



U.S. Department of Health and Human Services
Assistant Secretary for Planning and Evaluation
Office of Disability, Aging and Long-Term Care Policy



OPPORTUNITIES FOR ENGAGING LONG-TERM AND POST-ACUTE CARE PROVIDERS IN HEALTH INFORMATION EXCHANGE ACTIVITIES:

EXCHANGING INTEROPERABLE PATIENT ASSESSMENT INFORMATION

APPENDIX B: BACKGROUND REPORT ON INTELLECTUAL PROPERTY ISSUES AND THE DISSEMINATION OF STANDARDIZED FEDERALLY-REQUIRED PATIENT ASSESSMENTS

December 2011

TABLE OF CONTENTS

EXECUTIVE OVERVIEW	B-3
INTRODUCTION AND BACKGROUND	B-8
Federal Efforts at Defining Interoperability Standards.....	B-8
Post-Acute Care Assessment and Interoperability.....	B-9
Prospective Payment Systems for Post-Acute Care.....	B-11
Intellectual Property Issues and Mandated Assessment Instruments.....	B-12
Intellectual Property Issues and Government Contracts and Grants.....	B-14
RESIDENT ASSESSMENT INSTRUMENT/MINIMUM DATA SET	B-18
Regulatory Background.....	B-18
Creation and Development of the Minimum Data Set.....	B-19
Intellectual Property Issues.....	B-22
OUTCOME AND ASSESSMENT INFORMATION SET	B-29
Regulatory Background.....	B-29
Creation and Development of OASIS.....	B-30
Intellectual Property Issues.....	B-31
INPATIENT REHABILITATION FACILITY - PATIENT ASSESSMENT INSTRUMENT	B-33
Regulatory Background.....	B-33
Creation and Development of the IRF-PAI.....	B-35
Intellectual Property Issues.....	B-38
FOLLOW UP AND ADDITIONAL RESEARCH	B-49
ACRONYM LIST	B-51
COPYRIGHTS AND TRADEMARKS	B-54
MDS/RAI.....	B-54
OASIS.....	B-54
IRF-PAI.....	B-55
WeeFIM® II Software.....	B-56
MDS STAKEHOLDER LETTERS	B-57
REFERENCES	B-62
ENDNOTES	B-73

The research described in this report was conducted by library staff of the Foundation of the American Health Information Management Association for the Office of the Assistant Secretary for Planning and Evaluation (ASPE) of the U.S. Department of Health and Human Services (HHS), under contract no. HHSP2332007430EC.

The content of this publication does not necessarily reflect the views or policies of ASPE or HHS.

EXECUTIVE OVERVIEW

In 2007, the Office of the Assistant Secretary for Planning and Evaluation (ASPE) of the U.S. Department of Health and Human Services (HHS) contracted with the AHIMA Foundation to perform several activities related to standardizing federally-required post-acute care (PAC) assessments to support interoperable health information exchange. A primary goal of the project was the application of health information technology (HIT) standards adopted by the Consolidated Health Informatics (CHI) Initiative to two of the assessment tools currently mandated by the Centers for Medicare and Medicaid Services (CMS) for reimbursing PAC. These instruments are:

1. the Resident Assessment Instrument (RAI), including the Minimum Data Set (MDS), used in nursing facilities, and
2. the Outcome and ASsessment Information Set (OASIS), used by home health agencies (HHAs).

These two instruments, along with the Inpatient Rehabilitation Facility Patient Assessment Instrument (IRF-PAI), used by CMS for payment in inpatient rehabilitation facilities (IRFs), are standard data collection tools for particular care settings, designed to collect and submit information to CMS according to the agency's electronic submission requirements. The data collected, however, are not comparable across settings, are not standardized using interoperable vocabularies in support of health information exchange, require different and sometimes proprietary formats for reporting based on care setting, and frequently do not interface with a patient's electronic health record (EHR).

The CHI Initiative, which was transferred to the Federal Health Architecture (FHA) within the Office of the National Coordinator for Health Information Technology (ONC) in 2006, was an effort to establish messaging and vocabulary standards allowing federal agencies to exchange information efficiently and effectively in order to provide better care and lower administrative costs. CHI standards were considered for use through the public/private processes of the Healthcare Information Technology Standards Panel (HITSP), convened by the American National Standards Institute (ANSI) in 2005 under contract to HHS to administer ONC's standards harmonization initiative.

In 2006, the CHI recommended for adoption, across the federal health enterprise, HIT standards defining requirements for exchanging and reusing standardized, federally-required patient/client assessments for functioning and disability. These recommended standards were subsequently approved by the National Committee on Vital and Health Statistics (NCVHS) and the Secretary of the HHS, and forwarded to ONC. The adoption of the CHI-endorsed standards for disability and patient assessment (along with ones for allergy and multi-media) in federal HIT systems was announced in a *Federal Register* notice published in late 2007.^a

^a 72 *Federal Register* 71413-14 (December 17, 2007).

The purpose of the specific project task addressed in this report was to explore the intellectual property (IP) issues associated with the three assessment tools mandated by CMS for PAC reimbursement, investigate the implications of disseminating CHI-standardized MDS, OASIS and IRF-PAI assessment data sets, and develop recommendations for the future dissemination of HIT-encoded instruments.

IP issues with respect to these three assessment instruments vary as to the degree of restriction placed on the use of the data sets and tools within them. All three data sets were initially created with the aid of grant or contract money from the U.S. government. The developers of these data sets claim, or have in the past claimed, some ownership in the assessment instruments. Although work created under grant from or contract with the U.S. government can be copyrighted by the award recipient, government agencies generally reserve the right to use the work for government business, and to authorize others to do so.^b

The RAI/MDS is in the public domain, but only in the United States. Version 2.0 of the RAI/MDS, currently in use, was developed by the Hebrew Rehabilitation Center for Aged (HRCA) under a contract with the Health Care Financing Administration (HCFA), predecessor to the CMS. Lead authors on the 1995 edition of the User's Manual for the RAI version 2.0 were from HRCA and HCFA.^c The 2002 update to the User's Manual for 2.0 appears to have originated within CMS. A number of individuals are acknowledged, many of whom appear to have been members of the MDS Coordinating Team within CMS.^d Outside of the United States, the interRAI Association, a group of researchers in the field of long-term health care, claim the copyrights to version 2.0 of the RAI/MDS. InterRAI registered the copyright to the 1995 edition of the user manual for version 2.0, although they allow it to be used and copied freely within the United States. Version 3.0 of the MDS, currently scheduled for implementation in October 2010, represents a major revision to the assessment tool. This version appears to have originated within CMS, with considerable input from outside experts in long-term care (LTC) issues. The tool was evaluated and validated through a contract with the RAND Corporation, with principal investigators from RAND and the Harvard Medical School Department of Health Care Policy. The final version of the MDS 3.0 item set and data specifications were published by CMS in October 2009. Parts of the RAI manual for version 3.0 were published in November 2009 with the complete manual expected to be available in early 2010.^e While CMS has reported there will be no restrictions on the use of the MDS 3.0 and accompanying tools for the purpose of reporting to assessment data to CMS, it is unclear whether other IP issues might arise. Two screening tools that

^b CENDI Copyright Task Group. (2002, updated 2007). Frequently Asked Questions About Copyright: Issues Affecting the U.S. Government. Oak Ridge, TN: CENDI Secretariat, Information International Associates, Inc. Retrieved from <http://www.cendi.gov/publications/04-8copyright.html#40>.

^c Morris, John N., Katharine Murphy, and Sue Nonemaker. *Long Term Care Facility Resident Assessment Instrument (RAI) User's Manual*. (HCFA, October 1995).

^d U.S. Centers for Medicare & Medicaid Services. *Revised Long-Term Care Facility Resident Assessment Instrument User's Manual: Version 2.0*. (December 2002; revised March 2007).

