

# NATIONAL QUALITY FORUM

## National Voluntary Consensus Standards for Nursing Homes 2010

**Measure Number/Title:** Percent of Residents with Moderate to Severe Pain (Long Stay)

**Description:** The proposed long-stay pain measure reports the percent of long-stay residents of all ages in a nursing facility who reported almost constant or frequent pain and at least one episode of moderate to severe pain or any severe or horrible pain in the 5 days prior to the MDS assessment (which may be an annual, quarterly, significant change or significant correction MDS) during the selected quarter. Long-stay residents are those who have had at least 100 days of nursing facility care. This measure is restricted to the long stay population because a separate measure has been submitted for the short-stay residents (those who are discharged within 100 days of admission).

**Numerator Statement:** The numerator is the number of long-stay residents with an MDS assessment (which may be an annual, quarterly, significant change or significant correction assessment) during the selected quarter and who self-report (v200=1) almost constant or frequent pain on a scale of 1 to 4 (J0400 =1 or 2) AND at least one episode of moderate to severe pain (item J0600A = 5, 6, 7, 8, or 9 on a scale of 1–10, with 10 being the worst pain you can imagine, OR item J0600B = 2 or 3 on a scale of 0–4, with 4 being very severe, horrible pain) OR very severe/horrible pain of any frequency (item J0600A = 10 on a scale of 1 to 10 OR item J0600B = 4 on a scale of 0–4) in the 5 days prior to the assessment.

**Denominator Statement:** The denominator is the total of all long-stay residents in the nursing facility who have an MDS assessment which may be an annual, quarterly, significant change or significant correction assessment during the selected quarter and who do not meet the exclusion criteria.

**Level of Analysis:** Population: national, Facility/Agency

**Data Source:** Electronic clinical data

**Measure developer:** Research Triangle Institute International

**Type of Endorsement (full or time-limited):** Time-Limited

**Attachments:** Moderate to Severe Pain 2 Table

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## Measure Evaluation 4.1 December 2009

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)

<b>(for NQF staff use)</b> NQF Review #: NH-011-10      NQF Project: Nursing Homes 2010	
MEASURE DESCRIPTIVE INFORMATION	
De.1 Measure Title: <a href="#">Percent of Residents with Moderate to Severe Pain (Long Stay)</a>	
De.2 Brief description of measure: <a href="#">The proposed long-stay pain measure reports the percent of long-stay residents of all ages in a nursing facility who reported almost constant or frequent pain and at least one episode of moderate to severe pain or any severe or horrible pain in the 5 days prior to the MDS assessment (which may be an annual, quarterly, significant change or significant correction MDS) during the selected quarter.</a>	
<a href="#">Long-stay residents are those who have had at least 100 days of nursing facility care. This measure is restricted to the long stay population because a separate measure has been submitted for the short-stay residents (those who are discharged within 100 days of admission).</a>	
1.1-2 Type of Measure: <a href="#">Outcome</a>	
De.3 If included in a composite or paired with another measure, please identify composite or paired measure	
De.4 National Priority Partners Priority Area: <a href="#">Care coordination</a>	
De.5 IOM Quality Domain: <a href="#">Patient-centered</a>	
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:	<b>NQF Staff</b>
A. The measure is in the public domain or an intellectual property (measure steward agreement) is signed. <i>Public domain only applies to governmental organizations. All non-government organizations must sign a measure steward agreement even if measures are made publicly and freely available.</i>	A <input type="checkbox"/> Y <input type="checkbox"/> N
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)? <a href="#">Yes</a>	
A.2 Indicate if Proprietary Measure (as defined in measure steward agreement):	

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

A.3 Measure Steward Agreement: <a href="#">Government entity and in the public domain - no agreement necessary</a> A.4 Measure Steward Agreement attached:	
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. <a href="#">Yes, information provided in contact section</a>	B Y <input type="checkbox"/> N <input type="checkbox"/>
C. The intended use of the measure includes <u>both</u> public reporting <u>and</u> quality improvement. ► <b>Purpose:</b> <a href="#">Public reporting, Internal quality improvement</a>	C Y <input type="checkbox"/> N <input type="checkbox"/>
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: <a href="#">No, testing will be completed within 12 months</a> D.2 Have NQF-endorsed measures been reviewed to identify if there are similar or related measures? <a href="#">Yes</a>	D Y <input type="checkbox"/> N <input type="checkbox"/>
(for NQF staff use) Have all conditions for consideration been met? Staff Notes to Steward (if submission returned):	Met Y <input type="checkbox"/> N <input type="checkbox"/>
Staff Notes to Reviewers (issues or questions regarding any criteria): Staff Reviewer Name(s):	

TAP/Workgroup Reviewer Name:	
Steering Committee Reviewer Name:	
<b>1. IMPORTANCE TO MEASURE AND REPORT</b>	
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. <i>Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria.</i> (evaluation criteria) 1a. High Impact _____	Ev al Rat ing
(for NQF staff use) Specific NPP goal:	
1a.1 Demonstrated High Impact Aspect of Healthcare: <a href="#">Patient/societal consequences of poor quality</a> 1a.2 1a.3 Summary of Evidence of High Impact: This measure is a high impact measure given the high proportion of residents with pain and the potentially serious physiological consequences of it not being treated. Research indicates that at least 40-85% of nursing facility residents have persistent pain. The percentage may be even higher; research suggests that pain is often not fully documented.(1, 2, 3, 4, 5, 6, 7)  Failure to identify the presence of pain or to assess its severity and functional impact can leave a potentially treatable symptom unrecognized and therefore unlikely to be addressed. Indeed, evidence suggests that pain is consistently under-treated, particularly among individuals with cognitive impairment.(3, 8, 9) A standard measure of resident pain is needed because of gaps in nursing staff's knowledge of "best practice" pain management in hospitals and nursing homes.(4, 10, 11, 14, 15) A standard measure also provides a benchmark for pain management practices that vary widely across nursing homes.(13,14,15)  Among the potential adverse physiological and psychological effects of unrelieved pain are impaired gastrointestinal and pulmonary function; nausea and dyspnea; increased metabolic rate, including increased	1a C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/>

**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).

tumor growth and metastasis in cancer; impaired immune response; insomnia, delayed healing, increased blood clotting, loss of appetite, and inability to walk or move about; impairment of joint function with functional decline and increased dependency; and anxiety and depression.(16, 17, 18, 19) In the general population, unrelieved pain costs millions of dollars annually as a result of longer hospital stays, rehospitalizations, outpatient care, and emergency room visits.(20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31)

Resident pain in nursing facilities is a subject of great interest to the public. Pain management in nursing facilities is central to the Omnibus Budget Reconciliation Act of 1987 (OBRA 87) mandate to promote "maximum practicable functioning" among residents, and failure to identify and address pain denies a resident the right granted in OBRA 87 to freedom from neglect.(32) Advancing Excellence in America's Nursing Homes has made the management of resident pain one of its major goals. (33)

