

I. Overview of the MDS 3.0

The Centers for Medicare & Medicaid Services (CMS) has been working on the Minimum Data Set version 3.0 (MDS 3.0) that will replace the MDS 2.0 as a standardized assessment tool by all Medicare certified nursing/post-acute facilities in the United States. In April 2003, the Centers for Medicare & Medicaid Services (CMS) issued a contract to RAND to evaluate proposed revisions to the Minimum Data Set for Nursing Homes (MDS 3.0). The project goal is to create and validate a more useful MDS tool that reduces burden while updating sections to be more responsive to advances in the measurement of health conditions in nursing home populations. The MDS 2.0 is being revised based on this measurement science and on feedback and guidance received from stakeholders, users, and content experts. These revisions will then be evaluated on-site in a sample of nursing homes to ensure that the instrument does not change the payment system for nursing homes nor does it compromise the information gathered. The reasons for the MDS 3.0 revision are broad:

- To make the MDS more clinically relevant, while still achieving the federal payment mandates and quality initiatives;
- To improve ease of use;
- To increase MDS efficiency;
- To integrate selected standard scales; and
- To allow resident to be heard by introducing interview questions.

II. Delay in Original MDS 3.0 Timeline

CMS's original timeframe has been extended and there is no date set for release of MDS 3.0, because of unforeseen positive events.

1. A Memorandum of Understanding signed between the Veterans Health Administration (VHA) and CMS to work together to improve the MDS 3.0 on December 31, 2003. VHA Health Services Research and Development (VHA HSR&D) has recently funded a large research project entitled "Pilot Testing and Validation of Changes to the Minimum Data Set (MDS) for Veteran Administration (VA) Nursing Homes" that aims to contribute to the MDS 3.0 revision. Onsite validation activities have been delayed to align MDS work with this research that will pilot test and evaluate whether MDS 3.0 item related to diagnostic coding, delirium, pain, falls, mood, behavior disorders, quality of life, and palliative care has adequate validity to support efficient screening, for individual care planning in the VA for the new items (diagnostic coding, delirium, pain, falls, mood, behavior disorders, quality of life, and palliative care). This alignment allows the validity of these items to be further tested in a national sample of VA and community nursing homes.
2. Since MDS 3.0 revisions will aim to comply with the Department of Health &

Human Services (DHHS) Consolidated Health Informatics (CHI) initiative for interoperable terminology and vocabulary, CMS and the Assistant Secretary for Planning and Evaluation (ASPE) awarded a contract in August 2004 to Apelon Systems, a medical terminology and vocabulary contractor, to assure that wherever possible, MDS 3.0 complies with CHI endorsed standards. MDS and other new or revised instruments will incorporate government-wide terminology standards that aim to assure patient data is interoperable and can be compared across health care settings.

Whenever MDS 3.0 is finalized and made public, facilities will have an additional eleven months to implement the new instrument.

III. Electronic MDS (E-MDS)

The E-MDS vision is a long-range vision. The primary goals of E-MDS include, but are not limited to, the following:

- Allow population of the MDS from an electronic health record where possible, enabling Nursing Homes to more easily comply with CMS MDS reporting requirements
- Enable Nursing Home caregivers easy access to CMS information useful in providing quality care to residents.
- Ensure that the MDS incorporates government-wide terminology standards so that patient data is interoperable and can be compared across health care settings.
- Provide an updated network structure between CMS and Nursing Homes to facilitate a fast, flexible, easy to use communication vehicle.

CMS is proceeding with the initial E-MDS work via the below steps. The steps below are occurring concurrently:

1. Provide Nursing Homes access to a secure internet vehicle. The pilot for this will begin in early 2005. When nationally available, CMS expects this updated network will make it easier for Nursing Homes to both submit MDS information to CMS, and receive useful information from CMS.
2. Partner with the VA to build messaging specifications, iteratively, between the VA's EHR, and the current MDS . This work is underway, now, and a VA pilot will begin in early 2006.
3. Through a contract with Apelon Systems, begin mapping the MDS to CHI endorsed terminology vocabularies. This work will identify matches, near

matches, and gaps that exist between the current vocabularies and MDS items. Additionally, this contract will create CHI compliant messaging specifications, furthering the work described in 2. above. The contract is underway, now. The mapping and message building will be an iterative, relatively lengthy process.