^e Retrieved from http://www.cms.hhs.gov/Nursinghomequalityinits/25_NHQIMDS30.asp.

are integrated into MDS 3.0 are copyrighted. The Regenstrief Institute has received permission from the copyright holder of the Confusion Assessment Method (CAM) tool to incorporate that tool into the Logical Observation Identifiers Names and Codes (LOINC) database, and has previously worked with Pfizer in order to incorporate the Patient Health Questionnaire (PHQ) depression scales into LOINC.^f

Early versions of the OASIS (OASIS A, B, B-1) were developed by the Center for Health Services and Policy Research at the University of Colorado with funding from HCFA, the Robert Wood Johnson Foundation, and later the New York State Department of Health. Prior to 2008, rights to the OASIS instrument were retained by the Center for Health Services and Policy Research. As of late 2007, the OASIS data set had moved into the public domain, and permission to copy or use was no longer required. CMS contracted with Abt Associates and subcontractors at the University of Colorado Health Sciences Center and Case Western Reserve University in 2006 to revise the OASIS data set, resulting in OASIS-C, which HHAs began using in January 2010.^g While it appears there are no longer any IP issues attached to the OASIS data set itself, some of the tools available, but not required, for use with OASIS-C are copyrighted, in particular the Pfizer PHQ depression scales.^h As mentioned in relation to the MDS, Regenstrief Institute has worked with Pfizer in the past to secure permission to use the PHQ screening tools in LOINC.

MDS and OASIS data sets currently in use are available through the Unified Medical Language System (UMLS) of the National Library of Medicine (NLM) and Regenstrief Institute's LOINC database. There are slight differences in the license agreements for using these two instruments through the UMLS, primarily related to the additional restrictions placed on the use of the RAI/MDS outside of the United States. The copyright claims to the MDS and OASIS data sets as represented in LOINC are spelled out in the RELMA (Regenstrief LOINC mapping assistant). The versions of MDS and OASIS in the UMLS Metathesaurus are extracted from LOINC and not necessarily an exact representation of the original source. Since MDS and OASIS are updated in each Metathesaurus release along with LOINC, it is expected that MDS 3.0 and OASIS-C will be available when the version of LOINC containing the new versions of OASIS and MDS is available.ⁱ

The IRF-PAI was developed and validated through a combination of government grants, contracts, and license agreements with the University of Buffalo Foundation Activities, Inc. (UBFA) and the RAND Corporation. HCFA contracted with RAND to

^f Personal correspondence between Regenstrief and ASPE.

^g CMS. Supporting Statement for Paperwork Reduction Act Submission -- Part A -- revised Form #CMS-R-245 (OMB #0938-0760) -- OASIS C (3/4/2009).

^h Retrieved from

<http://www.cms.hhs.gov/HomeHealthQualityInits/Downloads/HHQIResponsesToPublicComments.pdf>.

ⁱ Retrieved from http://www.nlm.nih.gov/research/umls/sourcereleasedocs/2009AA/LNC_OASIS/ and http://www.nlm.nih.gov/research/umls/sourcereleasedocs/2009AA/LNC_MDS/.

evaluate the feasibility of using the Functional Independence Measure (FIM^j) as the foundation piece for the prospective payment system (PPS) for IRFs. UDSMR[®], a division of UBFA, claims exclusive ownership of the Functional Independence Measure (FIM), the core of the IRF-PAI, trademark rights to FIM[®], and compilation rights to the IRF-PAI training manual.^k Due to UDSMR[®] ownership claims, anyone other than a facility subject to the Medicare payment system who wishes to use the IRF-PAI can only do so through a license agreement with UDSMR[®]. The FIM has not been incorporated into either the UMLS or LOINC.

Both interRAI and UDSMR[®] have created assessment instruments for additional PAC settings, and are clearly aware of government mandates to utilize instruments that can work across multiple settings. Also, the recent revision of the OASIS data set was undertaken in part so that the data collected are more in alignment with the assessment data collected in other PAC settings. Given additional mandates arising out of the CHI Initiative, particularly the one requiring future federal health information acquisitions be based on CHI standards, instrument developers may be interested in participating in HIT standardization activities in order to remain relevant as the movement toward interoperability and standardization continues to gather steam.

References

CENDI Copyright Task Group. (2002). *Frequently Asked Questions About Copyright: Issues Affecting the U.S. Government*. Oak Ridge, TN: CENDI Secretariat, Information International Associates, Inc. Retrieved from <http://www.cendi.gov/publications/04-8copyright.html#41>.

CHI (2006). Standards Adoption Recommendation -- Functioning and Disability. Accessed January 2008 at <http://www.ncvhs.hhs.gov/061011p2b.pdf>.

HHS. "Additional Consolidated Health Information (CHI) Health Information Technology Standards" 72 *Federal Register* 71413-14 (December 17, 2007). Accessed January 2008 at <http://a257.g.akamaitech.net/7/257/2422/01jan20071800/edocket.access.gpo.gov/2007/07-6058.htm>.

^j The author is aware of the trademark status of FIM and understands that, according to UBFA guidelines (<http://www.udsmr.org/Documents/Trademark-service%20mark.pdf>), FIM should only be used as an adjective. For the purpose of this report, when FIM is used as a noun, it is used as an abbreviation for the Functional Independence Measure, similar to Graham et al. [including Carl Granger of UDSMR[®]] (2008), p.861. <http://biomed.gerontologyjournals.org/cgi/reprint/63/8/860>. When used as an adjective, its registered trademark status will be indicated.

^k UDSMR[®] and FIM[®] are trademarks of Uniform Data System for Medical Rehabilitation, a division of UB Foundation Activities, Inc. (<http://www.udsmr.org/Documents/Trademark-service%20mark.pdf>).

Kramer, Andrew, et al. *Case Studies of Electronic Health Records in Post-Acute and Long-Term Care*. (Washington, DC: HHS, ASPE, Office of Disability, Aging and Long-Term Care Policy, 2004. Accessed January 2008 at <http://aspe.hhs.gov/daltcp/reports/ehrpaltc.htm>.

Wark, Cynthia G., et al. "Government Issue: CHI Lays the Groundwork for Federal Data Exchange." *Journal of AHIMA* 75, No.8 (September 2004): 36-38. PubMed link <http://www.ncbi.nlm.nih.gov/pubmed/15455567>.

INTRODUCTION AND BACKGROUND

Federal Efforts at Defining Interoperability Standards

The CHI Initiative was a federal effort with a goal of establishing messaging and vocabulary standards to allow federal agencies to exchange health information efficiently and effectively in order to provide better care and lower administrative costs.¹ In 2006, the CHI Initiative was transferred to the FHA within the ONC, now an agency of the HHS. The FHA worked closely with the Health IT Policy Council (HITPC), which brought together entities within HHS and other federal agencies to advance short and long-term HIT policy.

In 2006, the CHI recommended for adoption, across the federal health enterprise, HIT standards defining requirements for exchanging and reusing standardized federally-required patient/client assessments for functioning and disability. The HIT standards approved were then presented to and approved by the NCVHS, and were subsequently approved by the Secretary of HHS, who forwarded them to the ONC.²

In late 2007, the adoption of the Disability and Assessments standards were one of three new domain areas and associated clinical standards announced in the *Federal Register*.

Disability and Assessments:

- Regenstrief Institute, Inc LOINC[®] (Logical Observation Identifiers Names and Codes)¹ representation and codes for questions and answers on federally-required assessment forms;
- CHI-endorsed semantic vocabulary matches linked with the LOINC[®] assessment questions and answers; and
- HL7[®] [Health Level Seven] v2.4 and higher messaging standard and the HL7[®] CDA (Clinical Document Architecture (CDA))^m for exchanging standardized federally-required assessment content.³

In conjunction with other federal initiatives, the HITSP, convened by the American National Standards Institute (ANSI) in 2005 under contract to HHS, led efforts to identify and harmonize HIT standards, including those endorsed by the CHI Initiative. Despite the change in presidential administration in 2009, HITSP remained under contract to ONC through January 2010 and continued to play a role in addressing interoperability standards in alignment with the goals of the American Recovery and Reinvestment Act (ARRA) of 2009. ARRA established two new oversight bodies within the ONC, the HIT

¹ “A public use set of codes and names designed to facilitate in particular the electronic transmission and storing of clinical laboratory results.” <http://www.openclinical.org/medTermLoinc.html>.

^m “the HL7 Standards -- are essentially freely available and can be used for free. As such, there are no usage licenses required or license fees payable when using the HL7 Standards to implement interfaces.” <http://www.hl7.com.au/FAW.htm#Licensing>.

