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)

#### MEASURE DESCRIPTIVE INFORMATION

**De.1 Measure Title:** Percent of Residents Who Have/Had a Catheter Inserted and Left in Their Bladder (Long-Stay)

**De.2 Brief description of measure:** This measure updates CMS’ current QM on catheter insertions. It is based on data from Minimum Data Set (MDS) 3.0 assessments of long-stay nursing home residents (those whose stay is longer than 100 days). This measure captures the percentage of long-stay residents who have had an indwelling catheter in the last 7 days noted on the most recent MDS 3.0 assessment, which may be annual, quarterly, significant change or significant correction during the selected quarter (3-month period).

Long-stay residents are those residents who have been in nursing care at least 100 days. The measure is restricted to this population, which has long-term care needs, rather than the short stay population who are discharged within 100 days of admission.

**De.3 Type of Measure:** Process

**De.4 National Priority Partners Priority Area:** Care coordination

**De.5 IOM Quality Domain:** Patient-centered

**De.6 Consumer Care Need:**

#### CONDITIONS FOR CONSIDERATION BY NQF

Four conditions must be met before proposed measures may be considered and evaluated for suitability as voluntary consensus standards:

A. The measure is in the public domain or an intellectual property (measure steward agreement) is signed. Public domain only applies to governmental organizations. All non-government organizations must sign a

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.1 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
A.2 Indicate if Proprietary Measure (as defined in measure steward agreement):
A.3 Measure Steward Agreement: Government entity and in the public domain - no agreement necessary
A.4 Measure Steward Agreement attached: B

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

C. The intended use of the measure includes both public reporting and quality improvement. Purpose: Public reporting, internal quality improvement

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
D.2 Have NQF-endorsed measures been reviewed to identify if there are similar or related measures? Yes

(if for NQF staff use) Have all conditions for consideration been met? Met
Staff Notes to Steward (if submission returned):
Staff Notes to Reviewers (issues or questions regarding any criteria):

TAP/Workgroup Reviewer Name:
Steering Committee Reviewer Name:

1. IMPORTANCE TO MEASURE AND REPORT

Extent to which the specific measure focus is important to making significant gains in health care quality (safety, timeliness, effectiveness, efficiency, equity, patient-centeredness) and improving health outcomes for a specific high impact aspect of healthcare where there is variation in or overall poor performance. Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria. (evaluation criteria)

1a. High Impact

(for NQF staff use) Specific NPP goal:

1a.1 Demonstrated High Impact Aspect of Healthcare: Affects large numbers, Patient/societal consequences of poor quality
1a.2

1a.3 Summary of Evidence of High Impact: At any given time, more than 100,000 residents in American nursing facilities have urethral catheters in place. (1) Catheters are commonly used for urinary retention, wound management, and in some circumstances, patient comfort. When not properly maintained and monitored, indwelling catheters can cause chronic pain or infections leading to a greater functional decline and decreased quality of life for the resident. (2) A thorough assessment of the resident and evaluation of the medical need for the catheter can sometimes decrease or prevent the use of catheters.

The indwelling catheter quality measure can potentially serve as a reminder to facilities of the importance of limiting catheter use. (3) Overuse of catheters to manage incontinence, other than for short-term periods, is a

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

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).
potential sign of suboptimal care and an indication that further assessment and alternative treatment could be offered. Among nursing facility residents, there is evidence that institutional policies and educational programs strongly impact care provider practices.

There are clear benefits to nursing homes conducting a thorough evaluation of the medical need for the catheterization of their residents. A determination regarding continued use or removal should be completed as soon as possible following admission. Nursing facilities need to assess the frequency of urinary catheterization practices to ensure that policies reflect current practice standards, and increase compliance with Centers for Disease Control guidelines for prevention of infection related to catheter use.

