevant OASIS items embedded in the home health agency's clinical assessment. OASIS data are collected by the home health agency during the care episode and submitted electronically to CMS via the Internet Quality Improvement and Evaluation System (iQIES). No issues regarding availability of data, missing data, timing or frequency of data collection, patient confidentiality or implementation have become apparent since OASIS-E was implemented January 1, 2023. No changes have been made to the measure specifications.

4.4 Proprietary Information

Not a proprietary measure and no proprietary components

5.1.1 Data Used for Testing

While all the data used to report results in this form are derived from the OASIS, the periods used to generate results vary. We restrict descriptive characteristics, reliability, and validity to CY 2022, the most recent calendar year of data currently available, and the results generated for exclusions and risk adjustment use CY 2021 data, the data used during the most recent maintenance reevaluation and risk adjustment update.

5.1.2 Differences in Data

Not applicable

5.1.3 Characteristics of Measured Entities

Table 4 (see supplemental attachment page 10) identifies the publicly reporting home health agencies by size and Census region. This distribution of home health agencies is used for reliability and validity testing. 7,498 home health agencies have 20 or more quality episodes starting and ending in CY 2022.

5.1.4 Characteristics of Units of the Eligible Population

Table 5 (see supplemental attachment page 11) identifies the patient characteristics of quality episodes treated by publicly reporting home health agencies. Characteristics are reported by sex, race, age, and Census region. This distribution of quality episodes is used for reliability and validity testing. 4,247,370 quality episodes started and ended in CY 2022 and met the denominator exclusion and public reporting requirements.

5.2.1 Level(s) of Reliability Testing Conducted

Person or encounter level (i.e., data element) (e.g., inter–abstractor reliability), Accountable entity level (i.e., measure score) (e.g., signal-to-noise analysis)

5.2.2 Method(s) of Reliability Testing

Below, we address reliability at two levels: (1) the performance measure and (2) the underlying data element: OASIS item M2020 (Management of Oral Medications: Patient's current ability to prepare and take all oral medications reliably and safely, including administration of the correct dosage at the appropriate times/intervals. Excludes injectable and IV medications. NOTE: This refers to ability, not compliance or willingness.).

Reliability of the Performance Measure Score: Abt measured the extent to which differences in each quality measure were due to actual differences in agency performance versus variation that arises from measurement error. Statistically, reliability depends on performance variation for a measure across agencies, the random variation in performance for a measure within an agency's panel of attributed beneficiaries, and the number of beneficiaries attributed to the agency. High reliability for a measure suggests that comparisons of relative performance across agencies are likely to be stable over different performance periods, and that the performance of one agency on the quality measure can confidently be distinguished from another. Potential reliability values range from zero to one, where one (highest possible reliability) means that all variation in the measure's rates is the result of variation in differences in performance across agencies, while zero (lowest possible reliability) means that all variation is a result of measurement error.

To assess measure reliability, Abt used a split-half reliability test. First, we randomly divided each publicly reporting home health agency's quality episodes into two separate equally sized groups. Then, we calculated risk-adjusted performance rates for each group. Then, using the paired performance rates, we calculated the absolute agreement intra-class correlation statistic or ICC(2,1) with a Spearman-Brown correction to address the artificial reduction in home health agency size by half. Additionally, we recalculate ICC(2,1) within each agency size decile, where size is measured as the number of quality episodes treated after denominator and public reporting exclusions.

- Reliability of the Underlying Data Element: The measure is calculated by comparing patient functioning at the start and end of a home health quality episode, as reported by the home health OASIS data set. Patient ability to ambulate is based on response to OASIS item M2020 (Management of Oral Medications: Patient's current ability to prepare and take all oral medications reliably and safely, including administration of the correct dosage at the appropriate times/intervals. Excludes injectable and IV medications):

1. Able to independently take the correct oral medication(s) and proper dosage(s) at the correct times.
2. Able to take medication(s) at the correct times if:
    1. individual dosages are prepared in advance by another person, OR
    2. another person develops a drug diary or chart.
3. Able to take medication(s) at the correct times if given reminders by another person at the appropriate times.
4. Unable to take medication unless administered by another person.

NA No oral medications prescribed.