- 1a.4 Citations for Evidence of High Impact:**
1. Ferrell BA, Ferrell BR, Osterweil D. Pain in the nursing home. *Journal of the American Geriatrics Society*. 1990;38(4):409-14.
  2. Parmelee P, Smith B, Katz I. Pain complaints and cognitive status among elderly institution residents. *Journal of the American Geriatrics Society*. 1993;41(5):517-22.
  3. Sengstaken E, King S. The problems of pain and its detection among geriatric nursing home residents. *Journal of the American Geriatrics Society*. 1993;41(5):541-44.
  4. Weiner D, Rudy T. Attitudinal barriers to effective treatment of persistent pain in nursing home residents. *Journal of the American Geriatrics Society*. 2002;50(12):2035-40.
  5. CMS. CMS MDS Quality Measure/Indicator Report. Available from [http://www.cms.hhs.gov/MDSPubQIandResRep/02\\_qmreport.asp?isSubmitted=qm3&group=08&qtr=14](http://www.cms.hhs.gov/MDSPubQIandResRep/02_qmreport.asp?isSubmitted=qm3&group=08&qtr=14).
  6. Mor V, Zinn J, Angelelli J, Teno J, Miller S. Driven to tiers: socioeconomic and racial disparities in the quality of nursing home care. *The Milbank Quarterly*. 2004;82(2):227-56.
  7. Wu N, Miller S, Lapane K, Gozalo P. The problem of assessment bias when measuring the hospice effect on nursing home residents' pain. *Journal of Pain and Symptom Management*. 2003;26(5):998-1009.
  8. Cook A, Niven C, Downs M. Assessing the pain of people with cognitive impairment. *International Journal of Geriatric Psychiatry*. 1999;14(6):421-25.
  9. Won A, Lapane K, Gambassi G, Bernabei R, Mor V, Lipsitz LA. Correlates and management of nonmalignant pain in the nursing home. SAGE study group. Systematic assessment of geriatric drug use via epidemiology. *Journal of the American Geriatrics Society*. 1999;47(8):936-42.
  10. McMillan S, Tittle M, Hagan S, Laughlin J, Tabler RE. Knowledge and attitudes of nurses in veterans hospitals about pain management in patients with cancer. *Oncology Nursing Forum*. 2000;27(9):1415-23.
  11. Mrozek J, Werner J. Nurses' attitudes toward pain, pain assessment, and pain management practices in long-term care facilities. *Pain Management Nursing: Official Journal of the American Society of Pain Management Nurses*, 2001;2(4):154-62.
  12. Sloman R, Ahern M, Wright A, Brown L. Nurses' knowledge of pain in the elderly. *Journal of Pain and Symptom Management*. 2001;21(4):317-22.
  13. Cramer G, Galer B, Mendelson M, Thompson GD. A drug use evaluation of selected opioid and nonopioid analgesics in the nursing facility setting. *Journal of the American Geriatrics Society*. 2000;48(4):398-404.
  14. Allcock N, McGarry J, Elkan R. Management of pain in older people within the nursing home: a preliminary study. *Health & Social Care in the Community*. 2002;10(6):464-71.
  15. Saliba D, Buchanan J. Development and validation of a revised nursing home assessment tool: MDS 3.0. Contract No. 500-00-0027/Task Order #2. Santa Monica, CA: Rand Corporation, Apr 2008. Available from <http://www.cms.hhs.gov/NursingHomeQualityInits/Downloads/MDS30FinalReport.pdf>.
  16. Scherder E, Bouma A. Visual analogue scales for pain assessment in Alzheimer's disease. *Gerontology*. 2000;46(1):47-53.
  17. Wrede-Seaman L. Treatment options to manage pain at the end of life. *American Journal of Hospice and Palliative Care*. 2001;18(2):89-101.
  18. Sachs G, Shega J, Cox-Hayley D. Barriers to excellent end-of-life care for patients with dementia. *Journal of General Internal Medicine*. 2004;19(10):1057-63.
  19. Hanson L, Tulskey J, Danis M. Can clinical interventions change care at the end of life? *Annals of Internal Medicine*. 1997;126(5):381-88. See also the statement of the American Pain Society at <http://www.ampainsoc.org/advocacy/treatment.htm>.
  20. Berry P, Dahl J. The new JCAHO pain standards: implications for pain management nurses. *Pain Management Nursing*. 2001;1(1):3-12.

21. Cousins M. Acute post-operative pain (3rd ed.) Pp. 357-385 in Textbook of Pain. Wall PD, Melzak R (Ed.). Churchill Livingstone: New York.

22. Sydow F. The influence of anesthesia and postoperative analgesic management on lung function. Acta Chirurgica Scandinavica. 1988;550(suppl.):159-65.

23. Wattine M. Postoperative pain relief and gastrointestinal motility. Acta Chirurgica Scandinavica. 1988;550(suppl.):140-45.

24. Desbiens N, Mueller-Rizner N, Connors A, Hamel MB, Wenger NS. Pain in the oldest-old during hospitalization and up to one year later. Journal of the American Geriatrics Society. 1997;45:1167-72.

25. Bendebba M, Torgerson W, Long D. Personality traits, pain duration and severity, functional impairment, and psychological distress in patients with persistent low back pain. Pain. 1997;72:115-25.

26. Liu S, Carpenter R, Neal J. Epidural anesthesia and analgesia. Anesthesia. 1995;82:1474-1506.

27. McCaffery M, Pasero C. Pain: clinical manual. 1999. Mosby, St. Louis.

28. Hughes S, Gibbs J, Dunlop D, Edelman P, Singer R, Chang RW. Predictors of decline in manual performance in older adults. Journal of the American Geriatrics Society. 1997;45:905-10.

29. Casten R, Parmalee P, Kleban M, Lawton MP, Katz IR. The relationships among anxiety, depression, and pain in a geriatric institutionalized sample. Pain. 1995;61:271-76.

30. Grant M, Ferrell B, Rivera L, Lee J. Unscheduled readmissions for uncontrolled symptoms: a health care challenge for nurses. Nursing Clinics of North America. 1995;30:673-82.

31. Sheehan J, McKay J, Ryan M. What cost chronic pain? Irish Medical Journal. 1996;89:218-19.

32. Wiener J, Freiman M, Brown D. Nursing home care quality twenty years after the Omnibus Budget Reconciliation Act of 1987. 2007. RTI International.

33. Advancing Excellence in America's Nursing Homes Web site. Accessed January 21, 2010. Available from [http://www.nhqualitycampaign.org/star\\_index.aspx?controls=eightgoals](http://www.nhqualitycampaign.org/star_index.aspx?controls=eightgoals).

**1b. Opportunity for Improvement**

**1b.1 Benefits (improvements in quality) envisioned by use of this measure:** Facilities can use this information to determine whether they need to improve their pain management practices for their long stay residents. Reduced pain among long stay nursing facility residents is the expected benefit of this measure.

**1b.2 Summary of data demonstrating performance gap (variation or overall poor performance) across providers:**

A version of this quality measure has been in use by CMS since 2002, drawing on data from an MDS 2.0 item based on staff assessment. A study of variability for this measure by the University of Colorado showed that in the first quarter of 2006, the measure demonstrated a good degree of variability across facilities.(1) See attached Table 1: Measure Variability Across Facilities .

Although the number of high-quality studies of pain management in nursing homes is limited, those studies agree that resident pain is under-recognized and under-treated.(2) A recent record audit of 291 residents in 14 long-term care facilities found a significant gap between evidence-based pain management recommendations and facility practices. Assessment was particularly weak, only 32% of the cases reported chronic pain once or twice a week, and only 3% of the cases reviewed had reported that pain impacted functioning and quality of life twice or more times during the previous 30 days.(3) One study focusing on pain in cancer patients reported underuse of analgesics and hospice, along with nursing facility staffing patterns as key issues in inadequate pain treatment for this population.(4) Many studies and literature maintain that almost all pain, including pain at the end of life, can be managed with appropriate assessment and treatment, and research in pain management has identified the adoption of systematic implementation models, clinical decision-making algorithms, interdisciplinary approaches, and ongoing outcome evaluations as effective means to deliver effective pain relief in nursing facilities.(5, 6, 7, 8, 9)

**1b.3 Citations for data on performance gap:**

1. Brega A, Goodrich G, Nuccio E, Hittle D. Transition of publicly reported nursing home quality measures to MDS 3.0—draft. Denver: Division of Health Care Policy and Research University of Colorado at Denver, 2008.

2. Herman A, Johnson T, Ritchie C, Parmelee P. Pain management interventions in the nursing home: a structured review of the literature. Journal of the American Geriatrics Society. 2009;57(7):1258-67.

3. Jablonski A, Ersek M. Nursing home staff adherence to evidence-based pain management practices. Journal of Gerontological Nursing. 2009;35(7):28-34.

4. Duncan J, Forbes-Thompson S, Bott M. Unmet symptom management needs of nursing home residents with cancer. Cancer Nursing. 2008;31(4):265-73.

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**Comment [KP2]:** 1b. Demonstration of quality problems and opportunity for improvement, i.e., data demonstrating considerable variation, or overall poor performance, in the quality of care across providers and/or population groups (disparities in care).

**Comment [k3]:** 1 Examples of data on opportunity for improvement include, but are not limited to: prior studies, epidemiologic data, measure data from pilot testing or implementation. If data are not available, the measure focus is systematically assessed (e.g., expert panel rating) and judged to be a quality problem.

5. Scherder E, Bouma A. Visual analogue scales for pain assessment in Alzheimer's disease. *Gerontology*. 2000;46(1):47-53.  
 6. Wrede-Seaman L. Treatment options to manage pain at the end of life. *American Journal of Hospice and Palliative Care*. 2001;18(2):89-101.  
 7. Sachs G, Shega J, Cox-Hayley D. Barriers to excellent end-of-life care for patients with dementia. *Journal of General Internal Medicine*. 2004;19(10):1057-63.  
 8. Hanson L, Tulskey J, Danis M. Can clinical interventions change care at the end of life? *Annals of Internal Medicine*. 1997;126(5):381-88. See also the statement of the American Pain Society at <http://www.ampainsoc.org/advocacy/treatment.htm> .  
 9. Swafford K, Miller L, Tsai P, Herr K, Ersek M. Improving the process of pain care in nursing homes: a literature synthesis. *Journal of the American Geriatrics Society*. 2009;57(6):1080-87.