Using MDS 2.0 data for April-June 2008, the national prevalence of indwelling catheters in nursing facilities was 7.7%, with a range from an average of 5.2% in Rhode Island to a high of an average of 11.3% in North Dakota. National measure results have been stable over time, ranging from 5.7% in 2003 to 5.8% in 2008. The current indwelling catheter quality measure is currently one of the 19 publicly reported quality measures for nursing facilities on the Centers for Medicare & Medicaid Services (CMS) Nursing Home Compare Web site.

Using MDS 2.0 data for April-June 2008, the national prevalence of indwelling catheters in nursing facilities was 7.7%, with a range from an average of 5.2% in Rhode Island to a high of an average of 11.3% in North Dakota. National measure results have been stable over time, ranging from 5.7% in 2003 to 5.8% in 2008. The current indwelling catheter quality measure is currently one of the 19 publicly reported quality measures for nursing facilities on the Centers for Medicare & Medicaid Services (CMS) Nursing Home Compare Web site.

1a.4 Citations for Evidence of High Impact:

1b. Opportunity for Improvement

1b.1 Benefits (improvements in quality) envisioned by use of this measure: Facilities can use information from this measure to determine whether they may be overusing catheters for their long stay residents. Reduced use of urinary catheters, and associated problems with catheter use including pain, infections and functional decline, are the expected benefits envisioned by use of this measure.

1b.2 Summary of data demonstrating performance gap (variation or overall poor performance) across providers:
A version of the current quality measure has been in use by CMS since 2002, drawing on data from a similar but less detailed MDS 2.0 item. An analysis by the Division of Health Care Policy and Research at the University of Colorado at Denver found that the measure demonstrated very limited variability across facilities. The quality measure varied from 2.9% at the 25th percentile, to 7.7% at the 75th percentile; having an interquartile range (the 75th percentile minus the 25th percentile) of less than 5 percentage points.

See attached Table 1: Measure Variability Across Facilities.

In a study to measure the quality of urinary continence care in long-term care facilities, catheterization rates were approximately 10% in nursing facilities, ranging from 0%-44% among fourteen nursing homes where data was collected on the outcome measure. Thus, there was great variability in this quality measure within
Although research suggests racial disparities in quality of care in nursing facilities between African Americans and whites (1, 2, 3, 4), no analyses have been conducted specifically examining racial disparities in catheterization use. No other research has been conducted on other types of disparities (e.g., ethnicity, rural/urban, or income) for this measure.

Although research suggests racial disparities in quality of care in nursing facilities between African Americans and whites (1, 2, 3, 4), no analyses have been conducted specifically examining racial disparities in catheterization use. No other research has been conducted on other types of disparities (e.g., ethnicity, rural/urban, or income) for this measure.

1b.4 Summary of Data on disparities by population group:
Racial segregation between nursing facilities has been shown to be a major factor in racial disparities in the nursing facility 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 facilities and 181 residential care/assisted living facilities in four states had similar findings. (2) Facilities serving African Americans have demonstrated a lower level of quality 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 have also had more limited access to nursing facility care than whites. (4)

Although research suggests racial disparities in quality of care in nursing facilities between African Americans and whites (1, 2, 3, 4), no analyses have been conducted specifically examining racial disparities in catheterization use. 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:

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 limiting catheter use in nursing facilities are well documented in the literature. Catheters are commonly used for urinary retention, wound management, and in some circumstances, patient comfort. When not properly maintained and monitored, indwelling catheters can cause chronic pain or infections leading to a greater functional decline and decreased quality of life for the resident. (1) Indwelling urinary catheterization can frequently cause bacteremia, or in many cases, urinary tract infections, in the elderly. Catherization causes bacteremia to occur at a rate of 3 to 10 percent of patients per day; a single in and out catheterization may cause bacteremia in as many as 20 percent of patients (2). At least 40% of all infections seen in the nursing homes are in the urinary tract system; of those infections, 80% are due to urinary tract catheterization and instrumentation (3).
Many times residents are admitted to a nursing facility from hospitals with catheters in place, and the facility must make a determination whether or not to continue use of the device. A thorough assessment of the resident and evaluation of the medical need for the catheter can sometimes decrease or prevent the use of catheters and the risks associated with their use.


