This form contains the measure information submitted by stewards. Blank fields indicate no information was provided. Attachments also may have been submitted and are provided to reviewers. The subcriteria and most of the footnotes from the evaluation criteria are provided in Word comments within the form and will appear if your cursor is over the highlighted area. Hyperlinks to the evaluation criteria and ratings are provided in each section.

TAP/Workgroup (if utilized): Complete all yellow highlighted areas of the form. Evaluate the extent to which each subcriterion is met. Based on your evaluation, summarize the strengths and weaknesses in each section.

Note: If there is no TAP or workgroup, the SC also evaluates the subcriteria (yellow highlighted areas).

Steering Committee: Complete all pink highlighted areas of the form. Review the workgroup/TAP assessment of the subcriteria, noting any areas of disagreement; then evaluate the extent to which each major criterion is met; and finally, indicate your recommendation for the endorsement. Provide the rationale for your ratings.

Evaluation ratings of the extent to which the criteria are met
C = Completely (unquestionably demonstrated to meet the criterion)
P = Partially (demonstrated to partially meet the criterion)
M = Minimally (addressed BUT demonstrated to only minimally meet the criterion)
N = Not at all (NOT addressed; OR incorrectly addressed; OR demonstrated to NOT meet the criterion)
NA = Not applicable (only an option for a few subcriteria as indicated)

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<table>
<thead>
<tr>
<th>Measure Title: Percent of Low Risk Residents Who Lose Control of Their Bowel or Bladder (Long-Stay)</th>
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</thead>
<tbody>
<tr>
<td>De.1 Measure Title: Percent of Low Risk Residents Who Lose Control of Their Bowel or Bladder (Long-Stay)</td>
</tr>
<tr>
<td>De.2 Brief description of measure: This measure updates CMS’ current QM on bowel and bladder control. It is based on data from Minimum Data Set (MDS) 3.0 assessments of long-stay nursing facility residents (those whose stay is longer than 100 days). This measure reports the percent of long-stay residents who are frequently or almost always bladder or bowel incontinent as indicated on the target MDS assessment (which may be an annual, quarterly, significant change or significant correction assessment) during the selected quarter (3-month period). The proposed measure is stratified into high and low risk groups; only the low risk group’s (e.g., residents whose mobility and cognition are not impaired) percentage is calculated and included as a publicly-reported quality measure.</td>
</tr>
<tr>
<td>De.3 Type of Measure: Outcome</td>
</tr>
<tr>
<td>De.4 National Priority Partners Priority Area: Care coordination</td>
</tr>
<tr>
<td>De.5 IOM Quality Domain: Patient-centered</td>
</tr>
<tr>
<td>De.6 Consumer Care Need:</td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>Conditions for Consideration by NQF</th>
</tr>
</thead>
<tbody>
<tr>
<td>Four conditions must be met before proposed measures may be considered and evaluated for suitability as voluntary consensus standards:</td>
</tr>
<tr>
<td>A. The measure is in the public domain or an intellectual property (measure steward agreement) is signed.</td>
</tr>
<tr>
<td>Public domain only applies to governmental organizations. All non-government organizations must sign a</td>
</tr>
</tbody>
</table>

Rating: C=Completely; P=Partially; M=Minimally; N=Not at all; NA=Not applicable
**measure steward agreement even if measures are made publicly and freely available.**

**A.** Do you attest that the measure steward holds intellectual property rights to the measure and the right to use aspects of the measure owned by another entity (e.g., risk model, code set)?

- Yes
- No

**A.2** Indicate if Proprietary Measure (as defined in measure steward agreement):

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
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**A.3** Measure Steward Agreement: Government entity and in the public domain - no agreement necessary

<table>
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<th>Y</th>
<th>N</th>
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**A.4** Measure Steward Agreement attached:

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
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**B.** The measure owner/steward verifies there is an identified responsible entity and process to maintain and update the measure on a schedule that is commensurate with the rate of clinical innovation, but at least every 3 years. Yes, information provided in contact section

<table>
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<tr>
<th>Y</th>
<th>N</th>
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**C.** The intended use of the measure includes both public reporting and quality improvement.

- Purpose: Public reporting, Internal quality improvement

<table>
<thead>
<tr>
<th>Y</th>
<th>N</th>
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**D.** The requested measure submission information is complete. Generally, measures should be fully developed and tested so that all the evaluation criteria have been addressed and information needed to evaluate the measure is provided. Measures that have not been tested are only potentially eligible for a time-limited endorsement and in that case, measure owners must verify that testing will be completed within 12 months of endorsement.

**D.1** Testing: Yes, fully developed and tested

<table>
<thead>
<tr>
<th>Y</th>
<th>N</th>
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**D.2** Have NQF-endorsed measures been reviewed to identify if there are similar or related measures?

<table>
<thead>
<tr>
<th>Y</th>
<th>N</th>
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**D.3** Have all conditions for consideration been met?