IV. EVALUATION OF MDS 3.0

Evaluation Team

The evaluation team, led by RAND, includes the Harvard Medical School, Department of Health Care Policy, the Colorado Foundation for Medical Care and Carelink. Since the onset of the project, the scope of work has been modified and the evaluation team has expanded to include a VA nursing home research collaborative. CMS has entered into a memorandum of understanding with the Veterans Administration that would allow the agencies to collaborate in improving the Minimum Data Set.

Evaluation Criteria: In undertaking this revision of the MDS, CMS worked with stakeholders to identify several objectives. A primary goal is that revisions should improve the clinical relevance of the MDS's screening and assessment items. This can best be accomplished by incorporating the experience of MDS users, incorporating advances in assessment science, and improving the accuracy of reports. Another important goal, closely related to relevance, is increasing the efficiency of reports or gaining useful information with the least possible provider burden. Finally, revisions will aim to maintain the ability of CMS to use MDS data for quality indicators, quality measures and case-mix adjustment for reimbursement (RUGs). The current MDS evaluation project is divided into 5 phases, described below.

Phase 1: Obtain Stakeholder Feedback on MDS 2.0 and proposed MDS 3.0

To initiate this process, CMS had worked with content experts and small working groups to explore possible revisions to the MDS. Based on experience with the MDS and this input, CMS released a draft MDS 3.0 for public comment in April 2003. RAND has subsequently employed several approaches to obtain and synthesize stakeholder feedback and input.

Matrix of Written Commentaries

CMS posted the April 2003 draft MDS 3.0 on a publicly available web-site and invited any interested party to submit written comments. RAND conducted content analysis of these comments. Over 1266 unique comments were received from 144 different groups or individuals. The comments included suggested modifications to the MDS, recommendations to add or delete items and policy questions or statements.

Townhall Meeting

Interested parties were provided an open forum in which they could hear plans for

the evaluation and provide comment on the MDS. The meeting was held at CMS offices in Baltimore, Maryland. Teleconference was also made available. Seventy-seven persons registered attendance and 426 conference call-ins were recorded. All oral comments were transcribed and reviewed by the research team.

Technical Expert Panel

The Commonwealth Fund provided RAND a grant to convene a national panel of nursing home experts. 45 groups nominated over 150 individuals for possible inclusion in this or the validation panel (described below). The research team reviewed the nominees' qualifications and resumes, aiming to identify a panel with a wide range of perspectives and with experience in NH care delivery, management & quality improvement across MDS items. Panel members, listed below, provided valuable input into the MDS.

Panelist	Organization
Sarah Greene Burger, RN	National Citizen's Coalition for NH Reform
Diane Carter, RN, MSN	Amer Assoc Nurse Assessment Coordinators
Anne Deutsch, Ph.D.	Northwestern University
Sandy Fitzler, BSN	American Health Care Association
Irene Fleshner, RN	Senior Clinicians Group
Christa Hojlo, PhD	VA Nursing Home Service
Ruta Kadonoff, MHS	Amer Assoc Homes & Services for the Aging
Sally Kaplan, PhD	Med PAC
Courtney Lyder, ND	University of Virginia, School of Nursing
Cherry Meier, RN	National Hospice and Palliative Care Org
Sue Nonemaker, RN	Hebrew Rehabilitation Center for the Aged
Joe Ouslander, MD	Emory University & Atlanta VHA
Peter Rabins, MD	John Hopkins University
Naomi Salamon, RN	North Shore Univ. Hosp Extended Care & Rehab
Judith Salerno, MD	National Institute on Aging
Eric Tangalos, MD	Mayo Clinic

The Technical Expert Panel (TEP) participated in a two-day meeting to discuss the current function of the MDS, short-range goals for the upcoming revision and long-range goals for future revisions of the MDS. The TEP's short-term goals included prioritizing MDS's function as a clinical tool and enhancing its efficiency to screen for important issues. The TEP identified a long-range goal of moving toward standardized nomenclature and integrated electronic health records. The panel also

reviewed sections of the MDS that generated significant commentary in written feedback and rated the clinical, quality and cost measurement utility of various MDS domains.

Validation Panel

RAND and Harvard convened a second panel, again selecting from the list of 150 nominations for expert panel membership. For the validation panel, the team aimed to identify members who had broad experience with nursing home care, evidence-based nursing home research and scientific review. The panel members are listed below. The panel was provided with a literature synthesis for several key sections of the MDS and available data on reliability for MDS items. In addition, the research team highlighted written feedback and technical expert panel input for the panel. A member of the technical expert panel was also on the validation panel in order to ensure communication of the expert panel feedback.