1c.10

1c.11

1c.12

Rating: C=Completely; P=Partially; M=Minimally; N=Not at all; NA=Not applicable
1c.13 Method for rating strength of recommendation (If different from USPSTF system, also describe rating and how it relates to USPSTF):

HICPAC used an adapted version of the GRADE Working group system.(1)


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>2. SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Extent to which the measure, as specified, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. (evaluation criteria)</td>
</tr>
</tbody>
</table>

2a. MEASURE SPECIFICATIONS

<table>
<thead>
<tr>
<th>S.1 Do you have a web page where current detailed measure specifications can be obtained?</th>
</tr>
</thead>
<tbody>
<tr>
<td>S.2 If yes, provide web page URL:</td>
</tr>
</tbody>
</table>

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 statement refers to a catheter that was inserted and left in the bladder by the facility during the assessment period.

During MDS 3.0 field testing, look-back periods were highlighted as a significant issue across the assessment tool. For clinical assessment items, longer look-back periods served to increase the amount of record review, increasing assessment burden and leading to more opportunities for error. During national testing of look-back periods for the MDS 3.0 proposed items, the 5-day look-back period performed well and likely contributed to the improved reliability of this item.(1)


The numerator is the number of long-stay residents who have/had a urinary catheter in the last 7 days (H0100A is checked).

2a.2 Numerator Time Window (The time period in which cases are eligible for inclusion in the numerator): Numerator data come from MDS 3.0 annual, quarterly, significant change or significant correction assessment conducted 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. The numerator includes residents who have indwelling catheters (H0100A is checked) on the

Comment [KP8]: 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).
most recent MDS 3.0 assessment (which may be an annual, quarterly, significant change or significant correction assessment). Exclusions are assessments where data for the urinary catheter item (H0100) is missing. Also, residents with diagnoses of neurogenic bladder (item I1550) or obstructive uropathy (item I1650) are excluded because these are conditions in which the person is unable to empty the bladder voluntarily or effectively, putting the person at risk or complications, such as overflow incontinence, recurrent infection, vesicoureteral reflux, or autonomic dysreflexia. 2a.8. (denominator details). 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 have had an annual, quarterly, significant change or significant correction MDS 3.0 assessment (A0130.A= 02,03,04,05 or 06) during the selected quarter, except for those who meet the exclusion criteria or have missing data in the responses to the relevant items in the MDS.

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 home who have been assessed with an annual, quarterly, significant change or significant correction MDS 3.0 assessment during the quarter (3-month period) and who do not meet the exclusion criteria.

2a.5 Target population gender: Male, Female
2a.6 Target population age range: The target population includes all long-stay residents of any age residing in 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 MDS 3.0 annual, quarterly, significant change or significant correction assessment conducted during each quarter (3-month period).

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 have had an annual, quarterly, significant change or significant correction MDS 3.0 assessment (A0130.A= 02,03,04,05 or 06) during the selected quarter, except for those who meet the exclusion criteria or have missing data in the responses to the relevant items in the MDS.

2a.9 Denominator Exclusions (Brief text description of exclusions from the target population): A resident is excluded from the denominator if the MDS assessment was conducted within 14 days of admission or if there is missing data in the responses to the relevant questions in the MDS assessment. Other exclusions include residents with neurogenic bladder or obstructive uropathy. Residents with diagnoses of neurogenic bladder (item I1550) or obstructive uropathy (item I1650) are excluded because these are conditions in which the person is unable to empty the bladder voluntarily or effectively, putting the person at risk of complications, such as overflow incontinence, recurrent infection, vesicoureteral reflux, or autonomic dysreflexia.

Facilities are excluded from public reporting if they have fewer than 30 residents due to small sample size.

2a.10 Denominator Exclusion Details (All information required to collect exclusions to the denominator, including all codes, logic, and definitions): 1. The target assessment is an OBRA admission assessment (item A0310A = 01). 2. There is missing data on indwelling catheter (item H0100A).