Staff Notes to Reviewers (issues or questions regarding any criteria):

Staff Reviewer Name(s):

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**1. IMPORTANCE TO MEASURE AND REPORT**

**1a.** Demonstrate High Impact Aspect of Healthcare: Affects large numbers, Patient/societal consequences of poor quality

<table>
<thead>
<tr>
<th>Y</th>
<th>N</th>
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</table>

1a.1 Demonstrated High Impact Aspect of Healthcare: Affects large numbers, Patient/societal consequences of poor quality

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
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</table>

1a.2 Summary of Evidence of High Impact: At least 17 million Americans have urinary incontinence (UI); it’s the second leading cause of institutionalization of the elderly and occurs in more than 50% of nursing home residents. It is important to treat UI as its prevention may reduce the likelihood of infections, pressure ulcers, and other health complications from poor health hygiene. Prevalence of urinary and fecal incontinence in nursing homes is reported to be between 30% and 65%. For the second quarter of 2008, the current measure (Percent of Low Risk Residents Who Lose Control of Their Bowels or Bladder) based on MDS 2.0 data averages 49.4% nationally, with statewide averages ranging from 37.2% to 71.0%. Although incontinence is often the result of age-related changes, it is not a normal part of aging. Loss of bowel or bladder control can often be successfully treated in cognitively intact residents.

**Comment [KP1]:** 1a. The measure focus addresses:

- A specific national health goal/priority identified by NQF's National Priorities Partners; OR
- A demonstrated high impact aspect of healthcare (e.g., affects large numbers, leading cause of morbidity/mortality, high resource use (current and/or future), severity of illness, and patient/societal consequences of poor quality).
Incontinence profoundly affects nursing home residents as well as staff. Incontinence can cause feelings of shame and embarrassment for the resident and increases the burden of care for caregivers. General health and quality of life factors, such as emotional well-being and social functioning, are also affected by incontinence. Nursing home staff may view incontinence care as both difficult and burdensome. As a result, it is frequently managed inappropriately. (5)

Loss of bowel and bladder control can be caused by:
- physical problems (e.g., constipation, muscle weakness, or a bladder infection),
- location problems (e.g., the bathroom is too far away),
- reaction to medication,
- limited ability to walk or move around,
- diet and fluid intake,
- toilet routine (e.g., timing trips to the bathroom),
- whether someone can provide assistance when needed, and
- certain medical conditions (e.g., residents with diabetes, dementia, spinal cord injury, or neurological disease are at a higher risk of losing bowel and bladder control). (4)

Incontinence, particularly reversible conditions of incontinence, is treatable in many cases, and incontinence programs do make a difference. Nursing facility residents who are incontinent of urine should have a targeted physical examination, including a urinalysis and a determination of postvoid residual urine volume done by catheterization or ultrasonography. (5) Scheduled toileting and bladder programs can be successfully implemented among nursing home residents. The key to the success of these programs is to appropriately identify residents who should be targeted for each specific program. (6) As with urinary incontinence, fecal incontinence may also be caused by potentially reversible conditions. After such conditions are excluded, fecal incontinence can generally be managed effectively by avoiding fecal impaction and by using a systematic bowel-training protocol. (5)

Determining the cause of and initiating treatment for problems with bowel and bladder control are important for many reasons. Physically, managing bowel and bladder control can help prevent infections, pressure ulcers, and other complications from poor health hygiene. Mentally, treatment can promote the well-being of the resident by restoring dignity and social interaction.

1a.4 Citations for Evidence of High Impact:

1b. Opportunity for Improvement

1b.1 Benefits (improvements in quality) envisioned by use of this measure: CMS expects nursing facilities will monitor and increase their efforts to address or manage incontinence due to the prevalence of this condition and the potential to improve this clinical condition with bladder or bowel training programs.

1b.2 Summary of data demonstrating performance gap (variation or overall poor performance) across providers:
A version of this quality measure, drawing on data from a similar but less detailed MDS 2.0 item, has been in use by CMS since 2002. An analysis by the Division of Health Care Policy and Research at the University of Colorado at Denver found that the measure demonstrated variability among facilities. The analytic team examined the rates for the measure at the facility level. Below are the measure scores from current use

<table>
<thead>
<tr>
<th>Rating</th>
<th>N=Not at all; P=Partially; M=Minimally; C=Completely</th>
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<tbody>
<tr>
<td>3</td>
<td>C=Completely; P=Partially; M=Minimally; N=Not at all; NA=Not applicable</td>
</tr>
</tbody>
</table>


Although research suggests racial disparities in the quality of care in nursing homes between African Americans and whites, no analyses have been conducted that specifically examine racial disparities in bladder or bowel incontinence. No other research has been conducted on other types of disparities (e.g., ethnicity, rural/urban, or income) for this measure.

1b.5 Citations for data on Disparities:

1b.4 Summary of Data on disparities by population group:
Racial segregation between nursing homes has been shown to be a major factor in disparities in the nursing home population, primarily for African Americans. In 2000, a study drawing on national MDS and Online Survey, Certification, and Reporting (OSCAR) data found that two thirds of all black residents were living in just 10% of all facilities. (1) A 2002 survey of a stratified sample of 39 nursing homes and 181 residential care/assisted living facilities in four states had similar findings. (2) Facilities serving African Americans demonstrate a lower level of quality of care than those serving whites, with lower staff to resident ratios and higher deficiency ratings. (3) Minority groups in general and African Americans in particular experience more limited access to nursing home care than whites. (4)

1b.3 Citations for data on performance gap:

1c. Outcome or Evidence to Support Measure Focus

1c.1 Relationship to Outcomes (For non-outcome measures, briefly describe the relationship to desired outcome. For outcomes, describe why it is relevant to the target population): The benefits of preventing and treating incontinence include improved quality of life, such as emotional well-being and social functioning, as well as avoidance of physical risk factors associated with incontinence. These risk factors include infections, pressure ulcers, and other complications from poor health hygiene. Mentally, the resident may lose a sense of dignity and independence and avoid social interaction because of the negative stigma associated with incontinence. Incontinence is treatable in many cases, and incontinence programs do make a difference.