**1b.4 Summary of Data on disparities by population group:**

Although there is evidence of racial segregation between nursing facilities, with African-Americans tending to be concentrated in facilities with higher deficiency ratings, there has been little study of resulting potential disparities in reported pain.(1, 2, 3) The research conducted on racial disparities in pain treatment has shown a greater incidence of untreated pain for black residents with cancer as compared to white residents with cancer.(4, 5)

Research has also identified disparities in pain management between cognitively intact residents and those who are cognitively impaired. In the current MDS 2.0 pain items, staff recording of cognitive status was inversely proportional to pain report; the most cognitively impaired residents were recorded as suffering the least pain and received the least pain therapy.(6) In the MDS 3.0, new pain items were included that focus on patient interview and have been shown to be able to be answered by cognitively impaired residents.(7)

**1b.5 Citations for data on Disparities:**

1. Smith D, Feng Z, Fennell M, Zinn J, Mor V. Separate and unequal: racial segregation and disparities in quality across U.S. nursing homes. *Health Affairs (Millwood)*. 2007;26(5):1448-1558.  
 2. Howard D, Sloane P, Zimmerman S, Eckert J, Walsh J, Buie V, Taylor P, Koch G. Distribution of African Americans in residential care/assisted living and nursing homes: more evidence of racial disparity? *American Journal of Public Health*. 2002;92(8):1272-77.  
 3. Grabowski D. The admission of blacks to high-deficiency nursing homes. *Med Care*. 2004;42(5):456-64.  
 4. Bernabei R, Gambassi G, Lapane K, Landi F, Garsonis C, Dunlop R, Lipsitz L, Steel K, Mov V. Management of pain in elderly patients with cancer. SAGE study group. Systematic assessment of geriatric drug use via epidemiology. *Journal of the American Medical Association*. 1998;279(23):1877-82.  
 5. Hanlon J, Wang X, Good C, Rossi M, Stone R, Selma T, Handler S. Racial differences in medication use among older, long-stay Veterans Affairs nursing home care unit patients. *The Consultant Pharmacist*. 2009;24(6):439-46.  
 6. Reynolds K, Hanson L, DeVellis R, Henderson M, Steinhauser K. Disparities in pain management between cognitively intact and cognitively impaired nursing home residents. *Journal of Pain and Symptom Management*. 2008;35(4):388-96.  
 7. Saliba D, Buchanan J. Development and validation of a revised nursing home assessment tool: MDS 3.0. Contract No. 500-00-0027/Task Order #2. Santa Monica, CA: Rand Corporation, Apr 2008. Available from <http://www.cms.hhs.gov/NursingHomeQualityInits/Downloads/MDS30FinalReport.pdf>.

**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):** Pain relief is associated with reduced physiologic complications and an increased quality of life. In addition to the discomfort associated with pain, pain leads to declines in autonomy and sense of well-being and increases of anxiety and depression.

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**Comment [k4]:** 1c. The measure focus is:  
 •an outcome (e.g., morbidity, mortality, function, health-related quality of life) that is relevant to, or associated with, a national health goal/priority, the condition, population, and/or care being addressed;  
 OR

- if an intermediate outcome, process, structure, etc., there is evidence that supports the specific measure focus as follows:
  - oIntermediate outcome - evidence that the measured intermediate outcome (e.g., blood pressure, Hba1c) leads to improved health/avoidance of harm or cost/benefit.
  - oProcess - evidence that the measured clinical or administrative process leads to improved health/avoidance of harm and if the measure focus is on one step in a multi-step care process, it measures the step that has the greatest effect on improving the specified desired outcome(s).
  - oStructure - evidence that the measured structure supports the consistent delivery of effective processes or access that lead to improved health/avoidance of harm or cost/benefit.
  - oPatient experience - evidence that an association exists between the measure of patient experience of health care and the outcomes, values and preferences of individuals/ the public.
  - oAccess - evidence that an association exists between access to a health service and the outcomes of, or experience with, care.
  - oEfficiency - demonstration of an association between the measured resource use and level of performance with respect to one or more of the other five IOM aims of quality.

**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 assessment of immunization status and recommending immunization are necessary steps, they are not sufficient to achieve the desired impact on health status - patients must be vaccinated to achieve immunity. This does not preclude consideration of measures of preventive screening interventions where there is a strong link with desired outcomes (e.g., mammography) or measures for multiple care processes that affect a single outcome.

<p><b>1c.2-3. Type of Evidence:</b> Randomized controlled trial, Observational study</p> <p><b>1c.4 Summary of Evidence</b> (as described in the criteria; for outcomes, summarize any evidence that healthcare services/care processes influence the outcome): Pain has been shown to have a negative effect on quality of life; it is associated with declines in autonomy, security, and spiritual well-being and increases in anxiety and depression. (1) Studies reviewing the impact of pain relief interventions at the actor, decision-support, treatment, and system levels consistently demonstrate that pain relief leads to increased quality of life. (2, 3, 4)</p> <p><b>1c.5 Rating of strength/quality of evidence</b> (also provide narrative description of the rating and by whom): The evidence has not been rated.</p> <p><b>1c.6 Method for rating evidence:</b></p> <p><b>1c.7 Summary of Controversy/Contradictory Evidence:</b> No contradictory evidence has been identified.</p> <p><b>1c.8 Citations for Evidence</b> (other than guidelines): 1. Herman AD, Johnson TM 2nd, Ritchie CS, Parmelee PA. Pain management interventions in the nursing home: a structured review of the literature. J Am Geriatr Soc. 2009 Jul;57(7):1258-67. 2. Degenholtz HB, Rosen J, Castle N, Mittal V, Liu D. The association between changes in health status and nursing home resident quality of life. Gerontologist. 2008 Oct;48(5):584-92. 3. Zanochi M, Maero B, Nicola E, Martinelli E, Luppino A, Gonella M, Gariglio F, Fissore L, Bardelli B, Obialero R, Molaschi M. Chronic pain in a sample of nursing home residents: prevalence, characteristics, influence on quality of life (QoL). Archives of Gerontology and Geriatrics. 2008 Jul-Aug;47(1):121-8. 4. Kenefick AL. Pain treatment and quality of life: reducing depression and improving cognitive impairment. Journal of Gerontological Nursing. 2004 May;30(5):22-9.</p> <p><b>1c.9 Quote the Specific guideline recommendation</b> (including guideline number and/or page number): This guideline is for long-stay residents with dementia. It is cited because it addresses pain in the long-stay resident population.  The specific recommendation is the dementia care practice recommendations for assisted-living residences and nursing homes. <a href="http://www.guideline.gov/summary/summary.aspx?doc_id=10620&amp;nbr=005562&amp;string=pain+AND+reduction">http://www.guideline.gov/summary/summary.aspx?doc_id=10620&amp;nbr=005562&amp;string=pain+AND+reduction</a></p> <p><b>1c.10 Clinical Practice Guideline Citation:</b> Tilly J, Reed P (Eds). Dementia care practice recommendations for assisted living residences and nursing homes. September 28, 2006. Washington (DC): Alzheimer's Association.</p> <p><b>1c.11 National Guideline Clearinghouse or other URL:</b> <a href="http://www.guideline.gov/summary/summary.aspx?doc_id=10620&amp;nbr=005562&amp;string=pain+AND+reduction">http://www.guideline.gov/summary/summary.aspx?doc_id=10620&amp;nbr=005562&amp;string=pain+AND+reduction</a></p> <p><b>1c.12 Rating of strength of recommendation</b> (also provide narrative description of the rating and by whom): The strength of the recommendation is not rated.</p> <p><b>1c.13 Method for rating strength of recommendation</b> (If different from USPSTF system, also describe rating and how it relates to USPSTF):</p> <p><b>1c.14 Rationale for using this guideline over others:</b> This guideline, registered with the National Guideline Clearinghouse, addresses pain management among residents with dementia, a group that is a significant part of the nursing home population.</p>	
<p><b>TAP/Workgroup:</b> What are the strengths and weaknesses in relation to the subcriteria for <i>Importance to</i></p>	<p><b>1</b></p>

**Comment [k6]:** 3 The strength of the body of evidence for the specific measure focus should be systematically assessed and rated (e.g., USPSTF grading system <http://www.ahrq.gov/clinic/uspstf07/methods/benefit.htm>). If the USPSTF grading system was not used, the grading system is explained including how it relates to the USPSTF grades or why it does not. However, evidence is not limited to quantitative studies and the best type of evidence depends upon the question being studied (e.g., randomized controlled trials appropriate for studying drug efficacy are not well suited for complex system changes). When qualitative studies are used, appropriate qualitative research criteria are used to judge the strength of the evidence.

**Comment [k7]:** USPSTF grading system <http://www.ahrq.gov/clinic/uspstf/grades.htm>: A - The USPSTF recommends the service. There is high certainty that the net benefit is substantial. B - The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial. C - The USPSTF recommends against routinely providing the service. There may be considerations that support providing the service in an individual patient. There is at least moderate certainty that the net benefit is small. Offer or provide this service only if other considerations support the offering or providing the service in an individual patient. D - The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits. I - The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.