In 2016 and 2017, Abt and partners conducted a field test of new and existing OASIS items on 12 home health agencies in four states for 213 home health patients.[1]Home health registered nurses and physical therapists, trained by the study team, collected data during home visits at start of care (SOC) or resumption of care (ROC), and/or at discharge. Follow-up visits were conducted within 24 hours of the initial field test visit, by a different registered nurse or physical therapist to test interrater reliability. M2020 was one of the existing OASIS items that was tested. Interrater reliability was assessed for SOC or ROC and at Discharge with a linear weighted kappa. The number patients for which inter-rater reliability could be tested was 105 at SOC/ROC and 84 at discharge.

The kappa statistic is generally considered to be the “gold standard” statistic associated with item reliability as it factors in the possibility of chance agreement. Kappa values are reported as decimal values between 0.00 (poor) and 1.00 (perfect). These can be interpreted using the following seven categories:[2]

- Poor < 0.10
- Slight = 0.10 to 0.20
- Fair = 0.21 to 0.40
- Moderate = 0.41 to 0.60
- Substantial = 0.61 to 0.80
- Near perfect = 0.81 to 0.99
- Perfect = 1.00

[1] Abt Associates (2018). “OASIS Field Test Summary Report: Outcome and Assessment Information Set (OASIS) Quality Measure Development and Maintenance Project.”

[2] Landis JR, Koch GG. The measurement of observer agreement for categorical data. Biometrics, 1977. 33(1):159-174.

5.2.3 Reliability Testing Results

Reliability of the Performance Measure Score: The table below summarizes the distribution of reliability scores for the 7,498 home health agencies exceeding the public reporting threshold of at least 20 eligible quality episodes of care.

Reliability of the Underlying Data Element: The inter-rater reliability (weighted kappa) values for M2020 Management of Oral Medications was 1.00 at SOC/ROC and 0.65 at discharge.

5.2.4 Interpretation of Reliability Results

Reliability of the Performance Measure Score: The ICC(2,1) statistics exceed 0.800, even within the decile with the smallest home health agencies, suggesting strong reliability and acceptability for drawing inferences about home health agencies.

Reliability of the Underlying Data Element: Based on the weighted kappa statistics the inter-rater reliability indicated perfect agreement at SOC/ROC (1.00) and substantial agreement at discharge (0.65). Given the scale of the response to this OASIS item (four possible responses and "NA"), we conclude that the item achieves sufficient reliability.

Table 2. Accountable Entity Level Reliability Testing Results by Denominator, Target Population Size

Accountable Entity-Level Reliability Testing Results

	Overall	Minimum	Decile_1	Decile_2	Decile_3	Decile_4	Decile_5	Decile_6	Decile_7	Decile_8	Decile_9	Decile_10	Maximum
Reliability	0.943		0.846	0.903	0.942	0.956	0.968	0.975	0.977	0.979	0.983	0.992	
Mean Performance Score	0.770	0.000	0.639	0.691	0.718	0.735	0.764	0.805	0.824	0.836	0.849	0.843	1.000
N of Entities	7,498		754	763	739	750	751	746	747	750	749	749	
N of Persons / Encounters / Episodes	4,247,370		20,480	36,075	55,085	84,116	126,528	189,978	286,724	448,677	752,046	2,247,661	

5.3.1 Level(s) of Validity Testing Conducted

Person or encounter level (i.e., data element) (e.g., sensitivity and specificity), Accountable entity level (i.e., measure score) (e.g., criterion validity)

5.3.3 Method(s) of Validity Testing

Below, we address validity at two levels: (1) the performance measure and (2) the underlying data element: OASIS item M2020 (Management of Oral Medications: Patient's current ability to

prepare and take all oral medications reliably and safely, including administration of the correct dosage at the appropriate times/intervals. Excludes injectable and IV medications. NOTE: This refers to ability, not compliance or willingness.).

Validity of the Performance Measure Score: Abt assessed the convergent validity of the measure. Convergent validity refers to the extent to which measures that are designed to assess the same construct are related to each other. To evaluate the convergent validity of the measure, Abt calculated the Spearman rank correlations of the *Improvement in Management of Oral Medications (#0176)* measure with other relevant OASIS-based measures and the fee-for-service (FFS) claims-based measure *Discharge to Community (#3477)* measure.

The Spearman rank correlation assesses the statistical dependence between the rankings of two variables. In our case, we rank home health agencies according to *the Improvement in Management of Oral Medications (#0176)* measure and other home health agency-level measures.

Validity of the Underlying Data Element: The OASIS item M2020: Management in Oral Medications has been used continuously as part of the OASIS since 2001. The behaviorally benchmarked responses were updated and improved based on input from clinicians and technical experts. The OASIS instrument has been published in the Federal Register for comment (both items and measures based off those items) and no objections or suggestions for revision have been noted regarding the response options.