1c.2 Variability Across Facilities

1c.3 Variability within a facility

1c.4 Variability over time

1c.5 Variability by payer

1c.6 Variability by location (urban, rural, etc.)

1c.7 Variability by other factors

Citations for data on Variability:


Comment [k5]: 4 Clinical care processes typically include multiple steps: assess → identify problem/potential problem → choose/plan intervention (with patient input) → provide intervention → evaluate impact on health status. If the measure focus is one step in such a multi-step process, the step with the greatest effect on the desired outcome should be selected as the focus of measurement. For example, although measurement of immunization status and recommending immunization are necessary steps, they are not sufficient to achieve the desired impact on health status. The focus measure should be selected based on the specific population of interest. The measure focus is therefore population specific.

Example: In the case of incontinence, the focus might be on the assessment of the resident's incontinence status or the evaluation of the effectiveness of the intervention. The specific focus will depend on the context and the goal of the measure.

Rating: C=Completely; P=Partially; M=Minimally; N=Not at all; NA=Not applicable
1c.1 Summary of Evidence (as described in the criteria; for outcomes, summarize any evidence that healthcare services/care processes influence the outcome): The benefits of preventing or treating incontinence are well-documented in the long-term care literature. Benefits include: improved quality of life; greater autonomy; and avoidance of physical and physiological risk factors, including infections, pressure ulcers, loss of dignity, and social isolation. Research findings show that incontinence and toileting programs can be effective. Residents who are responsive to assistance can benefit from participating in a 2-day run-in trial during which prompts are provided every 2 hours to encourage toileting. (1) Many residents (40%–60%) show immediate improvement when provided with consistent toileting assistance, which compensates for the immobility and dementia risk factors that prevent them from toileting independently. (1) In a prospective field trial, a multidisciplinary team of nursing home staff conducted a program that included a clinical assessment, toileting protocols, and the addition of an antimuscarinic drug, tolterodine, in selected residents who did not respond well to toileting alone. (2) The program resulted in significant increases in dryness rates for clinically stable nursing home residents.

As with urinary incontinence, fecal incontinence may be caused by potentially reversible conditions. After such conditions have been excluded, fecal incontinence can generally be managed by avoiding fecal impaction and by using a systematic bowel-training protocol. (3)


1c.2-3. Type of Evidence: Randomized controlled trial, Observational study, Expert opinion

1c.4 Rating of strength/quality of evidence (also provide narrative description of the rating and by whom): The body of evidence has not been rated.

1c.5 Summary of Controversy/Contradictory Evidence: No contradictory evidence has been identified.

1c.6 Method for rating evidence:

1c.7 Citation for Evidence (other than guidelines):

1c.8 Quote the Specific guideline recommendation (including guideline number and/or page number):

1c.9 Clinical Practice Guideline Citation: 1. Urinary incontinence (UI) in older adults admitted to acute care: http://www.guideline.gov/summary/summary.aspx?doc_id=13163&nbr=006726&string=incontinence

1c.10 National Guideline Clearinghouse or other URL:

1c.11 Rating of strength of recommendation (also provide narrative description of the rating and by whom): The body of evidence supporting this recommendation has not been rated.

1c.12 Method for rating strength of recommendation (If different from USPSTF system, also describe rating and how it relates to USPSTF):
1c.14 Rationale for using this guideline over others:
No contradictory evidence has been identified.

TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for Importance to Measure and Report?

<table>
<thead>
<tr>
<th>Rating</th>
<th>1c.14 Rationale for using this guideline over others:</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>No contradictory evidence has been identified.</td>
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</table>

Steering Committee: Was the threshold criterion, Importance to Measure and Report, met?

<table>
<thead>
<tr>
<th>Rationale:</th>
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2. SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES

Extent to which the measure, as specified, produces consistent (reliable) and credible (valid) results about the quality of care when implemented.

<table>
<thead>
<tr>
<th>Evaluation criteria</th>
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<tbody>
<tr>
<td>Eva Rating</td>
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2a. MEASURE SPECIFICATIONS

2a. Precisely Specified

2a.1 Numerator Statement (Brief, text description of the numerator - what is being measured about the target population, e.g. target condition, event, or outcome):
The numerator is the number of long-stay residents who have been assessed with an annual, quarterly, significant change or significant correction MDS 3.0 assessment during the selected time window and who are frequently or almost always incontinent of bowel or bladder.

2a.2 Numerator Time Window (The time period in which cases are eligible for inclusion in the numerator):
Numerator data come from the MDS 3.0 annual, quarterly, significant change or significant correction assessments during each quarter (3-month period).

2a.3 Numerator Details (All information required to collect/calculate the numerator, including all codes, logic, and definitions):
Residents are counted if they are long-stay residents, defined as residents whose length of stay is greater than 100 days. Residents who return to the nursing home following a hospital discharge will not have their stay reset to zero. Residents are counted if they are incontinent of bowel (H0300=2 or 3) or bladder (H0400=2 or 3). H0300-2=Frequently incontinent (7 or more episodes of bowel incontinence, but at least one episode of continent bowel movement). H0300-3=Always incontinent (no episodes of continent bowel voiding). H0400-2=rarely incontinent (2 or more episodes of bladder incontinence, but at least one continent bowel movement). H0400-3=Always continent (no episodes of continent bowel movements).

2a.4 Denominator Statement (Brief, text description of the denominator - target population being measured):
The denominator is the total of all long-stay residents in the nursing facility who have been assessed with an annual, quarterly, significant change or significant correction MDS assessment during the quarter and who do not meet the exclusion criteria.