<b>Measure and Report?</b>	
Steering Committee: Was the threshold criterion, <i>Importance to Measure and Report</i> , met? Rationale:	1 Y <input type="checkbox"/> N <input type="checkbox"/>
<b>2. SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES</b>	
Extent to which the measure, <u>as specified</u> , produces consistent (reliable) and credible (valid) results about the quality of care when implemented. (evaluation criteria)	Ev al Rat ing
<b>2a. MEASURE SPECIFICATIONS</b>	
S.1 Do you have a web page where current detailed measure specifications can be obtained? S.2 If yes, provide web page URL:	
2a. Precisely Specified	
<p><b>2a.1 Numerator Statement</b> (<i>Brief, text description of the numerator - what is being measured about the target population, e.g. target condition, event, or outcome</i>): The numerator is the number of long-stay residents with an MDS assessment (which may be an annual, quarterly, significant change or significant correction assessment) during the selected quarter and who self-report (v200=1) almost constant or frequent pain on a scale of 1 to 4 (J0400 =1 or 2) AND at least one episode of moderate to severe pain (item J0600A = 5, 6, 7, 8, or 9 on a scale of 1-10, with 10 being the worst pain you can imagine, OR item J0600B = 2 or 3 on a scale of 0-4, with 4 being very severe, horrible pain) OR very severe/horrible pain of any frequency (item J0600A = 10 on a scale of 1 to 10 OR item J0600B = 4 on a scale of 0-4) in the 5 days prior to the assessment.</p> <p><b>2a.2 Numerator Time Window</b> (<i>The time period in which cases are eligible for inclusion in the numerator</i>): The numerator data are from an MDS annual, quarterly, significant change or significant correction assessments conducted during each quarter (3-month period).</p> <p><b>2a.3 Numerator Details</b> (<i>All information required to collect/calculate the numerator, including all codes, logic, and definitions</i>): 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 the number of long-stay residents reporting almost constant or frequent pain on a scale of 1 to 4 for those who can self-report (J0200=1). These numeric ratings were defined as follows: 1 = the pain is experienced almost constantly (MDS 3.0 item J0400=1 or 2) AND at least one episode of moderate to severe pain (item J0600.A= 5,6,7,8, or 9 on a scale of 1-10, with 10 being the worst pain you can imagine, OR item J0600.B= 2 or 3 on a scale of 0-4, with 4 being very severe, horrible pain) OR very severe/horrible pain of any frequency (item J0600A=10 on a scale of 1 to 10 OR item J0600.B= 4 on a scale of 0-4) in the 5 days prior to the assessment.</p> <p><b>2a.4 Denominator Statement</b> (<i>Brief, text description of the denominator - target population being measured</i>): The denominator is the total of all long-stay residents in the nursing facility who have an MDS assessment which may be an annual, quarterly, significant change or significant correction assessment during the selected quarter and who do not meet the exclusion criteria.</p> <p><b>2a.5 Target population gender:</b> Female, Male</p> <p><b>2a.6 Target population age range:</b> The target population includes long-stay residents of all ages who reside in the nursing facility.</p> <p><b>2a.7 Denominator Time Window</b> (<i>The time period in which cases are eligible for inclusion in the denominator</i>):</p>	2a- spe cs C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/>

**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) .



Denominator data come from MDS 3.0 annual, quarterly, significant change or significant correction MDS, assessments 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 with a completed annual, quarterly, significant change or significant correction MDS 3.0 assessment (A0310.A= 02, 03, 04, 05, 06) during the selected quarter, and who can self-report (J0200=1), except for those who meet the exclusion criteria.

**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 are missing data in the responses to the relevant questions in the MDS assessment.

If the facility sample includes fewer than 30 residents, then the facility is excluded from public reporting because of small sample size.

**2a.10 Denominator Exclusion Details** (All information required to collect exclusions to the denominator, including all codes, logic, and definitions):

If the MDS 3.0 assessment is an admission assessment (item A10a = 01, indicating that the resident has completed an assessment within 14 days of admission), or if there are missing or inconsistent data for pain in any of the following items: J0400, J0600A, or J0600B. Item J0400 is the question about frequency of pain in the resident interview, with a 1 to 4 numeric rating response scale (with 1 being almost constantly). Item J0600A is the numeric rating question about intensity of pain in the resident interview, with a 0 to 10 numeric rating response scale (with 10 being the worst pain you can imagine). Item J0600B is the verbal descriptor scale question about intensity of pain in the resident interview, with a 1-4 verbal descriptor response scale. Data is inconsistent if the resident reports any frequency of pain in J0400 while reporting a pain intensity of 0 in J0600A or is unable to answer J0600B (code 9). Data are also inconsistent if the resident is unable to answer J0400 (code 9) while reporting a pain intensity of 1 or greater in J0600A or any pain intensity in J0600B

**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 was used for persons with independence or modified independence in daily decision making on prior MDS assessments (Item C1000—made decisions regarding tasks of daily life = 0 [independent—decisions consistent/reasonable] or 1 [modified independence—some difficulty in new situations only]).

**2a.15-17 Detailed risk model available Web page URL or attachment:** URL The following attachment provides details of the risk model: Abt Associates. National nursing home quality measures user's manual (v 1.2). November 2004. Available from <http://www.cms.hhs.gov/NursingHomeQualityInits/Downloads/NHQIQMUsersManual.pdf>.

**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):

**Comment [k9]:** 11 Risk factors that influence outcomes should not be specified as exclusions.  
12 Patient preference is not a clinical exception to eligibility and can be influenced by provider interventions.

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.22 Describe the method for discriminating performance (e.g., significance testing):**

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. These numbers are also counted for the covariate measure, which is independence or modified independence in daily decision making as reported on the resident's prior MDS assessment. The numeric rating scale for the response is a score of 0 for residents whose decisions are consistent and reasonable and a score of 1 for residents who have some difficulty in new situations only.

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. 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:

$C0 + C1 \cdot COVA + C2 \cdot COVB + \dots$  where C0 is the logistic regression constant, C1 is the logistic regression coefficient for the first covariate (where applicable), COVA is the resident-level score for the first covariate, C2 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.

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.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 data source or collection instrument is the 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](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](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)*

Population: national, 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)*

TESTING/ANALYSIS

2b. Reliability testing

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**Comment [KP10]:** 2b. Reliability testing demonstrates the measure results are repeatable, producing the same results a high proportion of the time when assessed in the same population in the same time period.

**2b.1 Data/sample (description of data/sample and size):** The proposed measure is based on two pain items in MDS 3.0, Section J items J0400 and J0600, with the numerator including all those residents who have been assessed during the selected quarter and have almost constant or frequent pain (MDS 3.0 item J0400 = 1 or 2) AND at least one episode of moderate to severe pain (item J0600A = 5, 6, 7, 8, or 9 OR item J0600B = 2 or 3) OR very severe/horrible pain of any frequency (item J0600A = 10 OR item J0600B = 4) in the 5 days prior to the assessment.

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Two major tests of the reliability of the current quality measure have been conducted. First, the MDS 2.0 measure items and the current 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 from April 1 to December 31, 2006. During this project, 173 two-stage reviews were performed.(1)

Second, the University of Colorado used national facility-level quality measure data from the third quarter (Q3) of 2003 through Q3 of 2006, which came from the Quality Improvement and Evaluation System (QIES) MDS Express Reports on the CMS Intranet; and Online Survey, Certification, and Reporting (OSCAR) data related to facility characteristics (e.g., state, resident census, number of beds, staffing) and certification survey results were downloaded from the 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, nearly complete data for April 2006, and partial data for May and June 2006.

1. Abt Associates, Inc.; Stepwise Systems, Inc.; Qualidigm. Data Assessment and Verification (DAVE 2) project—MDS two-stage discrepancy findings, April-December 2006. Cambridge, MA: Abt Associates, Inc, 2007.
2. Brega A, Hittle D, Goodrich G, Kramer A, Conway K, Levy C. Empirical review of publicly reported nursing home quality measures. Denver: Division of Health Care Policy and Research University of Colorado at Denver; Abt Associates, Inc, 2007.

**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 past 14 days. In Stage 1 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 Stage 2 of this assessment, the DAVE 2 nurse reviewer's assessment was compared to the corresponding nursing facility 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.

The national test of MDS 3.0 items by Saliba and Buchanan examined the agreement between assessors (reliability); the response rates for interview items; user satisfaction and feedback on changes; and the time to complete the assessment. The network of Quality Improvement Organizations was used to identify the 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 free-standing facilities. The gold-standard nurses were trained in the MDS 3.0 instrument, and they, 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):**

The DAVE 2 project found a two-stage discrepancy rate of 7.3% for the MDS 2.0 pain frequency item (J0400) and 9.1% for the MDS 2.0 pain intensity item (J0600).(1) These MDS 2.0 measure items correspond to J0400 and J0600 of MDS 3.0, which are essentially the same in scope, although they rely on a nurse assessment rather than a resident report.

The national pilot test of the MDS 3.0 items showed good reliability with little evidence of confusion. For the pain items, the average kappa for gold-standard nurse to gold-standard nurse agreement was .961, and the average kappa for gold-standard nurse to facility nurse agreement was .967.(2)

**Comment [k11]:** 8 Examples of reliability testing include, but are not limited to: inter-rater/abstractor or intra-rater/abstractor studies; internal consistency for multi-item scales; test-retest for survey items. Reliability testing may address the data items or final measure score.