The original OASIS item was originally carefully designed for measuring and ultimately enhancing patient outcomes as part of the National OBQI Demonstration project (1995 – 2000). OASIS items were derived by first specifying a set of patient outcomes considered critical by home care experts (e.g., nurses, physicians, therapists, social workers, administrators) for evaluating the effectiveness of care. These outcomes were chosen from the most important domains of health status addressed by home care providers. OASIS data items were developed, tested in hundreds of agencies, and refined for measuring outcomes to evaluate and enhance the effectiveness of home care. OASIS data items and measurement methods were reviewed by multidisciplinary panels of research methodologists, clinicians, home care managers, and policy analysts. Several tests of validity were conducted for each OASIS item, including Management in Oral Medications. Validity testing included:

1) Consensus validity by expert researcher/clinical panels for outcome measurement and risk factor measurement

2) Consensus validity by expert clinical panels for patient assessment and care planning

3) Criterion or convergent/predictive validity for outcome measurement/risk factor measurement

4) Convergent/predictive validity: case mix adjustment for payment

5) Validation by patient assessment and care planning

Descriptions for these validation assessments are taken from the "Volume 4: OASIS Chronicle and Recommendation" OASIS and Outcome-Based Quality Improvement in Home Health Care, November 2001, Center for Health Services Research, University of Colorado Health Sciences Center, Denver, CO.

5.3.4 Validity Testing Results

Validity of the Performance Measure Score: Table 7 (see supplemental attachment page 15) shows the Spearman rank correlations of the *Improvement in Management of Oral Medications (#0176)* measure with other publicly reported measures of home health quality derived from OASIS assessments and Medicare Fee-for-Service (FFS) claims.

Validity of the Underlying Data Element: As noted above,

1. *Consensus validity:* The item was reviewed by panels of researchers and clinicians and was recommended for measuring patient outcomes relevant to home health care provision and quality measurement, or for risk adjustment of outcome analyses.
2. *Consensus validity by expert clinical panels for patient assessment and care planning:* The item was reviewed by a panel of clinical experts and was recommended for inclusion in a core set of data items for patient assessment and care planning.
3. *Criterion or convergent/predictive validity for outcome measurement/risk factor measurement:* The item was tested empirically for use in conjunction with outcome measures or risk factors predictive of patient outcomes. The item was found to be related to other indicators of health status and patient outcomes in a statistically significant and clinically meaningful way.
4. *Convergent/predictive validity:* Case-mix adjustment for payment: The item was tested and is used in the grouping algorithm that, in part, determines the per-episode payment to home health agencies for care provided under the Medicare home health benefit.
5. *Validation by patient assessment and care planning:* The item has been used by clinicians for patient assessment and care planning in several hundred home health agencies and has been reported by practicing clinicians to be effective and useful for these purposes.

Results of these validation assessments are taken from the "Volume 4: OASIS Chronicle and Recommendation" OASIS and Outcome-Based Quality Improvement in Home Health Care, November 2001, Center for Health Services Research, University of Colorado Health Sciences Center, Denver, CO.

5.3.5 Interpretation of Validity Results

Validity of the Performance Measure Score: As detailed in **Table 7 (see supplemental attachment page 15)**, the *Improvement in Management of Oral Medications (#0176)* measure displays a statistically significant positive correlation with several publicly reported measures that similarly assess patient functioning and *Discharge to Community (#3477)*, which lends evidence to the measure's validity. While it is possible that patients independent with function such as ambulation, bathing and bed transferring are dependent with management of oral medications it is more likely that patients with higher levels of independence in functional abilities are also more independent with management of their medications. Alternatively, it may be that strong performance on the other OASIS-based measures directly leads to an improvement in management of oral medications. It may also be the case that high quality agencies perform well on both the *Improvement in Management of Oral Medications (#0176)* measure and other OASIS-based measures of patient functioning and communication due to cultural or organization-level factors.

Validity of the Underlying Data Element: Item validity was established based on results of testing described above. In addition, the item was also reviewed as part of the OMB/PRA review process for the most recent OASIS data set revision which allowed for two national comment periods (60 days and 30 days) wherein the face validity of the item was supported by the comments received.