2a.5 Target population gender: Female, Male
2a.6 Target population age range: All ages admitted to the nursing facility.

2a.7 Denominator Time Window (The time period in which cases are eligible for inclusion in the denominator):
Denominator data come from the MDS 3.0 annual, quarterly, significant change or significant correction assessments during each quarter (3-month period).

Comment [KP6]: 2a. The measure is well defined and precisely specified so that it can be implemented consistently within and across organizations and allow for comparability. The required data elements are of high quality as defined by NQF’s Health Information Technology Expert Panel (HITEP).
2a.8 Denominator Details (All information required to collect/calculate the denominator - the target population being measured - including all codes, logic, and definitions):
Residents are counted if they are long-stay residents defined as residents whose length of stay is greater than 100 days. Residents who return to the nursing home following a hospital discharge will not have their day count reset to zero. The target population includes all long-stay residents who had an annual, quarterly, significant change or significant correction MDS 3.0 assessment (A0310.A= 02, 03, 04, 05 or 06) during the selected quarter.

2a.9 Denominator Exclusions (Brief text description of exclusions from the target population): A resident is excluded from the denominator if the selected MDS 3.0 assessment was conducted within 14 days of admission (A0310A = 01) or if there is missing data in the response fields for the relevant questions in the MDS. Other exclusions include residents with severe cognitive impairment, total dependence in mobility, comatose, or with an indwelling catheter.

Facilities are excluded if they have fewer than 30 residents.

2a.10 Denominator Exclusion Details (All information required to collect exclusions to the denominator, including all codes, logic, and definitions):
1. High risk residents:
   a. Severe cognitive impairment on the target assessment as indicated by (C1000 = 3 and C0700 = 1) OR (C0500 less than or equal to 7)
   b. Totally dependent in mobility ADLs on the target assessment: (G0110.A.1 (Bed mobility Self-Performance=4), G0110.B.1 (Transfer Self-Performance =4), G0110.E.1 (Locomotion on unit Self-Performance =4) or if the items =7 (activity occurred only once or twice), or 8 (activity did not occur over the 7-day period)
2. The target assessment is an OBRA admission assessment (A0310.A = 01)
3. Residents who are comatose (B0100 = 1) or comatose status is unknown (B0100 = missing) on the target assessment
4. The resident has an indwelling catheter (H0100.A is checked) on the target assessment
5. The resident has an ostomy (H0100.C is checked) on the target assessment
6. The resident does not qualify as high risk (see above) and any of the cognitive impairment items (C0500, C0700, C1000) are missing on the target assessment
7. The resident does not qualify as high risk and any of the mobility ADL items are missing on the target assessment (G0110.A.1, G0110.B.1, G0110.E.1 is missing)

2a.11 Stratification Details/Variables (All information required to stratify the measure including the stratification variables, all codes, logic, and definitions):
This is not applicable.

2a.12-13 Risk Adjustment Type:  No risk adjustment necessary

2a.14 Risk Adjustment Methodology/Variables (List risk adjustment variables and describe conceptual models, statistical models, or other aspects of model or method):
This is not applicable.

2a.15-17 Detailed risk model available Web page URL or attachment:

2a.18-19 Type of Score: Ratio

2a.20 Interpretation of Score:

2a.21 Calculation Algorithm (Describe the calculation of the measure as a flowchart or series of steps):
For each facility, the number of residents meeting the numerator criteria and the number of (non-excluded) residents meeting the denominator criteria are counted. The facility observed score for the measure is a prevalence score calculated as the number of residents in the facility in the numerator divided by all non-excluded residents in the denominator.

2a.22 Describe the method for discriminating performance (e.g., significance testing):
Because the computed scores are not estimates, but include all residents who meet the measure criteria, in terms of discriminating performance, the computed scores can be used to make valid comparisons.

2a.23 Sampling (Survey) Methodology If measure is based on a sample (or survey), provide instructions for
obtaining the sample, conducting the survey and guidance on minimum sample size (response rate):
This is not applicable.

2a.24 Data Source (Check the source(s) for which the measure is specified and tested)
Electronic clinical data

2a.25 Data source/data collection instrument (Identify the specific data source/data collection instrument, e.g. name of database, clinical registry, collection instrument, etc.):
Nursing Home Minimum Data Set 3.0

2a.26-28 Data source/data collection instrument reference web page URL or attachment: URL
http://www.cms.hhs.gov/NursingHomeQualityInits/25_NHQIMDS30.asp#TopOfPage

2a.29-31 Data dictionary/code table web page URL or attachment: URL
http://www.cms.hhs.gov/NursingHomeQualityInits/25_NHQIMDS30.asp#TopOfPage

2a.32-35 Level of Measurement/Analysis (Check the level(s) for which the measure is specified and tested)
Facility/Agency

2a.36-37 Care Settings (Check the setting(s) for which the measure is specified and tested)
Nursing home (NH) /Skilled Nursing Facility (SNF)

2a.38-41 Clinical Services (Healthcare services being measured, check all that apply)

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TESTING/ANALYSIS

2b. Reliability testing

2b.1 Data/sample (description of data/sample and size): The MDS 3.0 items were found to have excellent reliability and to be a marked improvement over the MDS 2.0 items. Three major tests of the reliability of the incontinence measure have been conducted. First, the MDS 2.0 measure items and the existing quality measure were tested in the Data Assessment and Verification (DAVE 2) project conducted by Abt Associates. This project used a nationwide sample of randomly selected nursing homes using MDS assessments for the period April 1 to December 31, 2006. This project used a nationwide sample of randomly selected nursing homes using MDS assessments for the period April 1 to December 31, 2006. (1) DAVE 2 performed 173 two-stage reviews.