1. Abt Associates, Inc.; Stepwise Systems, Inc.; Qualidigm. Data Assessment and Verification (DAVE 2) project—MDS two-stage discrepancy findings, April-December 2006. Cambridge, MA: Abt Associates, Inc, 2007.  
 2. Saliba D, Buchanan J. Development and validation of a revised nursing home assessment tool: MDS 3.0. Contract No. 500-00-0027/Task Order #2. Santa Monica, CA: Rand Corporation, Apr 2008. Available from <http://www.cms.hhs.gov/NursingHomeQualityInits/Downloads/MDS30FinalReport.pdf>.

**2c. Validity testing**

**2c.1 Data/sample (description of data/sample and size):** The data came from two sources: national facility-level quality measure data from Q3 of 2003 through Q3 of 2006, which came from the QIES MDS Express Reports on the CMS Intranet; and OSCAR data related to facility characteristics (e.g., state, resident census, number of beds, staffing) and certification survey results were downloaded from the 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, nearly complete data for April 2006, and partial data for May and June 2006.

Information for this response and the other responses in regard to Validity Testing is from:

1. Brega A, Hittle D, Goodrich G, Kramer A, Conway K, Levy C. Empirical review of publicly reported nursing home quality measures. Denver: Division of Health Care Policy and Research University of Colorado at Denver; Abt Associates, Inc, 2007.
2. Brega A, Goodrich G, Nuccio E, Hittle D. Transition of publicly reported nursing home quality measures to MDS 3.0—draft. Denver: Division of Health Care Policy and Research University of Colorado at Denver, 2008.

**2c.2 Analytic Method (type of validity & rationale, method for testing):**

The analysis of the current measure evaluated measure validity to examine the expected positive influence of public reporting on quality of care, which is an assessment of the degree to which quality measure triggering rates have improved over time; evaluate convergent validity, which is an assessment of the correlation of the quality measure with all other measures; determine if the quality measure triggering rate was influenced by factors that are unrelated to facility quality, which is 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 where a facility was located.

**2c.3 Testing Results (statistical results, assessment of adequacy in the context of norms for the test conducted):**

These results reflect the performance of the current chronic care pain measure and the underlying MDS 2.0 items for those measures, which measure the same pain factors as the MDS 3.0 items for the proposed measure. In the proposed measure, data will be collected directly from the resident. See attached Table 2: Measure Trends Over Time.

Correlations with other clinical measures are weak. Only 8.0% of the variance in report rate for the current measure was explained by the state where a facility was located. The analysis found that public reporting may have had some influence on the decreased level of reported pain over time due to the decline in the triggering rate. See attached table.

There is little evidence of seasonal variations, as shown by the previously mentioned triggering rates, and the analysis found that only 8% of the variance in report rate for this measure was explained by the state where a facility was located. The limited correlation to other clinical measures may reflect the multiplicity of causes and potential treatments for pain, and the limited variation in seasonal rate and rate among states makes this measure a reliable guide to the level of reported pain.

**Comment [KP12]:** 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.

**Comment [k13]:** 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 < 140/90 is a marker of quality). If face validity is the only validity addressed, it is systematically assessed (e.g., ratings by relevant stakeholders) and the measure is judged to represent quality care for the specific topic and that the measure focus is the most important aspect of quality for the specific topic.

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<p><b>2d. Exclusions Justified</b></p> <p><b>2d.1 Summary of Evidence supporting exclusion(s):</b>                  All residents in long-stay for which complete data exist are included. 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.</p> <p><b>2d.2 Citations for Evidence:</b>                  This is not applicable.</p> <p><b>2d.3 Data/sample (description of data/sample and size):</b> This is not applicable.</p> <p><b>2d.4 Analytic Method (type analysis &amp; rationale):</b>                  This is not applicable.</p> <p><b>2d.5 Testing Results (e.g., frequency, variability, sensitivity analyses):</b>                  This is not applicable.</p>	2d C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/>
<p><b>2e. Risk Adjustment for Outcomes/ Resource Use Measures</b></p> <p><b>2e.1 Data/sample (description of data/sample and size):</b> Samples for two "target periods" were drawn:                  1. "Current Period" target sample for computing quality measures: all U.S. nursing facilities and residents selected from the target quarter.                  2. "Prior Year" target sample for estimating logistic regressions: residents from a 20% random sample of all U.S. nursing facilities with a chronic care admission during the fourth quarter (Q4) of 2001 through Q3 of 2002.                  b. CC resident records included, for each target period:                  1. A target assessment (most recent).                  2. A prior assessment preceding the target assessment, if available.                  3. A most recent full assessment, if available.</p> <p>The information for risk adjustment is from:                  Abt Associates. National nursing home quality measures user's manual (v 1.2). November 2004. Available from <a href="http://www.cms.hhs.gov/NursingHomeQualityInits/Downloads/NHQIQMUsersManual.pdf">http://www.cms.hhs.gov/NursingHomeQualityInits/Downloads/NHQIQMUsersManual.pdf</a>.</p> <p><b>2e.2 Analytic Method (type of risk adjustment, analysis, &amp; rationale):</b>                  The approach involves using logistic regression to adjust quality measure scores directly. This method of adjustment uses resident-level covariates that have been found to increase the risks of an outcome. First, resident-level covariates were used in a logistic regression model to calculate a resident-level expected quality measure score (the probability that the resident will evidence the outcome, given the presence or absence of characteristics measured by the covariates). Then, an average of all resident-level expected quality measure scores for the nursing facility was calculated to create a facility-level expected quality measure score. The final facility-level adjusted quality measure score was based on a calculation that combines the facility-level expected score and the facility-level observed score.</p>	2e C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/>

**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 [k15]:** 10 Examples of evidence that an exclusion distorts measure results include, but are not limited to: frequency of occurrence, sensitivity analyses with and without the exclusion, and variability of exclusions across providers.

**Comment [KP16]:** 2e. For outcome measures and other measures (e.g., resource use) when indicated:  
 •an evidence-based risk-adjustment strategy (e.g., risk models, risk stratification) is specified and is based on patient clinical factors that influence the measured outcome (but not disparities in care) and are present at start of care; OR  
 rationale/data support no risk adjustment.

**Comment [k17]:** 13 Risk models should not obscure disparities in care for populations by including factors that are associated with differences/inequalities in care such as race, socioeconomic status, gender (e.g., poorer treatment outcomes of African American men with prostate cancer, inequalities in treatment for CVD risk factors between men and women). It is preferable to stratify measures by race and socioeconomic status rather than adjusting out differences.

**2e.3 Testing Results (risk model performance metrics):**

A review by the University of Colorado used data from two sources: national facility-level quality measure data from Q3 of 2003 through Q3 of 2006, which came from the QIES MDS Express Reports on the CMS Intranet; and OSCAR data related to facility characteristics (e.g., state, resident census, number of beds, staffing) and certification survey results were downloaded from the 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, nearly complete data for April 2006, and partial data for May and June 2006. The analysis evaluated the risk adjustment model at the resident level and the facility level, generating R-square and C statistics. R-square indicates the proportion of the variance in measure performance that is accounted for by the covariates. The C-statistic gives the percentage of the time the observed value and the expected value move in the same direction, ranging from 0.5 (poor, no better than chance) to 1.0 (observed and predicted always move in the same direction). The analysis found an R-square of .016 and a C of .615; neither statistic met the threshold for predictive adequacy (0.10 for R-square and 0.70 for C).

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

**2f. Identification of Meaningful Differences in Performance**

**2f.1 Data/sample from Testing or Current Use (description of data/sample and size):** These results reflect the performance of the current chronic care pain measure and the underlying MDS 2.0 items for that measure, which measures the same pain factors as the MDS 3.0 items for the proposed measure. In this proposed measure, data will be collected directly from the resident.

The data came from two sources: national facility-level quality measure data from Q3 of 2003 through Q3 of 2006, which came from the QIES MDS Express Reports on the CMS Intranet; and OSCAR data related to facility characteristics (e.g., state, resident census, number of beds, staffing) and certification survey results were downloaded from the 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, 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):**

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. These numbers are also counted for the covariate measure, which is independence or modified independence in daily decision making as reported on the resident's prior MDS assessment. The numeric rating scale for the response is a score of 0 for residents whose decisions are consistent and reasonable and a score of 1 for residents who have some difficulty in new situations only.

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. 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:

$C0 + C1*COVA + C2*COVB + \dots$  where C0 is the logistic regression constant, C1 is the logistic regression coefficient for the first covariate (where applicable), COVA is the resident-level score for the first covariate, C2 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.

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.