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:

### 2a.14 Risk Adjustment Methodology/Variables (List risk adjustment variables and describe conceptual models, statistical models, or other aspects of model or method):

Resident-level limited covariate risk adjustment for residents who are bowel incontinent on prior MDS (item H0400 = 2 or 3), or had pressure sores at stage 2, 3, or 4 on prior MDS (M0300B1 > 0 or M0300C1 > 0 or M0300D1 > 0).

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

### 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 long-stay 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. The number of long-stay residents meeting the numerator criteria and the number of residents meeting the denominator criteria are also counted for the covariate measure, which is bowel incontinence or presence of pressure sores, as reported on the resident’s prior MDS assessment.

The covariate scores are then entered into a logistic regression equation, and the result is an expected score for the resident for that quality measure (QM). The logistic regression equations are of the form: where e is the base of natural logarithms and x is a linear combination of the logistic regression coefficients and the covariate scores of the form:

\[ C_0 + C_1 \cdot COVA + C_2 \cdot COVB + \ldots \]

where \( C_0 \) is the logistic regression constant, \( C_1 \) is the logistic regression coefficient for the first covariate (where applicable), \( COVA \) is the resident-level score for the first covariate, \( C_2 \) is the logistic regression coefficient for the second covariate, and \( COVB \) is the resident-level score for the second covariate (where applicable), etc. The regression constant and regression coefficients are numbers obtained through statistical logistic regression analysis.(1)

The expected score for the measure is then calculated as the expected number of residents in the facility meeting the numerator criteria 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.):

The proposed data source is the Nursing Home MDS 3.0.

### 2a.26-28 Data source/data collection instrument reference web page URL or attachment: URL

### 2a.29-31 Data dictionary/code table web page URL or attachment: URL

### 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)

<table>
<thead>
<tr>
<th>Rating</th>
<th>C</th>
<th>P</th>
<th>M</th>
<th>N</th>
<th>NA</th>
</tr>
</thead>
</table>

**TESTING/ANALYSIS**

2b. Reliability testing

2b.1 Data/sample (description of data/sample and size): Three major tests of the reliability of the catheter use 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. (1) 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 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 2.0 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 catheter use quality measure as well as a comparison with the MDS 2.0 quality measures was 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 facilities in 8 states, 19 Veterans Affairs (VA) nursing homes, and 1,402 nursing facility residents for the urinary tract infection 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. A trained nurse reviewer selected a current resident with a recent assessment performed by the nursing facility 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 to 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. (1)

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...
The national test of MDS 3.0 items 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. The network of Quality Improvement Organizations (QIOs) was employed to identify gold-standard (research) nurses and recruit community nursing facilities 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 facility in their home states.


### 2b.3 Testing Results

#### Reliability

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 catheter use, the two-stage review discrepancy rate was 0.0%, which the University of Colorado deemed performed well on the indicator of reliability. (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) They found that facility catheter rates for this measure were unstable over time: 18.9% of facilities had a three-decile-or-more change from one quarter to the next quarter.

Third, in the national analysis of assessing the reliability of the MDS 3.0 conducted by the RAND Corporation, agreement between MDS 3.0 assessors on bladder and bowel items, including catheter use, 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

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

The data came 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.