Policy Committee and the HIT Standards Committee. These committees report to the National Coordinator and are tasked with helping develop HIT data standards and implementation specifications, and with recommending the “meaningful use” criteria for EHR systems to be subsidized by CMS through incentive payments under ARRA.

Post-Acute Care Assessment and Interoperability

Currently, there are three federally-mandated assessment tools used by the CMS for the purpose of compensating and assessing PAC⁴ -- the RAI, including the MDS, used in nursing facilities and swing-bed settings, the IRF-PAI, used in IRFs, and the OASIS, used by HHAs. Each of these instruments is a data collection tool designed to collect information in a format specified by CMS that can be submitted according to CMS’s electronic submission requirements. However, the assessment instruments require information that is not comparable across settings, require different and sometimes proprietary formats for reporting based on care setting, do not use standardized, interoperable HIT vocabularies, do not support standardized health information exchange (e.g., using HL7 messaging standards), and frequently are incapable of interfacing with an individual patient’s EHR.⁵

A 2004 report studying EHRs in LTPAC settings outlined some of the issues that make the collection and subsequent use of this data burdensome:

A final limitation to interoperability that also could be improved by standards development is the integration between the EHR maintained in the various LTPAC sites and the government-mandated data sets: MDS, OASIS, and IRF-PAI. In every case, the information systems for the mandated data set were completely distinct from the EHR. None of the sites was able to import information from the comprehensive clinical assessments contained in the EHR and populate mandated data sets. In most cases, the process for completing the mandated data sets was separate from the process used to maintain the EHR. Thus, the lack of integration between mandated assessments and the clinical information recorded in the EHR was a major impediment to integrated care delivery. Further, the EHR was dominated by orders and assessments written by the physician and/or nurse practitioner, and by nursing and therapy reports of medical care issues such as medications, vital signs, and treatments. However, linkage of mandated data sets and the EHR requires standardized content and messaging not only for the EHR, but also for the federally mandated data sets.⁶

A 2006 report on the viability of a uniform PAC assessment system, prepared for CMS and the Iowa Foundation for Medical Care, explained that the “domains, actual items, item definitions, scoring methods, and metrics differ across tools.” Differences in the tools are partially due to the outcomes of care emphasized in a particular setting, so that “even when the domains of health and function are consistent across tools, many of the items used to measure them differ.” This study further found that “None of the three existing CMS assessment tools for PAC (MDS, OASIS, IRF-PAI) adequately covers the spectrum of patients and the necessary domains to be used across settings, and mapping across instruments is complex.”⁷

A 2008 study attempting to map between the MDS and IRF-PAI, confirmed the difficulty of evaluating and tracking changes in functional status from one setting to another due to the lack of a single comprehensive assessment instrument for measuring patient outcomes, but noted that attempts to change or replace measures currently in place would face strong resistance from practitioners and administrators who use and rely on these instruments on a daily basis.⁸

In 2009, CMS published in the *Federal Register* ([74FR10050 (March 9)] and [74FR22208 (May 12)]) plans for using revised versions of the OASIS and MDS data sets starting in 2010.⁹ In outlining plans for using a revised OASIS data set for HHAs, CMS stated:

In accordance with long-standing federal objectives, CMS ultimately plans to create a standard patient assessment instrument that can be used across all post-acute care settings. The revision of the OASIS instrument is an opportunity to consider various components of quality care and how patients might be better served as they (and information about them and their care) move among health care settings.¹⁰

In January 2009, anticipating the imminent move to a substantially revised version of MDS, the American Association of Homes and Services for the Aging, in a joint letter with other stakeholders, sent a letter to President-elect Obama's transition team urging them not to go forward with a proprietary format for reporting MDS 3.0 data.¹¹

In response to the *Federal Register* notices concerning OASIS and the MDS, a number of organizations reiterated concerns about the continued use of proprietary software for submitting data to CMS.

The National Association for Homecare and Hospice addressed the interoperability issues in comments co-signed by a number of other stakeholder parties:

The implementation of an updated OASIS data set is a unique opportunity to advance interoperability and make a significant impact on home care agencies/EHR products which is the direction healthcare is heading with a goal of widespread, interoperable electronic health records by 2014. The accepted standards exist, but CMS currently does not plan to adopt them for OASIS-C. Instead, CMS plans to continue to collect OASIS-C data using proprietary data exchange formats that are not interoperable -- this is inconsistent with the national agenda to advance EHRs and is short sighted in recognizing the opportunity with the OASIS-C rollout.¹²

AHIMA, in comments to CMS on proposed changes to the Skilled Nursing Facilities Inpatient Prospective Payment Systems published in the May 12, 2009 *Federal Register* [74FR22208], again addressed concerns about the continued use of proprietary resources for reporting data to CMS:

The proposed rule currently calls for custom transmission of MDS versus the use of HHS accepted standards. By requiring custom transmission of MDS, vendors and providers will be forced to slow their participation in national health information exchange initiatives by diverting resources and focus and develop programs for CMS compliance first, then focusing their efforts on health information exchange.¹³

CMS published the final rules for the skilled nursing facilities (SNFs) PPS [74FR40287, August 11, 2009] and HHAs PPS [74FR58077, November 10, 2009] and confirmed the 2010 implementation dates for MDS 3.0 and OASIS-C. In the final rule for the SNF PPS, CMS responded to stakeholder concerns by saying “CMS appreciates the comments that were submitted with regard to HIT standards and will consider these comments as the MDS 3.0 is implemented.”¹⁴

As CMS continues to improve upon PAC assessment instruments, it is clear that more work needs to be done in standardizing the data and data exchange formats to support continuity of care and interoperability of patient information maintained by the various care facilities.

Prospective Payment Systems for Post-Acute Care

Implementation of a PPS in inpatient acute care facilities in 1983, while exempting most PAC settings,ⁿ contributed to the spiraling costs of PAC, as patients were sometimes moved from one facility to another based on reimbursement policies rather than where they might receive the best care. Because of the PPS, there was impetus to move patients out of acute care facilities at a quicker rate. The growth in federally-funded post-acute health care expenditures led to the Balanced Budget Amendment (BBA) of 1997, which required that PPS be created for nursing homes, rehabilitation hospitals, home health care, and long-term care hospitals (LTCHs).¹⁵ PPS for these PAC settings, three of which are based on setting-specific assessment instruments, were implemented between 1998 and 2002.

Significant legislative activity since the BBA has included the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act (BBRA) of 1999,¹⁶ the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act (BIPA) of 2000,¹⁷ and the Deficit Reduction Act (DRA) of 2005.¹⁸ Both BIPA and the DRA contained requirements that HHS develop instruments to assess PAC that would be compatible across settings. BIPA required the Secretary of HHS to report to Congress on the "development of instruments to assess the health and functional status of beneficiaries using post-acute care and other specified services.... The assessment instruments required by BIPA are to have readily comparable, statistically compatible, common data elements and include only those elements necessary to meet program objectives."¹⁹

ⁿ These providers continued to be paid based on amendments to the Social Security Act by the Tax Equity and Fiscal Responsibility Act (TEFRA) of 1982, and were referred to as TEFRA facilities.

The BIPA legislation also specified that the standardized instruments developed were to supersede currently-mandated assessment tools:

SEC. 545. DEVELOPMENT OF PATIENT ASSESSMENT INSTRUMENTS.

(a) DEVELOPMENT.--

(1) IN GENERAL.--Not later than January 1, 2005, the Secretary of Health and Human Services shall submit to the Committee on Ways and Means and the Committee on Commerce of the House of Representatives and the Committee on Finance of the Senate a report on the development of standard instruments for the assessment of the health and functional status of patients, for whom items and services described in subsection (b) are furnished, and include in the report a recommendation on the use of such standard instruments for payment purposes.

(2) DESIGN FOR COMPARISON OF COMMON ELEMENTS.--The Secretary shall design such standard instruments in a manner such that--

- (A) elements that are common to the items and services described in subsection (b) may be readily comparable and are statistically compatible;
- (B) only elements necessary to meet program objectives are collected; and
- (C) the standard instruments supersede any other assessment instrument used before that date.