**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 meaningful differences in performance):**

For each facility, the number of long-stay residents meeting the numerator criteria and the number of (non-

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**Comment [KP18]:** 2f. Data analysis demonstrates that methods for scoring and analysis of the specified measure allow for identification of statistically significant and practically/clinically meaningful differences in performance.

**Comment [k19]:** 14 With large enough sample sizes, small differences that are statistically significant may or may not be practically or clinically meaningful. The substantive question may be, for example, whether a statistically significant difference of one percentage point in the percentage of patients who received smoking cessation counseling (e.g., 74% v. 75%) is clinically meaningful; or whether a statistically significant difference of \$25 in cost for an episode of care (e.g., \$5,000 v. \$5,025) is practically meaningful. Measures with overall poor performance may not demonstrate much variability across providers.

<p>excluded) residents meeting the denominator criteria are counted. These numbers are also counted for the covariate measure, which is independence or modified independence in daily decision making as reported on the resident's prior MDS assessment. The numeric rating scale for the response is a score of 0 for residents whose decisions are consistent and reasonable and a score of 1 for residents who have some difficulty in new situations only.</p> <p>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. 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:  <math>C0 + C1 \cdot COVA + C2 \cdot COVB + \dots</math> where C0 is the logistic regression constant, C1 is the logistic regression coefficient for the first covariate (where applicable), COVA is the resident-level score for the first covariate, C2 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.</p> <p>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.</p> <p>An analytical team at the University of Colorado's 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], identification of statistically significant and meaningful differences in performance). For 13,837 facilities, the mean triggering rate was 5.1%, with a standard deviation of 5.0%. The attached table reports the full results of the analysis. See attached Table 1: Measure Variability Across Facilities.</p>	
<p><b>2g. Comparability of Multiple Data Sources/Methods</b></p> <p><b>2g.1 Data/sample</b> (description of data/sample and size): This is not applicable.</p> <p><b>2g.2 Analytic Method</b> (type of analysis &amp; rationale): This is not applicable.</p> <p><b>2g.3 Testing Results</b> (e.g., correlation statistics, comparison of rankings): This is not applicable.</p>	<p><b>2g</b></p> <p>C <input type="checkbox"/></p> <p>P <input type="checkbox"/></p> <p>M <input type="checkbox"/></p> <p>N <input type="checkbox"/></p> <p>NA <input type="checkbox"/></p>
<p><b>2h. Disparities in Care</b></p> <p><b>2h.1</b> If measure is stratified, provide stratified results (scores by stratified categories/cohorts): The measure is not stratified.</p> <p><b>2h.2</b> If disparities have been reported/identified, but measure is not specified to detect disparities, provide follow-up plans:          Although 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, 2, 3)</p> <p>Research has also identified disparities in pain management between cognitively intact residents and those who are cognitively impaired. In the current MDS pain item, staff recording of cognitive status was inversely proportional to pain report; the most cognitively impaired residents were recorded as suffering the least pain and received the least pain therapy.(4) In the MDS 3.0, new pain items were included that focus on patient interview and have been shown to be able to be answered by cognitively impaired residents.(5) However, the sample size at the facility level may not support stratification, but this will be evaluated in the future as MDS 3.0 data become available.</p> <p>1. Smith D, Feng Z, Zinn J, Mor V. 2008. Racial disparities in access to long-term care: the illusive pursuit of equity. Journal of Health Politics, Policy, and Law. 2008;33(5):861-81.</p>	<p><b>2h</b></p> <p>C <input type="checkbox"/></p> <p>P <input type="checkbox"/></p> <p>M <input type="checkbox"/></p> <p>N <input type="checkbox"/></p> <p>NA <input type="checkbox"/></p>

**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.

<p>2. Smith D, Feng Z, Fennell M, Zinn J, Mor V. Separate and unequal: racial segregation and disparities in quality across U.S. nursing homes. <i>Health Affairs (Millwood)</i>. 2007;26(5):1448-1558.</p> <p>3. Mor V, Berg K, Angelelli J, Gifford D, Morris J, Moore T. 2003. The quality of quality measurement in U.S. nursing homes. <i>The Gerontologist</i>. 2003;43(Special Issue II):37-46.</p> <p>4. Reynolds K, Hanson L, DeVellis R, Henderson M, Steinhauer K. Disparities in pain management between cognitively intact and cognitively impaired nursing home residents. <i>Journal of Pain and Symptom Management</i>. 2008;35(4):388-96.</p> <p>5. Saliba D, Buchanan J. Development and validation of a revised nursing home assessment tool: MDS 3.0. Contract No. 500-00-0027/Task Order #2. Santa Monica, CA: Rand Corporation, Apr 2008. Available from <a href="http://www.cms.hhs.gov/NursingHomeQualityInits/Downloads/MDS30FinalReport.pdf">http://www.cms.hhs.gov/NursingHomeQualityInits/Downloads/MDS30FinalReport.pdf</a>.</p>	
<p><b>TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for <i>Scientific Acceptability of Measure Properties</i>?</b></p>	2
<p><b>Steering Committee: Overall, to what extent was the criterion, <i>Scientific Acceptability of Measure Properties</i>, met?</b> Rationale:</p>	<p>2 C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>
<b>3. USABILITY</b>	
<p>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)</p>	Eval Rat ing
<p><b>3a. Meaningful, Understandable, and Useful Information</b></p>	
<p><b>3a.1 Current Use:</b> In use</p>	
<p><b>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):</b> The predecessor version of this measure is currently used in Nursing Home Compare, and this measure is designed to replace it using the MDS 3.0 items instead of the MDS 2.0 items. <a href="http://www.medicare.gov/NHCompare/Include/DataSection/Questions/SearchCriteriaNEW.asp?version=default&amp;brower=IE%7C6%7CWinXP&amp;language=English&amp;defaultstatus=0&amp;pagelist=Home&amp;CookiesEnabledStatus=True">http://www.medicare.gov/NHCompare/Include/DataSection/Questions/SearchCriteriaNEW.asp?version=default&amp;brower=IE%7C6%7CWinXP&amp;language=English&amp;defaultstatus=0&amp;pagelist=Home&amp;CookiesEnabledStatus=True</a></p>	
<p><b>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):</b> CMS expects that the quality measure will be used by nursing facilities as a tool to monitor resident pain and improve pain management. The national level of pain reported by the current measure has remained constant at 7.8% in the Q1 of 2005 to the Q3 of 2009. (Data are available at <a href="http://www.cms.hhs.gov/MDSPubQIandResRep/02_qmreport.asp#TopOfPage">http://www.cms.hhs.gov/MDSPubQIandResRep/02_qmreport.asp#TopOfPage</a>)</p>	
<p>This measure is also cited by the Mission of the Advancing Excellence in America's Nursing Homes Campaign, a cooperative quality program sponsored by long-term care providers; consumers and advocates; and nursing facility practitioners, including nurses, health care professionals, medical directors, nursing home administrators, government agencies, quality improvement organizations, and private organizations supporting nursing home education. Based on projection from MDS Quality Measure reporting data, the Advancing Excellence in America's Nursing Homes Campaign outlined several goals to reduce the national level of</p>	<p>3a C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>

**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.



reported pain in long-term care by September 2008. The results to date on its Web site indicate that by the Q2 of 2009, two of the goals were achieved: (1) the national average of reported pain long-term care had reached 4% and (2) more than 30% of nursing facilities reported rates of pain in long-term care below 2%. However, two other goals were not met: (1) no nursing home reported a rate of pain in long-term care above 20% and (2) 40,000 fewer residents in long-term care have chronic pain.  
[http://www.nhqualitycampaign.org/star\\_index.aspx?controls=campaignReports](http://www.nhqualitycampaign.org/star_index.aspx?controls=campaignReports)

**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.(1)

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

1. Castle N. The Nursing Home Compare report card: consumers' use and understanding. *Journal of Aging and Social Policy*. 2009;21(2):187-208.

**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 to help them choose a nursing facility, 12% recalled using Nursing Home Compare, and, in general, the consumers' comprehension index scores were high, indicating a good understanding. The comprehension index for the current chronic care pain measure was the highest, 5.87 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:**

The proposed measure is intended to replace the currently endorsed NQF #0186 Recently hospitalized residents who experienced moderate to severe pain at any time during the 7-day assessment period, as the data source has changed; (the MDS 2.0, the current source of data, is being replaced by the MDS 3.0) NQF #0192—Residents who experience moderate to severe pain during the 7-day assessment period (risk-adjusted). NQF # 0177. NQF # 0523 Pain Assessment Conducted. NQF # 0420 Pain Assessment Prior to Initiation of Patient Therapy. NQF # 0524 Pain Interventions Implemented.

**(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/setting/data source or different topic but same target population):

**3b.2 Are the measure specifications harmonized? If not, why?**

No. All the above measures are based other instruments except for #0186 and #0192, which are based on a previous version of the MDS, version 2.0. NQF # 0192 is scheduled to be replaced by this proposed measure and NQF #0186 Percent of residents with moderate or severe pain (post acute care) is scheduled to be replaced by a measure being proposed at the same time. The measures being proposed to replace NQF # 0186 and # 0192 are based on a different denominator definition than the current measures and on different pain assessment items.