Second, the University of Colorado used national facility-level quality measure data from 2003 Quarter 3 (Q3) through 2006 Q3 came from the Quality Improvement and Evaluation System (QIES) MDS Express Reports on the Centers for Medicare & Medicaid Services (CMS) intranet; OSCAR data related to facility characteristics (e.g., state, resident census, number of beds, staffing) and certification survey results were downloaded from QIES Workbench. (2) A 10% random sample of all Medicare-certified nursing facilities was also downloaded from MDS assessment records. Analyses were based on complete MDS data from January 2005 through March 2006, as well as nearly complete data for April 2006 and partial data for May and June 2006.

Third, testing of the reliability of MDS 3.0 data items underlying the incontinence quality measure and a comparison with the MDS 2.0 quality measures were conducted by RAND as part of the MDS 3.0 development process. (3) A representative sample of for-profit and not-for-profit facilities and hospital-based and freestanding facilities was recruited for the study, which included 71 community nursing homes in 8 states, 19 VA nursing homes, and 1,402 nursing home residents for the incontinence quality measure.


2b.2 Analytic Method (Type of reliability & rationale, method for testing):
The DAVE 2 Project used a two-stage cluster sample design to examine MDS reporting. (1) Trained nurse reviewers selected a current resident with a recent assessment performed by the nursing home (NH) within the last 14 days. In the first stage of this review, the nurse reviewer conducted a blind reassessment of the resident using standard MDS assessment and coding procedures (examination of the medical record; observation of the resident; interview of staff, resident, and family; and use of coding criteria). In the second stage of this assessment (Stage 2), the DAVE 2 nurse reviewer’s assessment was compared with the corresponding nursing home assessment and each discrepancy was reconciled, with the nursing home assessor and the nurse reviewer agreeing on the appropriate response. In addition to data entering the facility MDS code, the DAVE 2 code, and the reconciled code into the MDS-QC data entry software, the DAVE 2 nurse reviewer entered a “reason code” to attribute the cause of the discrepancy, per MDS item reviewed, to an established list of reasons.

Second, the University of Colorado used national facility-level quality measure data from 2003 Q3 through 2006 Q3 came from the QIES MDS Express Reports on the CMS intranet; OSCAR data related to facility characteristics (e.g., state, resident census, number of beds, staffing) and certification survey results were downloaded from QIES Workbench. (2) A 10% random sample of all Medicare-certified nursing facilities was also downloaded from MDS assessment records. Analyses were based on complete MDS data from January 2005 through March 2006, as well as nearly complete data for April 2006 and partial data for May and June 2006.

The national test of MDS 3.0 items conducted by the RAND Corporation examined: agreement between assessors (reliability); validity of new cognitive, depression, and behavior items; response rates for interview items; user satisfaction and feedback on changes; and time to complete the assessment. (3) The network of Quality Improvement Organizations (QIOs) was employed to identify gold-standard (research) nurses and recruit community nursing homes to participate in the national evaluation, including a representative sample of for-profit and not-for-profit facilities and hospital-based and freestanding facilities. The gold-standard nurses were trained in the MDS 3.0 instrument and, in turn, trained a facility nurse from each participating nursing home in their home states. Residents participating in the test were selected to capture a representative sample of short- and long-stay residents.

2b.3 Testing Results (Reliability statistics, assessment of adequacy in the context of norms for the test conducted):
As part of the DAVE 2 project, Abt Associates assessed the reliability of the MDS 2.0 quality measures. (1) For each MDS data element, the rate of discrepancies between the reconciled and original facility assessments has been reported. For incontinence, the two-stage review discrepancy rate was 15.9%, which the University of Colorado deemed guarded. (2)

Second, in terms of measure stability, the University of Colorado examined the percentage of facilities that had a change in ranking from one quarter to the next of at least three deciles. (2) For incontinence, 5.1% of facilities had a change of three deciles or more from one quarter to the next. The range of stability measures across the 12 comparisons was small (i.e., the difference between the maximum and minimum values), indicating that measure stability (or instability) is quite constant over time. For incontinence, the minimum percentage was 4.7%, and the maximum percentage was 5.4%.

Third, in the national analysis conducted by the RAND Corporation to assess the reliability of the MDS 3.0, agreement between MDS 3.0 assessors on continence items was excellent. The average kappa for the gold-standard nurse to gold-standard nurse agreement was 0.949, and the average kappa for the gold-standard nurse to facility nurse agreement was 0.945. (3)


2c. Validity testing

2c.1 Data/sample (description of data/sample and size): The data come from two sources: national facility-level quality measure data from 2003 Q3 through 2006 Q3 came from the QIES MDS Express Reports on the CMS intranet; OSCAR data related to facility characteristics (e.g., state, resident census, number of beds, staffing) and certification survey results were downloaded from QIES Workbench. A 10% random sample of all Medicare-certified nursing facilities was also downloaded from MDS assessment records. Analyses were based on complete MDS data from January 2005 through March 2006, as well as nearly complete data for April 2006 and partial data for May and June 2006.