(3) CONSULTATION.--In developing an assessment instrument under paragraph (1), the Secretary shall consult with the Medicare Payment Advisory Commission, the Agency for Healthcare Research and Quality, and qualified organizations representing providers of services and suppliers under Title XVIII.²⁰

The DRA (Section 5008) charged HHS with developing a single comprehensive assessment to be used upon discharge from inpatient hospitals and in all post-acute sites. A demonstration program was to explore uniform patient assessment and develop payment groups based on severity of illness and resource utilization across post-acute settings.²¹ The Office of Management and Budget (OMB) clearance package supporting the development of the instrument mandated by DRA 2005 claimed: "The lack of a uniform post-acute assessment tool is one of the major limitations to understanding variation in post-acute outcomes, cost-effectiveness, and Medicare payments."²²

Despite regulatory activity, the three currently mandated assessment tools are not likely to be replaced in the very near term due to the fact that each instrument presently supports setting-specific payment methods, and they are considered by representatives of the individual care settings to be best at supporting clinical care decisions, resource-based reimbursement, and quality improvement initiatives.

Intellectual Property Issues and Mandated Assessment Instruments

The primary intent of this report is to review known IP issues that may affect the ability to use assessment instrument content in an increasingly interoperable

environment. Developers or contributors to portions or all of the three PAC assessment instruments under review, the MDS RAI, the OASIS, and the IRF-PAI, claim or have in the past claimed ownership to all or parts of these instruments. Typically, the developers copyrighted the instrument to maintain the quality and integrity of the instrument and the data derived there from, although as these instruments have become integral to reimbursement mechanisms, financial interests may also have played a role. Though likely not with outright intent, instrument developers have employed a two-pronged strategy in encouraging acceptance and then reliance on the instrument, first to promote the use of the instrument as being the most appropriate for the required use, and then to protect the instrument from unauthorized use, either for financial or quality control issues. This continues to hold true with the developers of the MDS/RAI 2.0 and the IRF-PAI.

Although there has been some momentum towards a single comprehensive assessment tool,²³ it is unlikely one will be developed, approved, and implemented in the near term that will completely replace all of the content in the existing instruments. Therefore the need exists to apply HIT standards to the setting-specific assessment data sets currently mandated by CMS. Since third party claims of ownership to all or part of these assessment instruments will likely persist, questions have arisen about the ability and inclination of standards development organizations (SDOs) to link HIT codes to assessment content without first settling the ownership issues and reconciling the IP issues. There are further questions, if HIT codes are linked to legitimately-copyrighted assessment content, as to whether and under what conditions or restrictions the coded assessment content can be disseminated.

It is not clear to what extent simply associating HIT codes with assessment content would constitute an infringing activity under the copyright laws. The copyright owners may argue that the creation of this association in and of itself is a derivative work, which only the copyright owner would have the right to create. In addition, dissemination of HIT coded assessments by a standard setting entity may infringe upon the copyright of an assessment instrument that a third party claims to own, because it could violate the copyright owner's exclusive right to reproduce, distribute and prepare derivative works based on the assessment instrument.

It also is not clear that claims to exclusive rights to some of the content of these instruments, or the instruments themselves, are always entirely legitimate, as IP issues are frequently complex. However, if non-government ownership of assessment instrument content is established, before undertaking the process of linking HIT codes to assessment content, standard setting entities may need to negotiate agreements and/or licenses with the owners of the assessments to lawfully distribute the HIT codes. Some of these issues have been addressed previously by the NLM in relation to the UMLS. A post on the Integrating the Healthcare Enterprise (IHE) collaborative web site (wiki) asserted that "UMLS is aware of the IP issues and challenges in general, and is exploring ways to address them."²⁴

It is evident that the creators or developers of all or parts of the MDS/RAI and the IRF-PAI are cognizant of the goal of having an assessment instrument that works across care settings, as both are developing additional, but compatible assessment instruments for use in settings other than that for which their assessment instrument is currently mandated. Carl Granger, representing UDSMR in comments to CMS regarding the adoption of the Continuity Assessment Record and Evaluation (CARE) tool [72FR55225, September 28, 2007], suggests CMS should consider that “using the AlphaFIM[®] instrument in acute care settings, the FIM[™] instrument in SNF, IRF, and LTCH settings, and the OmegaFIM[™] instrument (augmented with the LIFEwareSM System) in HHAs would be a more appropriate choice.”²⁵ Brant Fries, president of interRAI, in testimony before the National Commission for Quality in Long-Term Care, promoted the use of the assessment system created by interRAI, covering most of the LTC settings, including “frail elderly in the community, home care, assisted living, nursing homes, post-acute care, (for example, rehabilitation hospitals), palliative care, acute care, and inpatient and community-based mental health; with additional systems underway for intellectual disability and younger persons with disabilities.”²⁶

Intellectual Property Issues and Government Contracts and Grants

Rules concerning rights to works created under government grants or contracts are not black-and-white.²⁷ Competing rights of the contracting agency and the grant or contract recipient need to be weighed. Generally, for work created under contract to or grant by the U.S. government, the award recipient may copyright any work subject to copyright, but the U.S. government reserves the right to use the work for government business, and to authorize others to do so. If the grant or contract recipient is to retain exclusive IP rights, that is most appropriately spelled out in the terms of the contract or grant.²⁸ This does not appear to be the case, at least in the initial stages of development, of the instruments under review in this report. Copyright claimants to all or portions of the MDS/RAI and the IRF-PAI have asserted that their work is copyrightable. They emphasize the award recipient's rights but minimize the broad rights given to the Federal Government.²⁹ Since the Functional Independence Measure was developed as the result of a grant from the U.S. Department of Education, contractors for the IRF-PAI base their copyrights on OMB Circular no. A-110, which allows non-profit organizations that are recipients of grants or cooperative agreements, to copyright content created under the grant or agreement.

The text from OMB Circular no. A-110 reads:

36. Intangible property.

(a) The recipient may copyright any work that is subject to copyright and was developed, or for which ownership was purchased, under an award. The federal awarding agency(ies) reserve a royalty-free, nonexclusive and irrevocable right to reproduce, publish, or otherwise use the work for federal purposes, and to authorize others to do so.

(b) Recipients are subject to applicable regulations governing patents and inventions, including government-wide regulations issued by the Department of Commerce at 37 CFR part 401, "Rights to Inventions Made by Nonprofit Organizations and Small Business Firms Under Government Grants, Contracts and Cooperative Agreements."

(c) The Federal Government has the right to:

- (1) obtain, reproduce, publish or otherwise use the data first produced under an award; and
- (2) authorize others to receive, reproduce, publish, or otherwise use such data for federal purposes.³⁰

IP rights to works created under contract with federal government agencies are guided by the data rights sections of the Federal Acquisition Regulations (FARs).³¹ Under the *rights in general provisions*, unless provided otherwise in the contract, the government has unlimited rights to all data first produced under contract with civilian agencies of the Federal Government. Contractors can claim copyright in published articles, symposia proceedings, or the like, based on or containing content produced under the contract, but ordinarily must obtain permission from the contracting officer before asserting further rights to work produced through the contract. In cases where the contractor asserts rights to works produced under contract, the government customarily includes a contract clause granting the government agency a license to reproduce, prepare derivative works, distribute, perform and display the copyrighted work:

48 CFR §52.227-14 (c) Copyright--

(1) Data first produced in the performance of this contract.

The prior, express written permission of the Contracting Officer is required to establish claim to copyright subsisting in all other data first produced in the performance of this contract. When claim to copyright is made, the Contractor shall affix the applicable copyright notices of 17 U.S.C. 401 or 402 and acknowledgment of government sponsorship (including contract number) to the data when such data are delivered to the government, as well as when the data are published or deposited for registration as a published work in the U.S. Copyright Office. For data other than computer software the Contractor grants to the government, and others acting on its behalf, a paid-up, nonexclusive, irrevocable worldwide license in such copyrighted data to reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, by or on behalf of the government.

(2) Data not first produced in the performance of this contract. The contractor shall not, without prior written permission of the Contracting Officer, incorporate in data delivered under this contract any data not first produced in the performance of this contract and which contains the copyright notice of 17 U.S.C. 401 or 402, unless the contractor identifies such data and grants to the government, or acquires on its behalf, a license of the same scope as set forth in subparagraph (c)(1) of this clause...