**3c. Distinctive or Additive Value**

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

The proposed measure draws on revised items from the MDS 3.0 which are more reliable than those supporting

3b  
 C   
 P   
 M   
 N   
 NA   
 M   
 3c  
 C   
 P   
 M

**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).

the current measure from the MDS 2.0.	<input type="checkbox"/> <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/>
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? Rationale:	3 <input type="checkbox"/> C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/>
<b>4. FEASIBILITY</b>	
Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. (evaluation criteria)	Ev al Rat ing
4a. Data Generated as a Byproduct of Care Processes	4a
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)	<input type="checkbox"/> C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/>
4b. Electronic Sources	4b
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	<input type="checkbox"/> C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/>
4b.2 If not, specify the near-term path to achieve electronic capture by most providers. <a href="http://www.cms.gov/MDSPubQlandResRep/01_Overview.asp">http://www.cms.gov/MDSPubQlandResRep/01_Overview.asp</a>	
4c. Exclusions	4c
4c.1 Do the specified exclusions require additional data sources beyond what is required for the numerator and denominator specifications? No	<input type="checkbox"/> C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/>
4c.2 If yes, provide justification.	
4d. Susceptibility to Inaccuracies, Errors, or Unintended Consequences	4d
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. The proposed MDS 3.0 measure, which relies on resident report, is designed to replace a current MDS 2.0 measure, which was based on staff assessment. The current measure reported consistently and sometimes dramatically lower rates than those found in nursing homes in randomized controlled trial studies involving self-reporting. The proposed measure may itself underreport pain because it excludes those nursing home residents who are unable to report their pain, generally due to dementia. However, patient self-report of the presence and severity of pain, which is incorporated in the MDS 3.0 items supporting the proposed measure, is considered the most reliable and accurate approach to pain assessment. Both the American Geriatrics Society	<input type="checkbox"/> C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/>

**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.

Panel on Persistent Pain in Older Persons and the Department of Veterans Affairs endorse this approach.(1, 2) A growing number of studies and other literature demonstrate that even nursing home residents with moderate to severe cognitive impairment can reliably respond to questions about pain.(3, 4, 5, 6, 7, 8) Several studies in elders with varying cognitive status suggest that some tools may be more reliable and “user friendly” than others for obtaining self-reports of pain from this population, and the new items in MDS 3.0 incorporate these more reliable and user-friendly approaches.(9, 10, 11, 12, 13, 14) A national test of the MDS 3.0 items supporting the proposed measure found that 87% of the test sample of residents and 89% of a validation sample of residents were able to successfully complete the pain interview portion of the MDS 3.0 upon which this measure is based.(9) Further testing is needed though because at least one expert, Vincent Mor, believes that the number of residents who cannot be interviewed will be higher when MDS 3.0 is placed into general use.(15)

Recent research has found a general decline in the percentage of residents with pain (as defined by this measure) admitted to nursing facilities for long-term care by approximately 13% after the first publication of the current pain measure in 2002. Analysis associated with this study suggests that nursing homes exhibited a tendency to avoid such residents to improve their rating for the measure, although the authors concede that, due to the difficulty in accurately measuring pain, it is possible that the decline was due to ascertainment bias. (16)

The proposed measure addresses an additional significant issue with the current measure, in which pain is reported by the staff assessor, relying on the assessor’s own observations and those of other staff and without the use of a standard scale, and subject to ascertainment bias. The proposed measure employs a resident interview with a standardized scale of 1 (almost constantly) to 4 (rarely) for frequency of pain and a choice of standardized scales of 0 (no pain) to 10 (worst pain you can imagine) or 1 (mild) to 5 (very severe, horrible) for pain intensity.(9)

An example of an unintended consequence of this measure may occur if residents report that pain frequency decreased, however, pain intensity increased; or the reverse occurs, if pain intensity decreased but pain frequency increased. As part of the validation testing for this measure, RTI will examine responses for change, lack of change, and direction of change as well as patterns of both the frequency and intensity to assess whether there is an effect on the face validity of the measure.

1. American Geriatrics Society Panel on Persistent Pain in Older Persons. The management of persistent pain in older persons. *J Am Geriatr Soc.* 2002;50:S205-44.
2. Department of Veterans Affairs. VHA directive 2003-021: pain management. 2003.
3. Parmelee PA, Smith B, Katz IR. Pain complaints and cognitive status among elderly institution residents. *J Am Geriatr Soc.* 1993;41(5):517-22.
4. Engle V, Graney M, Chan A. Accuracy and bias of licensed practical nurse and nursing assistant ratings of nursing home residents’ pain. *J Gerontol A Biol Sci Med Sci.* 2001;56(7):M405-11.
5. Parmelee P. Pain in cognitively impaired older persons. *Clin Geriatr Med.* 1996;12(3):473-87.
6. Ferrell B, Ferrell B, Rivera L. Pain in cognitively impaired nursing home patients. *J Pain Symptom Manage.* 1995;10(8):591-8.
7. Weiner D, Peterson B, Ladd K, McConnell E, Keefe F. Pain in nursing home residents: an exploration of prevalence, staff perspectives, and practical aspects of measurement. *Clin J Pain.* 1999;15(2):92-101.
8. Wynne F, Ling S, Remsburg R. Comparison of pain assessment instruments in cognitively intact and cognitively impaired nursing home residents. *Geriatr Nurs.* 2000;21(1):20-3.
9. Saliba D, Buchanan J. Development and validation of a revised nursing home assessment tool: MDS 3.0. Contract No. 500-00-0027/Task Order #2. Santa Monica, CA: Rand Corporation, Apr 2008. Available from <http://www.cms.hhs.gov/NursingHomeQualityInits/Downloads/MDS30FinalReport.pdf>.
10. Ferrell BA, Ferrell BR, Osterweil D. Pain in the nursing home. *J Am Geriatr Soc.* 1990;38(4):409-14
11. Scherder EJ, Bouma A. Visual analogue scales for pain assessment in Alzheimer’s disease. *Gerontol.* 2000;46(1):47-53.
12. Krulewicz H, London M, Skakel V, Lundstedt GJ, Thomason H, Brummel-Smith K. Assessment of pain in cognitively impaired older adults: a comparison of pain assessment tools and their use by nonprofessional caregivers. *J Am Geriatr Soc.* 2000;48(12):1607-11.
13. Herr K, Mobily P. Comparison of selected pain assessment tools for use with the elderly. *Appl Nurs Res.* 1993;6(1):39-46.
14. Manz B, Mosier R, Nusser-Gerlach M, Bergstrom N, Agrawal S. Pain assessment in the cognitively impaired and unimpaired elderly. *Pain Manag Nurs.* 2000;1(4):106-115.

<p>15. RTI International. Transition of Publicly Reported Nursing Home Measures to MDS 3.0 Draft Technical Expert Panel Report. 2009.</p> <p>16. Mukamel D, Ladd H, Weimer D, Spector W, Ainn J. Is there evidence of cream skimming among nursing homes following the publication of the Nursing Home Compare report card? <i>The Gerontologist</i>. 2009;49(6):793-802.</p> <p>This was not audited.</p>	
<p><b>4e. Data Collection Strategy/Implementation</b></p> <p><b>4e.1</b> 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:  <i>The data collection method is already in operational use, and no issues are anticipated.</i></p> <p><b>4e.2</b> Costs to implement the measure (<i>costs of data collection, fees associated with proprietary measures</i>):  <i>Data are collected as part of an existing process with no additional cost.</i></p> <p><b>4e.3</b> Evidence for costs:  <i>This is not applicable.</i></p> <p><b>4e.4</b> Business case documentation: <i>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.</i></p>	<p>4e</p> <p>C <input type="checkbox"/></p> <p>P <input type="checkbox"/></p> <p>M <input type="checkbox"/></p> <p>N <input type="checkbox"/></p>
<p><b>TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for <i>Feasibility</i>?</b></p>	<p>4</p>
<p>Steering Committee: Overall, to what extent was the criterion, <i>Feasibility</i>, met?                  Rationale:</p>	<p>4</p> <p>C <input type="checkbox"/></p> <p>P <input type="checkbox"/></p> <p>M <input type="checkbox"/></p> <p>N <input type="checkbox"/></p>
<p style="text-align: center;"><b>RECOMMENDATION</b></p>	
<p><b>(for NQF staff use)</b> Check if measure is untested and only eligible for time-limited endorsement.</p>	<p>Time-limited <input type="checkbox"/></p>
<p>Steering Committee: Do you recommend for endorsement?                  Comments:</p>	<p>Y <input type="checkbox"/></p> <p>N <input type="checkbox"/></p> <p>A <input type="checkbox"/></p>
<p style="text-align: center;"><b>CONTACT INFORMATION</b></p>	
<p><b>Co.1 Measure Steward (Intellectual Property Owner)</b>  <b>Co.1 Organization</b>                  Centers for Medicare &amp; Medicaid Services, 7500 Security Boulevard , Mail Stop S3-02-01, Baltimore , Maryland, 21244-1850</p> <p><b>Co.2 Point of Contact</b>                  Judith, Tobin, PT, MBA, Judith.Tobin@cms.hhs.gov, 410-786-6892-</p>	
<p>Measure Developer If different from Measure Steward</p>	