Panelist	Organization
Dan Berlowitz, MD, MPH	Boston University & Bedford VHA
Barbara Bowers, RN, Ph.D.	University of Wisconsin
Richard Della Penna, MD	Kaiser Permanente Aging Network
Marcy Harris, RN, Ph.D	Mayo Clinic
Ira Katz, MD, Ph.D.	University of Pennsylvania & Philadelphia VHA
Paul Katz, MD	University of Rochester
Rosemary Lubinski, Ed.D.	University at Buffalo
David Mehr, MD, MS	University of Missouri
Vince Mor, Ph.D.	Brown University
Christine Ann Mueller, RN, Ph.D	University of Minnesota
Patricia Parmelee, Ph.D.	Emory University & Atlanta VHA
Margaret Schenkman, PT, Ph.D.	University of Colorado
Neville Strumpf, RN, FAAN, Ph.D.	University of Pennsylvania
Eric Tangalos, MD	Mayo Clinic
Christie Teigland, Ph.D.	NY Assoc. of Homes & Services for Aging
Sheryl Zimmerman, MSW, Ph.D.	University of North Carolina at Chapel Hill

The panel used a modified Delphi process to provide quantitative feedback on the validity and feasibility of 438 proposed MDS items. The panel voted by confidential ballot prior to the meeting, had a two-day face-to-face meeting for discussion and re-voted by confidential ballot. Follow-up calls have also been conducted to address specific topics and

challenges.

Phase 2: Item Revision and Developing Validation Protocols for Key MDS Items—Veterans Health Administration and CMS Collaboration

This phase includes revising the items to incorporate the stakeholder feedback from phase I, further literature review, work with CMS/ASPE contractors on standardized nomenclature, development and pilot testing of validation protocols , and ongoing feedback from stakeholders .

Veterans Health Administration Contributions

Improving the quality of nursing home care is a high priority within the Veterans Health Administration (VHA). The VHA is both a provider and purchaser of nursing home care, operating nursing homes throughout the US and purchasing contract care through community nursing homes. As part of its ongoing efforts to meet the needs of NH residents, the VHA National Nursing Home Care Service has voluntarily implemented the MDS in its system of nursing homes.

Recognizing their common interests in improving the MDS and nursing home care throughout the nation, VHA and CMS signed a memorandum of understanding (MOU) to facilitate coordination of MDS revisions across the two agencies. This MOU allows two large federal agencies to work together in improving the care of nursing home residents.

VHA Health Services Research and Development (VHA HSR&D) recently funded a large research project titled “Pilot Testing and Validation of Changes to the Minimum Data Set for VA Nursing Homes” that aims to contribute to the MDS 3.0 revision. The national VHA nursing home research team is listed below and will coordinate with the RAND/ Harvard team.

Lead Research Team VHACOE, Los Angeles Dr. Debra Saliba, PI

Research Group	Key Personnel	General Area	Specific Topic Area
Bedford VHA & Center for Health Outcomes Quality and Economics Research	Dr. Dan Berlowitz Ms. Elaine Hickey, RN	Medical Conditions & Complications	Diagnostic coding Delirium
Atlanta VHA & VA Geriatric Research Education and Clinical Care	Dr. Joe Ouslander Dr. Pat Parmelee	Geriatric Syndromes	Pain Falls
Philadelphia VHA & MIRECC	Dr. Ira Katz Dr. Katy Ruckdeschel	Mental Health	Depression Behavior Disorders

VHA Greater Los Angeles & Center of Excellence for the Study of Health Care Provider Behavior	Dr. Debra Saliba Dr. Karl Lorenz Dr. Josh Chodosh	Residential Life Quality Mental Status	Customary & routine Quality of life survey Symptoms Goals of Care Mental Status Measures
Harvard Medical School	Dr. Joan Buchanan Dr. Alan Zaslavsky	Evaluation & Analysis	