2c.2 Analytic Method (type of validity & rationale, method for testing): The analysis evaluated measure validity in a number of ways: to examine the expected positive influence of public reporting on quality of care, an assessment was conducted of the degree to which quality measure rates improved over time; to evaluate convergent validity, an assessment was conducted of the correlation of the quality measure with all other measures; to determine whether the quality measure rate was influenced by factors that are unrelated to facility quality, an evaluation was conducted of seasonal variations in incontinence rates across the 13 quarters of data. The analysis also computed descriptive statistics and conducted a one-way analysis of variance (ANOVA) to examine the amount of variance in rates was explained by geographic location, such as the state in which a facility was located.

2c.3 Testing Results (statistical results, assessment of adequacy in the context of norms for the test conducted): The analysis found a gradual but slight increase in the report of incontinence over time, as evidenced by an increase in the quality measure rate (1). See attached Table 2: Measure Trends Over Time.

Findings from the DAVE 2 showed that nurse reviewers found a high discrepancy rate for MDS 2.0 on the bladder incontinence item that is currently used in the measure calculations. Nurse reviewers noted that staff rarely used the 14-day look-back period, but instead used a 7-day review period. Additionally, reviewers reported difficulty validating this item, as nursing homes infrequently tracked the number of incontinent episodes per resident. The MDS 3.0 was revised to use the 7-day look-back period and new category definitions, which are intended to increase the reliability and validity of the measure.

The DAVE 2 Project showed that nurse reviewers found a high discrepancy rate for bladder incontinence that is used in the MDS 2.0 measure calculations. In 15.9% of cases, triggering of the measure differed among data collectors.


2d. Exclusions Justified

2d.1 Summary of Evidence supporting exclusion(s): Excluding missing data for existing quality measures is standard practice and was initially endorsed by NQF. Missing data is excluded from the calculation of the quality measures for several reasons. 1) There are legitimate reasons for facility staff not to select a ‘dash’ rather than a response; for example, if a resident is discharged or transferred abruptly, the staff may not be able to complete all items, however, an assessment is required for payment. The intent of the ‘dash’ is to allow the facility to submit an assessment when the staff are unable to complete the entire assessment. 2) Historically there has been very little missing data. For example, the current quality measure “Percent of residents who were physically restrained”, is based on three fields on the MDS 3.0. For all of the non-admission target assessments for calendar year 2009, there were 5,242,022 such assessments and 629 assessments (0.012%) had a dash for one or more of the three fields for the physical restraint measure. 3) We remain concerned about a change in measure definition that may result in incentivizing the facility staff to fill in a response to avoid a missing item. We believe that the result will lead to decreased validity and usefulness of the measure.
### 2.2 Citations for Evidence:


### 2.3 Data/sample (description of data/sample and size):

This is not applicable.

### 2.4 Analytic Method (type analysis & rationale):

This is not applicable.

### 2.5 Testing Results (e.g., frequency, variability, sensitivity analyses):

This is not applicable.

### 2.6 Risk Adjustment for Outcomes/ Resource Use Measures

#### 2.6.1 Data/sample (description of data/sample and size):

This is not applicable.

#### 2.6.2 Analytic Method (type of risk adjustment, analysis, & rationale):

This is not applicable.

#### 2.6.3 Testing Results (risk model performance metrics):

This is not applicable.

#### 2.6.4 If outcome or resource use measure is not risk adjusted, provide rationale: The measure is not currently risk adjusted. An analytical team at the University of Colorado Health Sciences Center tried to develop a risk-adjustment model for the incontinence measure, but the risk model did not meet their standards for risk-adjustment adequacy despite the model providing some degree of explanatory power.


### 2.7 Identification of Meaningful Differences in Performance

#### 2.7.1 Data/sample from Testing or Current Use (description of data/sample and size):

The data come from two sources: 1) national facility-level quality measure data from 2003 Q3 through 2006 Q3 came from the QIES MDS Express Reports on the CMS intranet; 2) OSCAR data related to facility characteristics (e.g., state, resident census, number of beds, staffing) and certification survey results were downloaded from QIES Workbench. A 10% random sample of all Medicare-certified nursing facilities was also downloaded from MDS assessment records. Analyses were based on complete MDS data from January 2005 through March 2006, as well as nearly complete data for April 2006 and partial data for May and June 2006.

#### 2.7.2 Methods to identify statistically significant and practically/meaningfully differences in performance (type of analysis & rationale):

Because the computed scores are not estimates, but include all residents who meet the measure criteria, in terms of discriminating performance, the computed scores can be used to make valid comparisons.

#### 2.7.3 Provide Measure Scores from Testing or Current Use (description of scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningfully differences in performance):

An analytical team at the University of Colorado Health Sciences Center examined the triggering rates for the measure at the facility level. Below are the measure scores from testing or current use (description of scores [e.g., distribution by quartile, mean, median, standard deviation, etc.] and identification of statistically significant and meaningfully differences in performance). For 11,928 facilities, the mean triggering rate was 48.4% with a standard deviation of 14.9%. The following table reports the full results of the analysis. See attached Table 1: Measure Variability Across Facilities.

#### 2.7.4 Comparability of Multiple Data Sources/Methods

This is not applicable.

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**Rating:** C=Completely; P=Partially; M=Minimally; N=Not at all; NA=Not applicable
2g.2 Analytic Method (type of analysis & rationale):
This is not applicable.

2g.3 Testing Results (e.g., correlation statistics, comparison of rankings):
This is not applicable.

2h. Disparities in Care

2h.1 If measure is stratified, provide stratified results (scores by stratified categories/cohorts): This is not applicable.