#### 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 of the degree to which quality measure triggering rates

<table>
<thead>
<tr>
<th>Rating</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>C</td>
<td>2c. Validity testing demonstrates that the measure reflects the quality of care provided, adequately distinguishing good and poor quality. If face validity is the only validity addressed, it is systematically assessed.</td>
</tr>
<tr>
<td>P</td>
<td>2c. Validity testing include, but are not limited to: determining if measure scores adequately distinguish between providers known to have good or poor quality assessed by another valid method; correlation of measure scores with another valid indicator of quality for the specific topic; ability of measure scores to predict scores on some other related valid measure; content validity for multi-item scales/tests. Face validity is a subjective assessment by experts of whether the measure reflects the quality of care (e.g., whether the proportion of patients with BP &lt; 140/90 is a marker of quality). If face validity is the only validity addressed, it is systematically assessed.</td>
</tr>
<tr>
<td>M</td>
<td>9 Examples of validity testing include, but are not limited to: determining if measure scores adequately distinguish between providers known to have good or poor quality assessed by another valid method; correlation of measure scores with another valid indicator of quality for the specific topic; ability of measure scores to predict scores on some other related valid measure; content validity for multi-item scales/tests. Face validity is a subjective assessment by experts of whether the measure reflects the quality of care (e.g., whether the proportion of patients with BP &lt; 140/90 is a marker of quality). If face validity is the only validity addressed, it is systematically assessed.</td>
</tr>
<tr>
<td>N</td>
<td>9 Examples of validity testing include, but are not limited to: determining if measure scores adequately distinguish between providers known to have good or poor quality assessed by another valid method; correlation of measure scores with another valid indicator of quality for the specific topic; ability of measure scores to predict scores on some other related valid measure; content validity for multi-item scales/tests. Face validity is a subjective assessment by experts of whether the measure reflects the quality of care (e.g., whether the proportion of patients with BP &lt; 140/90 is a marker of quality). If face validity is the only validity addressed, it is systematically assessed.</td>
</tr>
<tr>
<td>NA</td>
<td>9 Examples of validity testing include, but are not limited to: determining if measure scores adequately distinguish between providers known to have good or poor quality assessed by another valid method; correlation of measure scores with another valid indicator of quality for the specific topic; ability of measure scores to predict scores on some other related valid measure; content validity for multi-item scales/tests. Face validity is a subjective assessment by experts of whether the measure reflects the quality of care (e.g., whether the proportion of patients with BP &lt; 140/90 is a marker of quality). If face validity is the only validity addressed, it is systematically assessed.</td>
</tr>
</tbody>
</table>
have improved over time; to evaluate convergent validity, an assessment of the correlation of the quality
measure with all other measures; and to determine if the quality measure triggering rate was influenced by
factors that are unrelated to facility quality, an evaluation of seasonal variations in triggering rates across the
13 quarters of data. The analysis also computed descriptive statistics and conducted a one-way analysis of
variance (ANOVA) for the measure to examine the amount of variance in triggering rates explained by 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 trend shows a seasonal fluctuation in the rate for indwelling catheter over time, but from one year’s
quarter to the next, there is essentially no difference. There is a distinct peak in the first quarter of each
year, followed by a relatively flat rate trend in the other three quarters. This pattern is similar to seasonal
variation in hospital and skilled nursing facility utilization, indicating that it may reflect seasonal variations in
the general health of the nursing home population rather than seasonal variation in nursing home quality.(1)

See attached Table 2: Measure Trends Over Time.

In a clinical review conducted by the University of Colorado, participants expressed concern about the
inability to exclude residents for whom an indwelling catheter is a necessary component of high-quality
medical care.(2) To ensure that facilities are not penalized for having a large population of residents who
meet this criteria, participants recommended the exclusion of residents with obstructive uropathy or
neurogenic bladder. The proposed MDS 3.0 measure has been revised based on this recommendation.

home quality measures. Denver: Division of Health Care Policy and Research University of Colorado at Denver;

nursing home quality measures. Denver: Division of Health Care Policy and Research University of Colorado at

2d. Exclusions Justified

2d.1 Summary of Evidence supporting exclusion(s):
All long-stay residents for whom complete data exists are included. Post-acute care residents are not included
because they are likely to have had an indwelling catheter prior to their nursing facility stay in the hospital or
other acute setting. A Technical Expert Panel (TEP) convened in January 2009 expressed the need to exclude
residents with medical conditions requiring catheters. There are some cases in which catheter use is
warranted because of medical conditions that may be untreatable in a nursing facility setting. Therefore,
residents with diagnoses of neurogenic bladder and obstructive uroapthy are excluded because these are
conditions in which the person is unable to empty the bladder voluntarily or effectively, putting the person at
risk of complications, such as overflow incontinence, recurrent infection, vesicoureteral reflux, or autonomic
dysreflexia.