The FAR *special works contract clause* gives the government the right to control the release and use of data delivered under contract and in all data first produced under

contract. The government also has the right to limit the release of the data and can circumscribe the right to establish copyright.³² As with the general rights in data clause, under the special works clause the contractor, with permission from the government, can incorporate previously copyrighted works into the data being delivered if the government gets the same scope of rights that it would get otherwise.

Agreements entered into in the past between the federal agencies and the award recipients who created the data sets upon which the assessment instruments are based, indicate that both the agencies and the developers took a narrow view of what appear to be the government's rights to the works created under contract or grant, either by mandating how CMS can use the work, or by placing requirements on how and where ownership claims must be displayed. Although not addressing assessment instruments, one analyst wrote concerning copyrights and federally-funded research:

It also appears that the Federal Government does not protect their [sic] reserved rights, much less diligently exercise them on behalf of the public. *OMB Circular A-110* and its related CFR provisions represent a significant source of latent federal authority that could be used to enhance access to STM [Scientific, Technical and Medical] works.³³

An understanding of the terms of the contracts under which the assessment instruments were developed is vital to determining whether special provisions may have been included in the contracts, statements of work, or other written agreements regarding IP issues. Without access to the language of the contracts, in particular the FAR provisions concerning rights in the data produced through the contracts, it is difficult to determine whether this narrowing of the government's general rights in works created under contract was intentional and written into the contract, approved through written agreement with the contracting officer, or simply asserted beyond the provisions of the contracts.

The push towards interoperable health information systems may give rise to additional IP issues. In December 2007, the Department of HHS informed the public by means of a *Federal Register* notice of the adoption of the CHI Patient Assessment standards (as well as standards for Multimedia and Allergy) and announced that the "Federal Government will require all future federal health information acquisitions to be based on CHI standards..."³⁴ As CMS moves towards implementing new assessment instruments (e.g., the CARE instrument) it does so with the recognition that new assessments will have to be implemented using the HIT requirements for exchanging and reusing standardized federally required patient/client assessments. CMS included a requirement that the instrument comply with CHI standards in its contract to develop the CARE instrument.³⁵ Applying CHI standards to federally required patient assessments will support interoperability of health information if this standardized information can be exchanged and re-used across settings. However, as previously noted, IP claims often constrain the ability to freely disseminate standardized patient assessment content.

The following pages will outline the history and development of the three PAC assessment instruments currently mandated by CMS for reimbursement purposes, and will describe known IP issues. The summaries will address what the instruments are and what they are used for. Regulatory background concerning how and why the instruments were created and mandated for use will be reviewed, as well as how and by whom the instruments came to be created, and how and by whom the instruments have since been developed. Where known, the report will cover how IP issues that have previously arisen have been addressed. Understanding how federally-required patient assessments were developed in the past and the resultant IP claims may provide policy makers and others with information to support the development and standardization of patient assessment instruments for free and widespread use in an increasingly interoperable healthcare environment.

RESIDENT ASSESSMENT INSTRUMENT (RAI)/ MINIMUM DATA SET (MDS)

The RAI, which includes the MDS, is a standardized data collection instrument designed to assess and screen care given to residents in nursing facilities. The RAI is mandated for all residents in Medicare or Medicaid-certified nursing facilities in the United States. The assessment items that make up the core MDS are considered the minimum elements required to provide a comprehensive picture of a resident's functional status.³⁶ The MDS was designed to standardize assessment data nursing homes were collecting already as part of their routine business.³⁷ While the primary use of data collected through the MDS was to direct and improve clinical care, the MDS has also become the basis for setting payment levels and monitoring quality of care, in addition to directing certain state survey and certification activities for nursing homes.³⁸

Full MDS data must be collected on all nursing home residents within fourteen days of admission and either annually thereafter, or when there is a significant change in condition. Data from the MDS are used to trigger specialized Resident Assessment Protocols (RAPs), through which individual care plans for at-risk patients are developed. A subset of MDS data must be collected on a quarterly basis to assess how well the care plan is working. The MDS, RAPs, and utilization guidelines, instructions on when and how to use the RAI, are the three core components of the RAI. In version 3.0 of the RAI, scheduled for implementation in October 2010, the Care Area Assessment (CAA) process replaces the RAPs.

MDS assessments must be encoded and electronically transmitted from the care facility to the CMS contractor in the state government. This data is then forwarded to CMS. In the FY 2010 proposed rule for SNF PPS published May 12, 2009 [74FR222208], CMS proposed that LTC facilities be required to transmit MDS data directly to the national CMS System, instead of to the states. The transmission file of MDS data must meet the data specification standards set by CMS. CMS makes available free software (RAVEN) that Medicare and Medicaid nursing facilities may use to electronically transmit MDS assessments.³⁹

Regulatory Background⁴⁰

The Omnibus Budget Reconciliation Act (OBRA) of 1987 included a sweeping set of regulatory reforms for nursing homes. Even prior to, but particularly when Medicare began reimbursing for post-acute nursing home care and Medicaid began paying for long-term nursing home care, there were complaints about the quality of care. These complaints led to a class action lawsuit filed in the late 1970s against the HCFA to ensure nursing homes met regulatory standards.⁴¹ In 1983, Congress directed HCFA to study how to improve nursing home regulation. HCFA contracted with the Institute of Medicine (IOM) of the National Academy of Sciences to investigate the quality of care in

nursing homes, and to study and recommend changes to existing regulations to ensure quality care. Concurrently, HCFA funded a number of demonstration projects to assess regulatory alternatives for improving the quality of care.⁴²

Prior to OBRA of 1987, the Conditions of Participation for nursing homes were based on the facility's potential to provide care more than the actual quality of care provided.⁴³ One of the major findings in the IOM study published in 1986 was that a uniform comprehensive assessment of each nursing home resident was essential to improving the quality of care. OBRA of 1987 incorporated many of the recommendations in the IOM report, including amending the Social Security Act to require that the Secretary of HHS specify a minimum data set for use in conducting comprehensive assessments and to designate one or more resident assessment instruments based on the minimum data set. Regulations mandating the completion of the RAI for every nursing home resident went into affect on October 1, 1990, although implementation was postponed until the spring of 1991.⁴⁴ A revised RAI/MDS 2.0 was implemented across all nursing homes in 1996, and a significantly revised MDS 3.0 is scheduled to be implemented nationally on October 1, 2010.⁴⁵

In addition to the quality issues addressed by OBRA of 1987, spiraling costs of federally-funded PAC, partially attributable to the implementation of a PPS for acute care in 1983 while exempting PAC facilities, were addressed in the BBA of 1997, which dictated cuts in Medicare spending growth and changes in the way PAC was reimbursed.⁴⁶ The PPS for nursing facilities, using Resource Utilization Groups (RUGs) based on data collected in the MDS, went into affect in July 1998. In some states Medicaid payments also are based on MDS data. Electronic submission of MDS data to a national repository housed at CMS to facilitate payment and quality evaluation was made mandatory in July 1998.⁴⁷

Creation and Development of the Minimum Data Set

Based on recommendations in the 1986 IOM study, in 1988 the HCFA's Health Standards and Quality Bureau contracted with a project team led by the Research Triangle Institute (RTI), with subcontractors from the Social Gerontological Research Center, HRCA (Boston), the Center for Gerontology and Health Care Research, Brown University (Providence, Rhode Island), and the Institute of Gerontology, University of Michigan (Ann Arbor) to develop and evaluate a national assessment instrument and data system for nursing home assessment in the United States.⁴⁸ The Minimum Data Set for Nursing Home Resident Assessment and Care Screening (MDS) and the RAPs, which are triggered by MDS assessment items or combinations of items, were developed through this contract. An expert panel representing a wide variety of clinical disciplines and professional organizations involved in geriatrics served in an advisory role. From 1989 to 1991, these experts participated at every stage of the design and testing of the MDS.⁴⁹