2h.2 If disparities have been reported/identified, but measure is not specified to detect disparities, provide follow-up plans:
While MDS 3.0 collects data on the resident’s race there are no current plans to stratify the measure by race because facilities tend to be homogenous by race, making disparities generally evident in the rating of the facility. (1)


TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for Scientific Acceptability of Measure Properties?

Steering Committee: Overall, to what extent was the criterion, Scientific Acceptability of Measure Properties, met? Rationale:

3. USABILITY

Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand the results of the measure and are likely to find them useful for decision making. (evaluation criteria)

3a. Meaningful, Understandable, and Useful Information

3a.1 Current Use: In use

3a.2 Use in a public reporting initiative (disclosure of performance results to the public at large) (If used in a public reporting initiative, provide name of initiative(s), locations, Web page URL(s). If not publicly reported, state the plans to achieve public reporting within 3 years):
Nursing Home Compare

3a.3 If used in other programs/initiatives (If used in quality improvement or other programs/initiatives, name of initiative(s), locations, Web page URL(s). If not used for QI, state the plans to achieve use for QI within 3 years):
CMS expects that the quality measure will be used by nursing facilities as a tool to evaluate their own performance and develop quality improvement programs.

Testing of Interpretability (Testing that demonstrates the results are understood by the potential users for public reporting and quality improvement)
### 3a. Data/sample (description of data/sample and size):
A recent study found that consumers could accurately interpret the quality information given for all the measures reported by Nursing Home Compare.

Data were collected from 4,754 family members of nursing home residents.


### 3a.5 Methods (e.g., focus group, survey, QI project):
A comprehension index was used to examine whether the information contained in Nursing Home Compare for each quality measure was understood by family members.

### 3a.6 Results (qualitative and/or quantitative results and conclusions):
The study found that 31% of the consumers used the Internet in choosing a nursing home, 12% recalled using Nursing Home Compare, and in general, the consumers' comprehension index scores were high, indicating good understanding. The comprehension index for the incontinence measure was among the highest at 5.83 on a scale of 1 to 8.

### 3b/3c. Relation to other NQF-endorsed measures

#### 3b.1 NQF # and Title of similar or related measures:
This measure is intended to replace NQF # 0183 Low risk residents who frequently lose control of their bowel or bladder because the data source has changed; the MDS 2.0 is being replaced by the MDS 3.0. The measure is related to the following endorsed measures; NQF # 0030 Urinary Incontinence Management in Older Adults - a. Discussing urinary incontinence, b. Receiving urinary incontinence treatment, NQF # 0098 Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women, NQF # 0099 Urinary Incontinence: Characterization of Urinary Incontinence in Women, NQF # 0100 Urinary Incontinence: Plan of Care for Urinary Incontinence in Women.

### Notes on similar/related endorsed or submitted measures:

#### 3b.                     

**Harmonization**

If this measure is related to measure(s) already endorsed by NQF (e.g., same topic, but different target population/settings/data source or different topic but same target population):

- **3b.2 Are the measure specifications harmonized? If not, why?**
  Harmonization is not applicable because the measure deals with different populations, settings and interventions.

#### 3c. Distinctive or Additive Value

- **3c.1 Describe the distinctive, improved, or additive value this measure provides to existing NQF-endorsed measures:**
  The current measure is being retired due to the change in the data source. The proposed measure will replace it. The proposed measure differs from other NQF-endorsed measures because it focuses on nursing facilities versus outpatient populations and includes both men and women.

- **5.1 If this measure is similar to measure(s) already endorsed by NQF (i.e., on the same topic and the same target population), Describe why it is a more valid or efficient way to measure quality:**

#### TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for Usability?

- **3**

**Steering Committee: Overall, to what extent was the criterion, Usability, met?**

- **3**

**Rationale:**

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**Rating: C=Completely; P=Partially; M=Minimally; N=Not at all; NA=Not applicable**

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**Comment [KP23]:** 3b. The measure specifications are harmonized with other measures, and are applicable to multiple levels and settings.

**Comment [K24]:** 16 Measure harmonization refers to the standardization of specifications for similar measures on the same topic (e.g., influenza immunization of patients in hospitals or nursing homes), or related measures for the same target population (e.g., eye exam and HbA1c for patients with diabetes), or definitions applicable to many measures (e.g., age designation for children) so that they are uniform or compatible, unless differences are dictated by the evidence. The dimensions of harmonization can include numerator, denominator, exclusions, and data source and collection instructions. The extent of harmonization depends on the relationship of the measures, the evidence for the specific measure focus, and differences in data sources.

**Comment [KP25]:** 3c. Review of existing endorsed measures and measure sets demonstrates that the measure provides a distinctive or additive value to existing NQF-endorsed measures (e.g., provides a more complete picture of quality for a particular condition or aspect of healthcare, is a more valid or efficient way to measure).
## 4. FEASIBILITY

Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. 

### 4a. Data Generated as a Byproduct of Care Processes

4a.1-2 How are the data elements that are needed to compute measure scores generated?

**Data generated as byproduct of care processes during care delivery** (Data are generated and used by healthcare personnel during the provision of care, e.g., blood pressure, lab value, medical condition), Coding/abstraction performed by someone other than person obtaining original information (E.g., DRG, ICD-9 codes on claims, chart abstraction for quality measure or registry)  

### 4b. Electronic Sources

4b.1 Are all the data elements available electronically? **(elements that are needed to compute measure scores are in defined, computer-readable fields, e.g., electronic health record, electronic claims)**  

No  

4b.2 If not, specify the near-term path to achieve electronic capture by most providers. 