5.3.2 Type of Accountable Entity Level Validity Testing Conducted (derived)

Empirical validity testing at the accountable entity-level (e.g., criterion validity, construct validity, known groups analysis)

5.4.1 Methods Used to Address Risk Factors

Statistical risk adjustment model with risk factors

5.4.2 Conceptual Model Rationale

A patient's improvement in management of oral medications is dependent on a variety of factors, including social risk factors, clinical and behavioral risk factors, and access to care. The conceptual model shown in **Figure 2 (see supplemental attachment page 18)** is inspired by a similar conceptual model proposed by the Committee on Accounting for Socioeconomic Status in Medicare Payment Programs. In this conceptual model, social risk factors influence access to care and clinical and behavioral risk factors, as well as the measure itself. In turn, clinical and behavioral risk factors influence health care and resource use, access to care, and the measure itself. Access to care only influences health care and resource use. Finally, the home health agency affects the measure through interventions like skilled nursing, therapy, and care coordination. These interventions *may be able to address some social, clinical, or behavioral risk factors, in part if not fully.*

Improvement in Management of Oral Medications (#0176) attempts to measure a home health agency's ability to improve patient management of oral medications while the patient is in its care; however, because certain factors are outside of its control, we risk-adjust the measure. Risk adjustment is used to promote incentives for home health agencies to provide the same care to patients regardless of patient characteristics at SOC/ROC.

The risk factors that can be fully addressed should not be included in the risk adjustment model because the home health agency is expected to be responsible for addressing that risk factor. For instance, if all other risk factors are identical, a home health agency is expected to provide two patients with identical quality care regardless of race or ethnicity.

By contrast, a patient who is living alone will have different needs than a patient who lives in a congregate setting. While a home health agency is expected to adapt its care to different living situations, it is not expected to address all the needs for a patient living alone, like having professionals on staff readily available during emergencies. Similarly, a home health agency is not expected to influence the patient's clinical and behavioral status at SOC/ROC. As a result, relevant clinical and behavioral risk factors to oral medication management are included in the risk adjustment model.

5.4.3 Variable Distribution Across Measured Entities

Table 8 (see supplemental attachment pages 18-21) shows the mean and standard deviation of the observed value for *Improvement in Management of Oral Medications (#0176)* by risk factor in CY 2022.

5.4.4 Risk/Case-Mix Adjustment Modeling and/or Stratification Results

The risk adjustment methodology used is based on logistic regression analysis which results in a statistical prediction model for each outcome measure. For each patient who is included in the denominator of the outcome measure, the model is used to calculate the predicted probability that the patient will experience the outcome. The predicted probability for a patient is calculated using the following formula:

$$P(x) = 1/(1+^{-(a+\Sigma b_i x_i)})$$

Where:

$P(x)$ = predicted probability of achieving outcome x

a = constant parameter listed in the model documentation

b_i = coefficient for risk factor i in the model documentation

x_i = value of risk factor i for this patient

Predicted probabilities for all patients included in the measure denominator are then averaged to derive an expected outcome value for the agency. This expected value is then used, together with the observed (unadjusted) outcome value and the expected value for the national population of patients for the same data collection period, to calculate a risk-adjusted outcome value for the home health agency. The formula for the adjusted value of the outcome measure is as follows:

$$X(A_{ra}) = X(A_{obs}) + X(N_{exp}) - X(A_{exp})$$

Where:

$X(A_{ra})$ = Agency risk-adjusted outcome measure value

$X(A_{obs})$ = Agency observed outcome measure value

$X(A_{exp})$ = Agency expected outcome measure value

$X(N_{exp})$ = National expected outcome measure value

If the result of this calculation is a value greater than 100%, the adjusted value is set to 100%. Similarly, if the result is a negative number the adjusted value is set to zero.

For a more detailed summary of risk adjustment specifications including definitions of the risk factors, please consult the Home Health Quality Reporting Program Risk Adjustment Technical Specifications 2024 (PDF).[1]

The risk adjustment model was developed using OASIS national repository data from assessments submitted between January 1, 2021, and December 31, 2021 (~6.2 million quality episodes). The population of 6.2 million quality episodes for calendar year 2021 was split in half such that 3.1 million quality episodes were used as a developmental sample and 3.1 million quality episodes were used as a validation sample. The following process was used to identify unique contributing risk factors to the prediction model:

1. Risk factors were identified based on OASIS items that will remain or will be added following the transition to OASIS-E. The statistical properties of the items were examined to specify risk factors (e.g., item responses were grouped when there was low prevalence of certain responses). Team clinicians then reviewed all risk factors for clinical relevance and redefined or updated risk factors as necessary. These risk factors were divided into 31 content focus groups (e.g., functional status, Hierarchical Condition Categories, etc.). Where possible, risk factors were defined such that they flagged mutually exclusive subgroups within each content focus group. When modelling these risk factors, the exclusion category was set to be either the risk factor flag for most independent or the most frequent within

each content focus group.