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.

2d.2 Citations for Evidence:
This is not applicable.

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

Comment [KP14]: 2d. Clinically necessary measure exclusions are identified and must be:
• supported by evidence of sufficient frequency of occurrence so that results are distorted without the exclusion;
AND
• a clinically appropriate exception (e.g., contraindication) to eligibility for the measure focus;
AND
• precisely defined and specified:
  • if there is substantial variability in exclusions across providers, the measure is specified so that exclusions are computable and the effect on the measure is transparent (i.e., impact clearly delineated, such as number of cases excluded, exclusion rates by type of exclusion);
  • if patient preference (e.g., informed decision-making) is a basis for exclusion, there must be evidence that it strongly impacts performance on the measure and the measure must be specified so that the information about patient preference and the effect on the measure is transparent (e.g., numerator category computed separately, denominator exclusion category computed separately).

Comment [K13]: 10 Examples of evidence that an exclusion distorts measure results include, but are not limited to: frequency of occurrence, sensitivity analyzes with and without the exclusion, and variability of exclusions across providers.
2d.3 Data/sample (description of data/sample and size):  This is not applicable.

2d.4 Analytic Method (type analysis & rationale):  
This is not applicable.

2d.5 Testing Results (e.g., frequency, variability, sensitivity analyses):  
This is not applicable.

2e. Risk Adjustment for Outcomes/ Resource Use Measures

2e.1 Data/sample (description of data/sample and size):  
The data came 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.

2e.2 Analytic Method (type of risk adjustment, analysis, & rationale):  
Bowel incontinence and pressure ulcers on prior MDS are risk factors for this measure. The University of Colorado attempted to improve risk adjustment for this measure. They found bowel incontinence to be a valuable covariate and recommended retaining it as a risk adjuster and further evaluating the use of pressure ulcers as a risk adjuster to individual catheter use.(1)


2e.3 Testing Results (risk model performance metrics):  
Although the U. of Colorado’s risk adjustment model had better fit statistics than the unadjusted measure, the improvement was insufficient for meeting their criteria for predictive performance (C = 0.6960, R2 = 0.0790). A C-statistic equal to or greater than 0.70 met the University of Colorado’s criteria for risk-adjustment adequacy, but they also required an R2 value of 0.10 or greater. Thus, while the C-statistic was close to an acceptable threshold for risk adjustment adequacy the R2 value was not.

2e.4 If outcome or resource use measure is not risk adjusted, provide rationale:

2f. Identification of Meaningful Differences in Performance

2f.1 Data/sample from Testing or Current Use (description of data/sample and size):  
The data came 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.

2f.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.

2f.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 analytic team at the University of Colorado Health Sciences Center examined the 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.; identification of statistically significant and meaningfully differences in performance). For 11,928 facilities, the mean rate was 5.6% with a standard...
deviation of 4.0%. (1)

See attached Table 1: Measure Variability Across Facilities.


2g. Comparability of Multiple Data Sources/Methods

2g.1 Data/sample (description of data/sample and size): This is 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): The measure is not stratified.

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:

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

Comment (KP20): 2g. If multiple data sources/methods are allowed, there is demonstration they produce comparable results.

Comment (KP21): 2h. If disparities in care have been identified, measure specifications, scoring, and analysis allow for identification of disparities through stratification of results (e.g., by race, ethnicity, socioeconomic status, gender); OR rationale/data justifies why stratification is not necessary or not feasible.

Comment (KP22): 3a. Demonstration that information produced by the measure is meaningful, understandable, and useful to the intended audience(s) for both public reporting (e.g., focus group, cognitive testing) and informing quality improvement (e.g., quality improvement initiatives). An important outcome that may not have an identified improvement strategy still can be useful for informing quality improvement by identifying the need for and stimulating new approaches to improvement.
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.4 Data/sample (description of data/sample and size): A recent study examined whether 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.(1)


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. However, this specific measure was not evaluated.