Version 2.0 of the RAI/MDS was developed under a second contract awarded by HCFA in 1994 to the HRCA, a subcontractor on the original contract.⁵⁰ The 1995 training manual for version 2.0 was written by HRCA in conjunction with HCFA. The 2002 and 2007 updates to the manual appear to have been written by CMS (HCFA's successor agency) staff. The interRAI web site states that members of interRAI developed the RAI and the RAPs for the MDS version 2.0, and calls the RAI "The interRAI LTCF".⁵¹ InterRAI refers to the RAPs as Clinical Assessment Protocols (CAPs), "in recognition of their applicability to more populations than nursing home residents alone."⁵² While it is undoubtedly true that those who were major contributors to MDS 2.0 are or were also members of the interRAI, a 2001 letter to the editor of *The Gerontologist* from an employee at HCFA made it clear that in terms of the contract for developing MDS 2.0, there was no direct relationship between HCFA and interRAI.⁵³

The MDS 3.0 revision appears to have originated within the Office of Clinical Standards and Quality at CMS and revised based on comments received from the nursing home industry, professional groups, individual providers and expert panels. To initiate the revision, CMS worked with stakeholders in identifying objectives, chief of which was to improve clinical relevance.⁵⁴ CMS' goal with respect to the revision was to reduce provider burden and improve clinical items such that data collected would be clinically relevant, accurate, and useful. CMS also sought to limit the data submitted to information the Federal Government needed to know, such as issues surrounding payment, quality, and regulatory oversight.⁵⁵ The data collection form was restructured for greater usability, and items that were confusing or unnecessary were deleted. Another goal of MDS 3.0 was improving user satisfaction and increasing the efficiency of collecting data for reporting purposes. Long-term goals include moving toward standardized nomenclature and integration of the assessment into EHRs.⁵⁶

A draft MDS 3.0 was released in April 2003 for public comment. At the same time, CMS awarded a contract to the RAND Corporation to evaluate the revision, including validating new and revised sections of the draft in community populations and facilities. Areas of emphasis in the revision include diagnostic coding, delirium, pain, falls, depression, behavior disorders, quality of life, and palliative care. Key changes include basing assessments, when possible, on resident interview, and also a focus on improving accuracy and efficiency.⁵⁷ The Commonwealth Fund provided RAND with grant money to convene a panel of nursing home experts to provide input.⁵⁸

The evaluation team, in addition to RAND, included the Harvard Medical School Department of Health Care Policy, the Colorado Foundation for Medical Care (a Quality Improvement Organization), Carelink (for developing the Instructions and Guides), the Kleinmann Group, and RSS Consulting Services.⁵⁹ In December 2003, the scope of the project was expanded when CMS signed a Memorandum of Understanding (MOU) with the Veterans Health Administration (VHA) to work together to improve the MDS 3.0. In October 2004, VHA Health Services Research and Development (VHA HSR&D) initiated a large research project to validate changes in MDS 3.0 in VA nursing homes, in order to contribute to the 3.0 revision.⁶⁰

As part of the RAND study, a workgroup was assembled to review the instruction manual developed for MDS 3.0. This workgroup included representatives from the RAI Coordinator Group, the American Association of Nurse Assessment Coordinators, the American Health Care Association, the American Association of Homes & Services for the Aging, and the VHA. The RAND contract for evaluating MDS 3.0 ended March 31, 2008, and the report was released in April 2008.⁶¹

Initially, MDS 3.0 appeared to be on a fast track, with a revision expected to be available by December 2004.⁶² However, a coalition of stakeholder organizations in LTC submitted a letter of concerns, including the need for development of MDS 3.0 to be coordinated with activities promoting HIT and HIT standards.⁶³ In August 2004, HHS's ASPE and CMS co-funded a project through which Apelon Systems, a medical terminology and vocabulary contractor, would attempt to apply HIT standards to a sample of the MDS to demonstrate how standardization would support the use of content and messaging standards and assure that patient data be interoperable and comparable across settings.⁶⁴ As noted above, these HIT content and messaging standards were approved by the Secretary of HHS as accepted CHI standards and announced in a *Federal Register* notice in 2007.⁶⁵ In 2007, the AHIMA Foundation, with subcontractors from Regenstrief (LOINC), Apelon Systems, and Altshuler Associates (HL7), began work on a contract with ASPE to apply content and exchange standards to the full MDS, starting with the MDS 2.0 data set and moving to MDS 3.0 when CMS made clear their intent to implement the revised assessment tool and data set.

Based partially on concerns voiced by a number of stakeholders regarding how data submitted to CMS under the MDS 3.0 would work with electronic records and the limited time available to implement system updates and provide staff training from the time when materials would be ready to the proposed implementation date, CMS extended the original implementation date from October 2009 to October 2010. The American Association of Homes and Services for the Aging wrote a letter to President-elect Obama's transition team encouraging the delay in order to make the MDS 3.0 interoperable, arguing that CMS could achieve interoperability under the MDS by adopting certain standards instead of CMS' proprietary data exchange formats.⁶⁶ Others voiced similar concerns after the proposed rule for implementing MDS 3.0 was published in May 2009.

In the FY 2010 proposed rule for skilled nursing facility (SNF) PPS [74FR222208], CMS acknowledged the concerns about interoperability issues, and announced they would implement MDS 3.0 using the LOINC representation of the MDS 3.0 data set. CMS considered use of the HL7 Clinical Document Architecture (CDA) for exchanging standardized assessment content, but did not feel comfortable with its adoption without further study to gauge the impact of its use on such a large scale process as the submission of MDS data, which numbers approximately 30 million submissions annually. Similarly, CMS studied the use of the Systematized Nomenclature of Medicine-Clinical Terms (SNOMED-CT), but did not feel the semantic matching to MDS data was sufficient for CMS' payment, survey, and quality measurement needs. CMS indicates they have no plans to include the HL7 Clinical Document Architecture (CDA),

messaging standards, or SNOMED-CT in the October 2010 release of MDS 3.0. CMS is considering the use of HL7 messaging standards with the CARE tool, but stated, “We are soliciting comments on the most appropriate clinical standards to use for clinical assessment instruments.”⁶⁷ In the final 2010 SNF PPS rule [74FR40288], the issue of interoperability standards was not addressed.

The final version of the MDS 3.0 item set, data specifications and resident assessment manual, also was delayed to provide time to work on pieces such as the care area assessments, which replace the RAPs, the RAI user’s manual, quality measurements, and CMS’ Five Star Quality Rating System for nursing homes. Portions of *The Long-Term Care Facility Resident Assessment Instrument User’s Manual* for Version 3.0 were released in November 2009 and the complete manual was expected to be available sometime in early 2010. Copyright information contained in the RAI manual indicate it is a public document and may be copied freely. The manual recognizes a number of organizations and stakeholders, LTC experts, contractors, and CMS staff for their contributions to the “development, testing, writing, formatting, and review of the MDS 3.0 RAI Manual, MDS 3.0 Data Item Set, and MDS 3.0 Data Specifications.”⁶⁸ The RUG Version IV (RUG-IV), a new classification system designed for use with MDS 3.0, was developed through the CMS-sponsored STRIVE (**S**taff **T**ime and **R**esource **I**ntensity **V**erification) project carried out by the Iowa Foundation for Medical Care of West Des Moines, Iowa.⁶⁹

The development of MDS 3.0, though separate from, is linked to the development of a new assessment tool, the CARE instrument, and MDS expertise has been shared with the developers of CARE. The principal investigator on the MDS 3.0 project is also an advisor to the CARE demonstration project.⁷⁰ CMS is developing a roadmap to address the future, and a strategic vision for the assessment instruments, including CARE and MDS. Despite the delays, MDS 3.0 is now on schedule for implementation in October 2010, while a report to Congress with the results from the CARE demonstration is required in 2011.⁷¹

Intellectual Property Issues

The copyright notice for RAI/MDS 2.0 on the CMS web site states: “Please note that InterRAI [sic] holds the copyright to Version 2.0 of the RAI for long-term care outside of the US. Therefore, this revised Version 2.0 of the RAI/MDS manual should not be reproduced outside of the United States without permission of InterRAI [sic]. Within the US, Version 2.0 is in the public domain.”⁷²

The RAI/MDS Version 2.0, currently in use, and related training materials were developed by the HRCA under a contract with HCFA. Lead authors on the 1995 edition of the User’s Manual for Version 2.0 were John N. Morris and Katharine Murphy from HRCA and Sue Nonemaker from HCFA.⁷³ The 2002 and 2007 revisions to the User’s Manual for Version 2.0 appear to have originated within CMS. A number of individuals

are acknowledged, many of whom appear to have been members of the MDS Coordinating Team within CMS.⁷⁴

IP issues with respect to the RAI/MDS are complicated because the assessment instrument and data set have always been considered to be in the public domain, but only in the United States. Beyond United States borders, interRAI claims rights to version 2.0 of the RAI and MDS, and use of the RAI/MDS requires a license agreement with interRAI. IP issues are further complicated by the fact that the 1995 edition of the user's manual for version 2.0, written for and with HCFA, has been copyrighted by interRAI with the U.S. Copyright Office, which is unusual for a work considered to be in the public domain.