**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).

<p><b>Co.3 Organization</b>  RTI International, 1440 Main Street, Suite 310, Waltham, Massachusetts, 02451-1623</p>
<p><b>Co.4 Point of Contact</b>  Roberta, Constantine, RN, MBA, PhD, rconstantine@rti.org, 781-434-1700-1711</p>
<p><b>Co.5 Submitter If different from Measure Steward POC</b>  Roberta, Constantine, RN, MBA, PhD, rconstantine@rti.org, 781-434-1700-1711, RTI International</p>
<p><b>Co.6 Additional organizations that sponsored/participated in measure development</b></p>
<p><b>ADDITIONAL INFORMATION</b></p>
<p><b>Workgroup/Expert Panel involved in measure development</b>  <b>Ad.1 Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development.</b>  See Table 4: Nursing Home Quality Measures Technical Expert Panel (January 2009)</p> <p>This technical expert panel met during 2 days in January 2009 to review an environmental scan of the current quality measures and make recommendations regarding their transition from MDS 2.0 to MDS 3.0. The attached table provides a list of workgroup or panel member names and organizations.</p>
<p><b>Ad.2 If adapted, provide name of original measure:</b> This measure was adapted from the measure of the same name derived from MDS 2.0 data.</p>
<p><b>Ad.3-5 If adapted, provide original specifications URL or attachment</b> MedQIC Resource Manual. Available from <a href="http://www.qualitynet.org/dcs/ContentServer?cid=1138050766910&amp;pagename=Medqic%2FOtherResource%2FOtherResourcesTemplate&amp;c=OtherResource">http://www.qualitynet.org/dcs/ContentServer?cid=1138050766910&amp;pagename=Medqic%2FOtherResource%2FOtherResourcesTemplate&amp;c=OtherResource</a></p>
<p><b>Measure Developer/Steward Updates and Ongoing Maintenance</b>  <b>Ad.6 Year the measure was first released:</b> 2002  <b>Ad.7 Month and Year of most recent revision:</b> 02, 2010  <b>Ad.8 What is your frequency for review/update of this measure?</b> Every 3 years  <b>Ad.9 When is the next scheduled review/update for this measure?</b> 02, 2013</p>
<p><b>Ad.10 Copyright statement/disclaimers:</b></p>
<p><b>Ad.11 -13 Additional Information web page URL or attachment:</b> Attachment Moderate to Severe Pain Long Stay tables_FINAL-634045006711205000.doc</p>
<p><b>Date of Submission (MM/DD/YY):</b> 07/12/2010</p>

**Project Name:** NQF Nursing Home Project

**Measure Title:** Percent of Residents with Moderate to Severe Pain (Long Stay)

**Planned Date of Measure Submission:** March 19, 2010

**Steward Name:**

**Developer/Submitter Name:**

Point of Contact

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**Table 1. Measure Variability Across Facilities**

Quality Measure (QM)	N of Facilities <sup>1</sup>	Mean	Std Dev	10 <sup>th</sup> Percentile	25 <sup>th</sup> Percentile	50 <sup>th</sup> Percentile	75 <sup>th</sup> Percentile	90 <sup>th</sup> Percentile	Facilities with QM = 0%
Pain	13,714	5.1%	5.0%	0.6%	1.7%	3.8%	7.0%	11.3%	9.0%

**Table 2. Measure Trends Over Time**

Quality Measure (QM)	Mean of Facility Triggering Rates (%)												
	Q3, 2003	Q4, 2003	Q1, 2004	Q2, 2004	Q3, 2004	Q4, 2004	Q1, 2005	Q2, 2005	Q3, 2005	Q4, 2005	Q1, 2006	Q2, 2006	Q3, 2006
Pain (Chronic Care)	6.7	6.4	6.3	6.2	6.4	6.4	6.3	6.4	6.3	5.6	5.2	5.1	5.1

**Table 3. Correlations of Quality Measures**

Pairwise N (Above Diagonal) and Correlation (Below Diagonal)	More Depressed or Anxious	ADL Decline	Mobility Decline	Incontinence (Low Risk)	Bedfast	Indwelling Catheter	Urinary Tract Infection
Pain (Chronic Care)	0.11	0.02	0.01	-0.05	0.11	0.12	0.12

**Table 4. Nursing Home Quality Measures Technical Expert Panel (January 2009)**

<b>Name</b>	<b>Title</b>	<b>Affiliation</b>
Barbara Anglin, RN	Program Services Consultant	American Association of Nurse Assessment Coordinators (AANAC)
Bonnie Burak-Danielson, MSM, EXP, LPTA	Rehab Manager of Reimbursement	Spaulding Rehab Network
Sarah Burger, MPH, RN	Senior Advisor and Coordinator	Coalition of Geriatric Nursing Organizations The John A. Hartford Institute for Geriatric Nursing
Diane Carter, MSN, RN, CS	President	AANAC
Kate Dennison, RN, RAC-MT	Minimum Data Set (MDS) Coordinator	The Cedars
Mary Ellard, RN, MPA/H, RAC-CT	Clinical Assessment Specialist	Five Star Quality Care, Inc.
Sandy Fitzler, RN	Senior Director of Clinical Services	American Health Care Association
David F. Hittle, PhD	Assistant Professor	Division of Health Care Policy and Research University of Colorado Denver, School of Medicine
Steve Levenson, MD, CMD	Multi-Facility Medical Director, Baltimore, MD	
Carol Maher, RN-BC, RAC-CT	Director of Clinical Reimbursement	Ensign Facilities Services
Barbara Manard, PhD	Vice President, Long Term Care/Health Strategies	American Association of Homes and Services for the Aging

Debra Saliba, MD, MPH	Anna and Harry Borun Chair in Geriatrics and Gerontology at UCLA Research Physician VA GLAHS GRECC Director of UCLA/JHA Borun Center for Gerontological Research Senior Natural Scientist RAND Health	University of California, Los Angeles (UCLA), Veterans Affairs (VA), RAND Corporation
Eric Tangalos, MD	Professor of Medicine	Mayo Clinic
Jacqueline Vance, RNC, CDONA/LTC	Director of Clinical Affairs	(American Medical Directors Association) AMDA
Mary Van de Kamp, MS/CCC-SLP	Vice President, Clinical Rehabilitation	Peoplefirst Rehabilitation
Charlene Harrington, PhD, RN, FAAN*	Professor Emeritus	University of California, San Francisco Fellow in the American Academy of Nursing



**Measure #/Title/Steward**

NH-011-10: Percent of Residents with Moderate to Severe Pain (Long Stay)  
(Centers for Medicare & Medicaid Services)

**Description:** The proposed long-stay pain measure reports the percent of long-stay residents of all ages in a nursing facility who reported almost constant or frequent pain and at least one episode of moderate to severe pain or any severe or horrible pain in the 5 days prior to the MDS assessment (which may be an annual, quarterly, significant change or significant correction MDS) during the selected quarter. Long-stay residents are those who have had at least 100 days of nursing facility care. This measure is restricted to the long stay population because a separate measure has been submitted for the short-stay residents (those who are discharged within 100 days of admission).

**Initial In-Person Vote:**

Recommended for time-limited endorsement with conditions – 18

Not recommended for endorsement – 2

<b><u>Steering Committee Questions/Conditions for Measure Developer:</u></b>	<b><u>Response from Measure Developer</u></b>
<ul style="list-style-type: none"><li>The developer further examines what missing data indicates in light of concerns that data may not be reported in order to improve the reported quality of care.</li></ul>	<ul style="list-style-type: none"><li>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 as cited previously for other measures.</li></ul>
<ul style="list-style-type: none"><li>The definition of long-stay residents needs to be clarified</li></ul>	<ul style="list-style-type: none"><li>Long -stay residents are 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.</li></ul>
<ul style="list-style-type: none"><li>The developer address concerns regarding frequency and intensity of pain, as well as patient preference</li></ul>	<ul style="list-style-type: none"><li>The Steering Committee concerns were noted and the developer expressed willingness to address these issues as they are able in future testing</li></ul>
<ul style="list-style-type: none"><li>The Steering Committee requested that the measure evaluate the patient’s cognitive status when reporting on patient experience of pain</li></ul>	<ul style="list-style-type: none"><li>The developer agreed that cognitive status is important to measure, and it is evaluated as part of the MDS 3.0, however, it has not been included in the development of this pain measure. The developer agreed to examine the association between cognitive status and reported pain when further testing occurs.</li></ul>