The VHA HSR&D project will evaluate, within VHA nursing homes, the validity and performance of eight new or revised sections of the Minimum Data Set (MDS). The 8 targeted sections are: diagnostic coding, delirium, pain, falls, depression, behavior disorders, quality of life and palliative care. The project design has 4 primary phases: 1) Refinement of candidate MDS items 2) condition-specific protocol development & pilot testing, 3) protocol integration and pilot testing, and 4) national VA validation & reliability testing. In the first phase, the 4 regional teams have reviewed provider feedback, convened additional work groups as needed, proposed item revisions and identified common pilot elements for regional testing. In phase 2, each of 4 regional research groups will develop, pilot test and refine validation protocols for 2 conditions. In the third phase (which coincides with CMS phase 3), the lead team will integrate the resulting 8 refined condition-specific protocols into a single validation protocol. The four regional research groups will pilot test the resulting integrated protocol for feasibility and clarity. In the fourth phase (which will coincide with CMS phase 4), the integrated protocols will be used to test the validity of the 8 concepts in a national sample of 20 VA NHs.

Phase 3: Integration and Alignment of Pilot Activities This phase includes translation of VHA validation items for community-based protocols, developing instructions for new MDS items and pilot testing integrated protocols and MDS items in VHA and community nursing homes.

After VA validation pilot testing is complete, the VA HSR&D research team will present its pilot work to VA leadership, CMS leadership and NH stakeholder groups. Feedback will be incorporated into the development of an integrated validation protocol and identification of items for national testing. The integrated protocols will be pilot testing in VHA nursing homes.

The RAND research team will finalize validation protocols and MDS items to be tested in a national sample of community nursing homes during phase 3 of MDS revisions. To create the community validation protocols, the RAND/Harvard research team will consider the VA pilot test results, stakeholder feedback, recommendations from CMS standardized nomenclature contractor, and feedback from the CMS –MDS Phase I project. Carelink will work closely with

RAND/Harvard to develop instructions for the new MDS items. The community validation protocols will be pilot tested by the Colorado Foundation for Medical Care.

Impact Analysis

The evaluation will include an assessment of the impact of redesigned MDS items on CMS that are dependent on Version 2.0 of the MDS. Areas being considered include, but are not limited to program integrity, prospective payment, and quality measurement for public reporting.

Phase 4: National Validation and Evaluation of Proposed MDS 3.0

National Validation and Performance Testing

The current plans for the national validation and evaluation of the MDS 3.0 include approximately 70 community nursing homes and 2800 residents, regionally distributed throughout the United States. The sample will aim to include hospital based and free standing facilities and for-profit and not-for-profit facilities in proportions similar to those currently found in the US. The Colorado Foundation for Medical Care will identify quality improvement organizations throughout the US to participate. The QIOs, in turn, will participate in the identification of data collection staff and recruitment of the community NHs that will be involved in the national evaluation.

We plan to capture a representative sample of short and long stay residents and to employ algorithms to ensure that the sample includes admission, quarterly & annual evaluations. Testing and analyses will address inter-rater reliability for facility and research staff, validity of key sections, and time needed to complete the MDS. The field test is planned for Spring and Summer of 2006. The analysis of these data is scheduled for completion in early 2007.

A component of the analysis will look at how revised reliable and valid MDS 3.0 items would potentially impact on quality indicators and RUGs payment items.

Phase 5: Final Revisions to MDS 3.0

Consolidate and Summarize Feedback from National Validation

The research team will maintain a database of questions and responses throughout the data collection period. CFMC will initiate regular contacts and elicit feedback throughout the national evaluation. The research team also will obtain structured feedback from the facility staff who participated in the national validation activity at the conclusion of the national testing. The feedback will be combined with the analytic work above and discussed with CMS leadership, VHA leadership and content experts. This feedback will be used to make final changes to the proposed MDS, the instructions and will be summarized as a section in the final report.

In those instances where the proposed MDS 3.0 item performance is no better than the MDS 2.0 item, we plan to recommend retaining the MDS 2.0 item with

which facilities have pre-existing experience and training. Other recommendations will be discussed before final revisions are made.

Town Hall Meeting

A revised MDS and instructions will be made publicly available. A Town Hall meeting will be scheduled by CMS to provide information about the revision and to obtain feedback from stakeholders.

V. Resident Assessment Protocol Recommendations

CMS received excellent suggestions from the Ad Hoc Resident Assessment Protocol (RAP) Workgroup regarding RAPs and have participated in an Agency for Healthcare Research and Quality Care Planning Technical Expert Panel. Further revisions to RAPs are envisioned after identification of final MDS 3.0 items and instructions.