Not applicable.

### 4c. Exclusions

4c.1 Do the specified exclusions require additional data sources beyond what is required for the numerator and denominator specifications?  

No  

4c.2 If yes, provide justification.

### 4d. Susceptibility to Inaccuracies, Errors, or Unintended Consequences

4d.1 Identify susceptibility to inaccuracies, errors, or unintended consequences of the measure and describe how these potential problems could be audited. If audited, provide results.  

Because of the possible lack of correspondence between the staff-assessment and BIMS items, it may be difficult to specify a score on the BIMS that would trigger the severe cognitive impairment exclusion exactly as the staff-assessment items do. The implication is that residents may trigger the exclusion differently depending on which set of data are available. Although the BIMS may be the better set of items, it cannot be completed for all residents. Thus, it may be reasonable to complete the staff-assessment items for all residents and use these as the source of the severe cognitive impairment exclusion for the Incontinence measure.  


### 4e. Data Collection Strategy/Implementation

Comment [KP26]: 4a. For clinical measures, required data elements are routinely generated concurrent with and as a byproduct of care processes during care delivery. (e.g., BP recorded in the electronic record, not abstracted from the record later by other personnel; patient self-assessment tools, e.g., depression scale; lab values, meds, etc.)  

Comment [KP27]: 4b. The required data elements are available in electronic sources. If the required data are not in existing electronic sources, a credible, near-term path to electronic collection by most providers is specified and clinical data elements are specified for transition to the electronic health record.

Comment [KP28]: 4c. Exclusions should not require additional data sources beyond what is required for scoring the measure (e.g., numerator and denominator) unless justified as supporting measure validity.

Comment [KP29]: 4d. Susceptibility to inaccuracies, errors, or unintended consequences and the ability to audit the data items to detect such problems are identified.

Comment [KP30]: 4e. Demonstration that the data collection strategy (e.g., source, timing, frequency, sampling, patient confidentiality, etc.) can be implemented (e.g., already in operational use, or testing demonstrates that it is ready to put into operational use).
4e.1 Describe what you have learned/modified as a result of testing and/or operational use of the measure regarding data collection, availability of data/missing data, timing/frequency of data collection, patient confidentiality, time/cost of data collection, other feasibility/implementation issues:
The data collection method is already in operational use. However, the MDS items used for cognitive function are new (BIMS scale) and the incontinence categories have been slightly revised.

4e.2 Costs to implement the measure (costs of data collection, fees associated with proprietary measures):
Data is collected as part of an existing process with no additional cost.

4e.3 Evidence for costs:
This is not applicable.

4e.4 Business case documentation: The proposed measure relies on data from the MDS 3.0. As there is no change in the data collection method for the MDS 3.0 as compared with its predecessor, the MDS 2.0, we do not anticipate any additional burden to nursing facilities. MDS 2.0, and soon to be MDS 3.0, data are collected as part of an existing, federally mandated process used for payment and quality monitoring purposes.

TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for Feasibility?
Steering Committee: Overall, to what extent was the criterion, Feasibility, met?
Rationale:

RECOMMENDATION
(for NQF staff use) Check if measure is untested and only eligible for time-limited endorsement.

Steering Committee: Do you recommend for endorsement?
Comments:

CONTACT INFORMATION
Co.1 Measure Steward (Intellectual Property Owner)
Co.1 Organization
Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mail Stop S3-02-01, Baltimore, Maryland, 21244-1850
Co.2 Point of Contact
Judith, Tobin, PT, MBA, Judith.Tobin@cms.hhs.gov, 410-786-6892

Measure Developer if different from Measure Steward
Co.3 Organization
RTI International, 1440 Main Street, Suite 310, Waltham, Massachusetts, 02451-1623
Co.4 Point of Contact
Roberta, Constantine, RN, MBA, PhD, rconstantine@rti.org, 781-434-1711

Co.5 Submitter If different from Measure Steward POC
Roberta, Constantine, RN, MBA, PhD, rconstantine@rti.org, 781-434-1711-, RTI International

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<th>Co.6 Additional organizations that sponsored/participated in measure development</th>
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**ADDITIONAL INFORMATION**

Workgroup/Expert Panel involved in measure development
Ad.1 Provide a list of sponsoring organizations and workgroup/panel members’ names and organizations. Describe the members’ role in measure development.

This technical expert panel met over 2 days in January 2009 to review the environmental scan of the current quality measures and make recommendations regarding their transition from MDS 2.0 to MDS 3.0.

Ad.2 If adapted, provide name of original measure: This measure was adapted from the measure of the same name derived from MDS 2.0 data.
Ad.3-5 If adapted, provide original specifications URL or attachment: MedQIC resource manual - http://www.qualitynet.org/dcs/ContentServer?cid=1138050766910&pagename=Medqic%2FOtherResource%2FOtherResourcesTemplate&c=OtherResource

**Measure Developer/Steward Updates and Ongoing Maintenance**
Ad.6 Year the measure was first released: 2002
Ad.7 Month and Year of most recent revision: 02, 2010
Ad.8 What is your frequency for review/update of this measure? Every 3 years
Ad.9 When is the next scheduled review/update for this measure? 02, 2013

Ad.10 Copyright statement/disclaimers:

Ad.11 -13 Additional Information web page URL or attachment: Attachment Incontinence Long Stay tables_FINAL-634045260397142500.doc

**Date of Submission (MM/DD/YY):** 03/03/2011