InterRAI is an international consortium of researchers in the area of LTC systems, formed in 1992, whose aim is to use MDS data to study LTC in individual countries and to enable cross-national comparisons.⁷⁵ Brant Fries, a founding member of interRAI and an investigator for the HCFA contracts, described interRAI in testimony before the National Commission for Quality Long-Term Care in 2005:

Let me say a few words about interRAI, and then about what it has developed. interRAI is a cross-national collaboration of 47 expert clinicians, researchers and policy-makers from 26 nations spanning the globe. We develop assessment systems that can accomplish the tasks I have been describing. As a non-profit corporation that holds the copyrights, interRAI gives its assessment systems for free to any government or caregiving organization around the world.⁷⁶

The interRAI web site indicates that use is granted freely to government agencies worldwide. However, issues concerning use of the MDS outside of the United States, including barriers, were addressed in a 2003 Milbank Memorial Fund report, entitled *Implementing The Resident Assessment Instrument: Case Studies Of Policymaking For Long-Term Care In Eight Countries*. This report made it clear that "free" did not necessarily mean unhindered. Regarding Ontario, Canada, the report indicated there were a variety of factors that made introducing MDS 2.0 a challenge, including the fact that there was not a "pre-existing working relationship with interRAI, the international research group that developed and owns the rights to the MDS." Also, the government had mandated that data be submitted electronically, "but interRAI had not licensed any software vendors to sell MDS software in Canada." About Japan, it was written: "The fact that the MDS items were protected by copyright presented another hurdle to the adoption of an MDS-based instrument. The government would have had to negotiate with interRAI if any changes had been necessary, which the government was unwilling to do." The Japan report goes on to say: "If MDS items had been used in the assessment form, they would have been embedded in the LTCI [long-term care insurance] and integrated with care planning. This might have been possible if interRAI had adopted a more flexible attitude toward the copyright issue, because the government's concern lay in maintaining a free hand in negotiation rather than actually making substantive revisions." In Spain, Spanish translations were completed, software was created to support the data collection needs, and "the software company formalized a contract with interRAI to produce and distribute RAI-NH software commercially." In

Italy, the pharmaceutical company Pfizer obtained an interRAI license for the RAI for home care, and financed its “translation, computerization, and implementation.”⁷⁷

Fairly extensive copyright and licensing information for use of the set of RAI instruments is provided on the interRAI web site.⁷⁸ InterRAI claims copyright to version 2.0 of the RAI/MDS outside of the United States, and a set of additional assessment instruments, presumably both within and outside United States borders. The interRAI web site lists these major clauses as part of their royalty-free license agreements:

- the instrument is not to be changed substantially (excepting individual identifiers and demographics);
- the license is limited to non-commercial use (i.e., the instrument will not be incorporated into products to be sold to others);
- no royalties will be charged;
- the organization will make appropriate efforts to inform others of the copyright status of the instrument;
- interRAI's logo and copyright notice are to appear on the form;
- authors, author institutions, and translators (as appropriate) are to be acknowledged in any document where authors would regularly be indicated (e.g., publication of a training manual);
- publication of any training manual is limited to the period until a commercially-published version is available;
- data from use of the instrument are to be shared with interRAI, subject to existing laws on confidentiality.⁷⁹

Licensing for commercial use generally requires that royalties be paid to interRAI. All of the clauses that apply to royalty-free licenses apply to licenses for commercial use as well, although interRAI indicates they may omit the requirement that data collected using the instrument be shared with interRAI.

InterRAI's policies concerning collaboration and instrument development include willingness in “contract negotiations to acknowledge the participation of individuals or organizations which have played a substantial role in getting the instrument to the point of implementation.”⁸⁰ InterRAI and the Ontario Joint Policy and Planning Committee, a partnership of the Ontario Ministry of Health and Long Term Care and the Ontario Hospital Association, collaborated, beginning in 1996, on a RAI for mental health (RAI-MH). A research team based in Ontario led the effort. Those two organizations share copyright ownership with interRAI for that particular instrument, and use without additional license agreement in Canada is allowed. The copyright notice for that instrument reads: “The RAI-MH is a copyrighted instrument that is owned jointly by the Ontario Ministry of Health, the Ontario Hospital Association, and interRAI.”⁸¹

The other instruments in the suite of data collection tools for assessing across the continuum of care, for example home care, assisted living, palliative care, and acute care, appear to be solely the IP of interRAI, and their use subject to licensing

agreements with interRAI. InterRAI has promoted the complete set of assessment instruments as suitable for assessing all PAC patients.⁸²

Since publication of the Milbank report, Canada, or at least the province of Ontario, appears to have developed a close working relationship with interRAI. A number of assessments from the interRAI suite are used in Canada, and three have been adopted by the Canadian Institute for Health Information (CIHI) as national standards,⁸³ with interRAI retaining ownership rights. On the CIHI web site, interRAI's ownership of MDS 2.0 is prominently displayed. Manuals for RAI MDS 2.0 and RAPs Canadian Version: User's Manual are available electronically for free downloading from the web site for LTC facilities, but must be ordered.⁸⁴ Samples of other copyright notices from English-speaking countries using the RAI are available on the interRAI web sites from the United Kingdom^o, Australia^p, and Hong Kong^q.⁸⁵

IP issues with respect to the MDS are known to the NLM and the Regenstrief Institute, the owner of Clinical LOINC, an HL7-approved coding system for observation identifiers and a CHI-endorsed standard for federally-required assessment forms.⁸⁶ The NLM and Regenstrief have negotiated with, presumably, interRAI, to incorporate MDS 2.0 into LOINC and the UMLS. Contact information for MDS 2.0 in the UMLS does not mention interRAI, but instead names Brant Fries at the Institute of Gerontology of the University of Michigan, who is also president of the interRAI consortium.

The designation for the MDS in the UMLS is LNC_MDS20 -- Minimum Set 2.0, Institute of Gerontology, University of Michigan, 300 North Ingalls, Ann Arbor, Michigan 48109-2007 USA. Use of the MDS 2.0 through the UMLS is subject to category 3 (for non-United States users) and category 4 (for United States users) restrictions, as outlined below:

Category 3:

LICENSEE's right to use material from the source vocabulary is restricted to internal use at the LICENSEE's site(s) for research, product development, and statistical analysis only. Internal use includes use by employees, faculty, and students of a single institution at multiple sites. Notwithstanding the foregoing, use by students is limited to doing research under the direct supervision of faculty. Internal research, product development, and statistical analysis use expressly excludes: use of material from these copyrighted sources in routine patient data creation; incorporation of material from these copyrighted sources in any publicly accessible computer-based information system or public electronic bulletin board including the Internet; publishing or translating or creating derivative works from material from these copyrighted sources; selling, leasing, licensing, or otherwise making available material from these copyrighted works to any unauthorized party; and copying for any purpose except for back up or archival purposes.

^o Refer to http://www.kent.ac.uk/chss/interrai/develop/what_is_interrai.htm.

^p Refer to <http://www.interrai-au.org/authorisation.htm>.

^q Refer to <http://ageing.hku.hk/interrai/index.html>.

LICENSEE may be required to display special copyright, patent and/or trademark notices before displaying content from the vocabulary source. Applicable notices are included in the list of UMLS Metathesaurus Vocabulary sources, that is part of this Agreement.