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

3b.1 NQF # and Title of similar or related measures:

The proposed measure is intended to replace the currently endorsed NQF measure #0184, Residents who have a catheter in their bladder at any time during the 14 day assessment period because the data source has changed; the MDS 2.0 is being replaced with the MDS 3.0. NQF #0138-Urinary catheter-associated urinary tract infection for intensive care unit (ICU) patients. NQF #0453 -Urinary catheter removed on Postoperative Day 1 (POD1) or Postoperative Day 2 (POD2) with day of surgery being day zero. NQF #0183- Low-risk residents who frequently lose control of their bowel or bladder. (This quality measure is paired with the current measure.) NQF#0184 Home health care: percentage of patients with improvement in urinary incontinence.

(for NQF staff use) 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?

This measure specifically addresses urinary catheter use in the last 5 days for the long-stay nursing facility population while other the measures listed focus on either UTIs associated with catheter use in ICU patients, catheter removal during day 1 or 2 for post-op acute care patients, or catheter use associated with urinary incontinence for home health patients.

3c. Distinctive or Additive Value

3c.1 Describe the distinctive, improved, or additive value this measure provides to existing NQF-endorsed measures:

A new measure is needed based on the MDS 3.0 assessment specifications as it is replacing the current data source, the MDS 2.0. The measure has also been improved by excluding residents with medical conditions requiring catheterization (neurogenic bladder and obstructive uropathy).

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?
### 4. FEASIBILITY

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

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

**Rationale:**

<table>
<thead>
<tr>
<th></th>
<th>C</th>
<th>P</th>
<th>M</th>
<th>N</th>
<th>NA</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Eval Rating</th>
</tr>
</thead>
</table>

### 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.

A technical expert panel convened in January 2009 to make recommendations to retain, retire, or revise the quality measures as they transitioned from MDS 2.0 to MDS 3.0. TEP members recommended revising the measure to exclude residents with medical conditions requiring catheterization (neurogenic bladder and obstructive neuropathy).

**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. Data Collection Strategy/Implementation

**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, and there are no issues with these areas.

**4e.2 Costs to implement the measure (costs of data collection, fees associated with proprietary measures):**

Data are 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**?

<table>
<thead>
<tr>
<th>Rationale:</th>
<th>A</th>
<th>C</th>
<th>M</th>
<th>P</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th></th>
<th>A</th>
<th>C</th>
<th>M</th>
<th>P</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### RECOMMENDATION

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

<table>
<thead>
<tr>
<th></th>
<th>A</th>
<th>C</th>
<th>M</th>
<th>P</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Steering Committee:** Do you recommend for endorsement?

<table>
<thead>
<tr>
<th></th>
<th>Y</th>
<th>N</th>
<th>A</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Y</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### CONTACT INFORMATION

**Co.1 Measure Steward (Intellectual Property Owner)**
**Co.2 Point of Contact**
Judith, Tobin, PT, MBA, Judith.Tobin@cms.hhs.gov, 410-786-6892-
Judith, Tobin, PT, MBA, Judith.Tobin@cms.hhs.gov, 410-786-6892-

**Co.3 Organization**
Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mail Stop S3-02-01, Baltimore, Maryland, 21244-1850

**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-

**Co.6 Additional organizations that sponsored/participated in measure development**
RTI International, 1440 Main Street, Suite 310, Waltham, Massachusetts, 02451-1623

### 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 TEP 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

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

<table>
<thead>
<tr>
<th>Ad.10 Copyright statement/disclaimers:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ad.11-13 Additional Information web page URL or attachment: Attachment Catheter tables_FINAL-634045010523392500.doc</td>
</tr>
</tbody>
</table>

Date of Submission (MM/DD/YY): 10/08/2010