2. A logistic regression specification was used to estimate coefficients among the full set of candidate risk factors. Those risk factors that are statistically significant at probability <0.0001 are flagged for further review in Step 3.
3. Each risk factor flagged in Step 2 was reviewed to determine which one of the two groups its content focus group resided. Either its content focus group was explicitly tiered by increasing severity or it was not. This classification determined which risk factor covariates were kept and which were dropped from the final risk adjustment specification. For content focus groups that are explicitly tiered by increasing severity, either all risk factors are included within a content focus group or none of them. For example, if response option levels 1 and 2 for M1800 Grooming were statistically significant at a probability of <0.0001 for a particular outcome, then response option level 3 for M1800 Grooming was added to the list even if it was not statistically significant. If none of the risk factors within an explicitly tiered content focus group was statistically significant at <0.0001, the entire content focus group was removed from the model.
4. A logistic regression was computed on the list of risk factors kept after Step 3 above.
5. Goodness of fit and reliability statistics (McFadden's R^2, C-statistic, and Intra-Class Correlation) were calculated to measure how well the predicted values generated by the prediction model were related to the actual outcomes. Separate bivariate correlations were constructed between the risk factors and the outcomes to confirm the sign and strength of the estimated coefficients in the logistic model.
6. The initial model was reviewed by a team of at least three experienced home health clinicians. Each risk factor was reviewed for its clinical plausibility. Clinicians were asked about the direction indicated by the coefficient in the risk adjustment model and how it compares to their perceived bivariate relationship given their experience treating patients in the home. Risk factors that were not clinically plausible were revised or eliminated if revisions were not possible.
7. The risk factors that were deemed not clinically plausible were revised or eliminated, and Steps 3, 4, and 5 in this process were repeated. The resulting logistic regression equation was designated as the risk adjustment model for the outcome.
8. The risk adjustment model was applied to the validation sample and goodness of fit statistics were computed. The statistics were similar to the goodness of fit statistics computed with the development sample. As additional testing, home health agencies were stratified across several observable characteristics, and the distributions of the risk-adjusted outcomes were checked to confirm that values remained similar across strata.

Using CY 2021 data, the updated risk adjustment model specification yielded a McFadden's R^2 of 0.1980 and a C-Statistic of 0.8139 on the validation sample. Please refer to **Appendix A (see supplemental attachment pages 29-33)** for details on the risk factor coefficients, including standard deviations and p-values.

[1] https://www.cms.gov/files/document/risk-adjustment-technicalspecificati…

5.4.5 Calibration and Discrimination

We calibrated the most recent risk adjustment update by comparing changes in performance for home health agencies overall and by important subgroups (urbanicity/rurality, size, and share of quality episodes with non-white patients) to the prior risk adjustment specification. The results in **Figure 3 (see supplemental attachment page 24)** indicate that most home health agencies overall and by subgroup perform equally well based on the updated risk adjustment model compared to the prior model, ranging between 86 percent among urban home health agencies and 88.6 percent among home health agencies with the highest percentage of non-white patients.

5.4.6 Interpretation of Risk/Case-mix Factor Findings

A patient's improvement in managing oral medications is dependent on a variety of factors, including social risk factors, clinical and behavioral risk factors, and access to care. Risk adjustment is used to promote incentives for home health agencies to provide the same care to patients regardless of patient characteristics at SOC/ROC. All risk factors that are expected to impact the ability to improve management of oral medications between SOC/ROC and EOC and are based on OASIS items that will remain or will be added following the transition to OASIS-E are considered for model inclusion. The statistical properties of the OASIS items were examined to specify risk factors (e.g., item responses were grouped when there was low prevalence of certain responses). Team clinicians then reviewed all risk factors for clinical relevance and redefined or updated risk factors, as necessary. These risk factors were divided into 31 content focus groups (e.g., functional status, Hierarchical Condition Categories, etc.). The final risk adjustment model was selected by considering model fit statistics, statistical significance of risk factor coefficients, and clinical plausibility of magnitude and direction of coefficients. Please refer to other sections for details on the risk factor selection methodology.

5.4.7 Final Approach to Address Risk Factors

Statistical risk adjustment model with risk factors

6.1.1 Current Status

In use

6.1.3 Current Use(s)

Public Reporting, Payment Program, Quality Improvement with Benchmarking (external benchmarking to multiple organizations), Quality Improvement (Internal to the specific organization)

6.1.3 Program Details

Name of the program and sponsor
Public Reporting and Home Health Star Ratings; CMS
URL of the program
https://www.medicare.gov/care-compare/?providerType=HomeHealth; https://www.cms...
Purpose of the program
Quality Improvement
Geographic area and percentage of accountable entities and patients included

Yes and see below
Applicable level of analysis and care setting

The Home Health Compare website is a federal government website managed by the Centers for Medicare & Medicaid Services (CMS). It provides information to consumers about the quality of care provided by Medicare-certified home health agencies throughout the nation. The measures reported on Home Health Compare include all Medicare-certified agencies with at least 20 home health quality episodes. In the period ending December 31, 2022, there were 7,612 such agencies (77.78 percent of the 9,787 agencies with at least one quality episode) that met the measure denominator criteria for reporting of Improvement in Management of Oral Medications. This included 4,283,502 episodes of care nationally.

CMS's Home Health Quality Initiative provides all Medicare-certified home health agencies with opportunities to use outcome measures for outcome-based quality improvement. The report allows agencies to benchmark their performance against other agencies across the state and nationally, as well as their own performance from prior time periods.

6.2.1 Actions of Measured Entities to Improve Performance

All home health agencies with at least 20 qualifying quality episodes of care receive quarterly measure reports on all their publicly reported measures. In addition, providers can run on-demand, confidential reports showing individual measure results and national averages, through CMS' iQIES system. There is an email box that home health agencies may submit questions to as well as a website on which the latest measure updates are posted. The OASIS Guidance Manual describes the OASIS-based reports that are available, report use(s), and provides guidance about OASIS and quality improvement. Home health agencies make use of these reports to monitor and improve the quality of care.

6.2.2 Feedback on Measure Performance

Home health agencies receive quarterly measure reports on all their measures. There is an email box that home health agencies may submit questions to as well as a website on which the latest measure updates are posted. Because of the changes made to the OASIS in the OASIS-E version (effectively January 1, 2023), risk models for publicly reported outcome measures have been updated. CMS makes available information about risk models and covariates on its website.

6.2.3 Consideration of Measure Feedback

No measures specifications changes requested or made.

6.2.4 Progress on Improvement

The measure is important to report publicly. Although improvements in performance are small,

home health agencies continue to improve overall, and for each subgroup measured over time. Performance gaps still exist, indicating that further improvement is possible. Publicly reported measure results illustrate variation in performance across home health agencies that may inform patient and family choice of a home health agency.

Figure 5 (see supplemental attachment page 27) presents trends in risk-adjusted *Improvement in Management of Oral Medications (#0176)* by subgroup. In addition to overall improvement from CY 2019 to CY 2022, each subgroup improves. We expect improvement to be driven in part by the implementation of the Quality of Patient Care (QoPC) Star Rating beginning in July 2015 and the Home Health Value Based Purchasing (HHVBP) Model in 2016. Results prior to 2019 showed dramatic improvement (not shown), while improvement in 2019-2022 was smaller. Nonetheless, QoPC Star Rating and HHVBP still provide incentives for home health agencies to improve on this measure. We anticipate continued improvement as HHVBP expands nationwide in 2023. Data will not reflect this policy change, as we only report results through CY2022.

6.2.5 Unexpected Findings

Recent improvement in this measure has been relatively large compared to historical trends. We believe these large improvements are due to the implementation of two initiatives that involve this measure – the QoPC Star Ratings and HHVBP – beginning in 2015 and 2016. We do not find any unexpected findings during implementation of this measure at this time.

7.1 Supplemental Attachment

draft Full-Measure-Submission-Form 0176 for CMS_508c.pdf

Developer POC email

Alrick_Edwards@abtassoc.com

Measure Developer POC

Alrick Edwards
Abt Global
5001 S Miami Blvd #210
Durham, NC 27703
United States

The measure developer is different from the measure steward

Yes

Steward Address

Kristina Rabarison

CMS
7500 Security Boulevard
Baltimore, MD 21244
United States

Steward Organization

Centers for Medicare & Medicaid Services

Steward Organization URL

https://www.cms.gov/medicare/quality/home-health/home-health-quality-measures

Steward POC email

kristina.rabarison@cms.hhs.gov