Category 4:

LICENSEE is prohibited from translating the vocabulary source into another language or from altering the vocabulary source content. 12.4.2. LICENSEE's right to use the vocabulary source is restricted to use in the United States by LICENSEE's employees, contractors, faculty, students, clients, patients, or constituents within electronic systems or devices built, purchased, licensed, or used by LICENSEE for United States governmental purposes or for any health care, public health, research, educational, or statistical use in the United States. Use by students is limited to research or educational activities under the direct supervision of faculty. 12.4.3. LICENSEE has the right to distribute the vocabulary source in the United States, but only in combination with other UMLS Metathesaurus content. Further, LICENSEE's right to distribute is restricted to: 1. Electronic distribution to LICENSEE's direct United States affiliates, or to other United States entities that have signed the UMLS license, in order to facilitate use of the vocabulary for health care, public health, research, educational or statistical purposes in the United States only. 1. LICENSEE must take reasonable precautions to prevent distribution of the vocabulary source to non-US entities. 2. LICENSEE must include in its annual report a list of all United States affiliates or other United States entities to whom it has distributed content from the vocabulary source. 2. Distribution of encoded patient level data sets or knowledge encoded in the vocabulary source by LICENSEE to any United States entity for use in the United States only. 3. Inclusion of encoded records or content from the vocabulary source in: (1) free publicly accessible retrieval systems or (2) fee-based retrieval systems that are accessible within the United States only, provided that these systems do not permit users to copy or extract any significant portion of the vocabulary source. 12.4.4. DEFINITIONS 1. United States is defined as all United States states, territories, and the District of Columbia; any United States government facility or office, whether permanent or temporary, wherever located; and access to a system in any of these locations by United States government employees, designated representatives or contractors, wherever located, for United States government purposes. 2. United States entity is defined as (i) for government entities, an agency or department of the United States government, (ii) for corporations, as a corporation incorporated and operating in the United States and (iii) for other entities as an entity organized under the laws of the United States.⁸⁷

The LOINC database is a public-use set of codes accessible in the United States and internationally. MDS information in LOINC, including supplemental material added to LOINC representations, cannot be reproduced without interRAI permission outside of the United States.

Generic agreement text on the LOINC web site reads:

third party content is either used with permission or under the applicable terms of use. In all such cases, we have included the copyright notice. This third party content is highlighted in the program as follows: When such copyright content appears in the RELMA [Regenstrief LOINC mapping assistant] look-up grid, RELMA will highlight the row containing that content by printing in a different background color and using italics. It will also include a link in the (EXT (C)) column. By clicking on that link, users will get to the copyright notice and to the terms of use for the content of those LOINC-mapped terms. In the case of a LOINC database (e.g., the tab delimited file and the LOINC Access database) we include the copyright notice (up to 250 characters).⁸⁸

RELMA provides the following language concerning the interRAI MDS copyright claim:

As a not for profit corporation under the U.S. Tax Code, interRAI holds the copyright to a number of assessment systems, including the Resident Assessment Instrument (RAI) for long-term care facilities outside of the United States (the RAI is in the public domain within the United States), as well as the assessment systems for Home Care (HC), Assisted Living (AL), Palliative Care.⁸⁹

An IP issue that may have been addressed although, if so, it is not clear how it was resolved, regards the creation of scales based on the MDS. Copyright information on the interRAI web site includes the statement: "The scales, algorithms, and case-mix measures based on these assessment instruments cannot be copyrighted and are thus available to everyone (although the individual items on which they are based are usually copyrighted)."⁹⁰ Presumably, this refers to scales created by interRAI, since LTCQ, Inc. claims ownership rights to the Cognitive Performance Scale (CPS), a well-known scale based on the MDS. It is unclear whether claiming copyright to the MDS-based CPS is in direct conflict with the terms on the interRAI web site. LTCQ, a consulting company formed in 1992 by other participants in the HCFA MDS contracts, has patented or trademarked Data Integrity Audit, Performance Portfolio, RiskRx, and Q-Metrics. In addition to the CPS, LTCQ claims copyrights to the Pain Scale (PS), Pressure Ulcer RAP Items [scale], Pressure Ulcer Risk Model [scale], Depression Rating Scale (DRS), and the Social Engagement Scale, all of which are based on v.2.0 MDS data.⁹¹

A large number of organizations, government agencies, contractors, and industry experts have been involved in the creation and development of the third revision of the MDS item set along with associated pieces such as the data specifications, resident assessment instrument and user manual, care area assessments, and RUGs classification. At this point, there do not appear to be restrictions on the use of any of the parts of the version of the RAI scheduled for implementation in 2010. MDS 3.0 incorporates screening tools for depression (PHQ-9[®]) and delirium (CAM[®]), that are copyrighted, but presumably fall under the *rights in general provisions* of the FARs which states that a Contractor may not, without permission of the Contracting Officer, incorporate any copyrighted material unless the Contractor grants to the Government, or acquires on its behalf, a license to use the material. The CMS indicates copyright permission for the PHQ-9[®] and the CAM extends to any use of the instrument made in

connection with reporting to CMS, as long as the copyright symbol is present.⁹² The CARE tool displays the statement, "Copyright© 1990 *Annals of Internal Medicine*. All rights reserved. Adapted with permission."

Use not associated with reporting to CMS and any replication of the CAM requires this acknowledgement:

Adapted from: Inouye SK, vanDyck CH, Alessi CA, Balkin S, Siegal AP, Horwitz RI. Clarifying confusion: The Confusion Assessment Method. A new method for detection of delirium. *Ann Intern Med*. 1990; 113: 941-948. Confusion Assessment Method: Training Manual and Coding Guide, Copyright 2003, Sharon K. Inouye, M.D., MPH.⁹³

Information concerning the CAM© in the Agency for Healthcare Research and Quality's (AHRQ) National Quality Measures Clearinghouse is contradictory. According to the copyright statement on the NQMC web site, no copyright restrictions apply,⁹⁴ but the measure availability statement states: "Please note that the CAM is copyright protected, therefore you must apply for permission to replicate the CAM within your facility."

While it is not know what restrictions might be placed on the use of these tools by third parties in the future, the Regenstrief Institute has made arrangements with Pfizer in the past to resolve IP issues in relation to incorporation of the PHQ tools into LOINC and has also received permission from the copyright holder of the CAM to include that tool in the worldwide LOINC distribution.⁹⁵

OUTCOME AND ASSESSMENT INFORMATION SET (OASIS)

The OASIS is a data collection instrument designed to measure adult, non-maternity patient outcomes in the home health care setting. The data elements "represent core items of a comprehensive assessment for an adult home care patient; and form the basis for measuring patient outcomes for purposes of outcome-based quality improvement (OBQI)."⁹⁶ While the primary objectives of creating the OASIS were to support both systematic collection of data and quality improvement initiatives to benefit HHAs and their patients, secondary objectives were to meet the needs of payers, regulators, and the government.

OASIS data must be collected on all home health patients at the initial visit and at certain other episodic and periodic time points, including time of discharge.⁹⁷ The complete OASIS assessments must be electronically transmitted within 30 days of assessment completion date to the state health agency (or Medicare contractor) for storage in an electronic database, and are then forwarded to the CMS.

CMS makes available free software (HAVEN) which Medicare and Medicaid HHAs may use to electronically transmit MDS assessments.⁹⁸

CMS expects to continue to collect data using OASIS for the foreseeable future, but indicates that priorities like pay for performance, standardizing assessment and quality measurement, integration of measures of process and systems, and EHRs may impact future use of OASIS.⁹⁹

Regulatory Background¹⁰⁰

Since mid-1999, the CMS and its predecessor agency, the HCFA have required all certified HHAs to systematically use the OASIS to measure functional status and medical conditions of Medicare beneficiaries receiving home health care and to send assessment data to a central repository. The Conditions of Participation for Home Health Agencies were revised in 1999 to reflect the regulation first published in the *Federal Register* (64 FR 3764) that stated each patient must receive from the HHA a "patient-specific, comprehensive assessment that accurately reflects the patient's current health status and includes information that may be used to demonstrate the patient's progress toward achievement of desired outcomes. The comprehensive assessment must identify the patient's continuing need for home care and meet the patient's medical, nursing, rehabilitative, social, and discharge planning needs." (CFR 42 §484.55). The Conditions of Participation also require that the comprehensive assessment "incorporate the use of the current version of the OASIS items, using the language and groupings of the OASIS items, as specified by the Secretary." (CFR 42 §484.55).

A second rule, published concurrently with the initial regulations requiring the use of OASIS, provided guidelines for the electronic transmission of the OASIS data set, set out the responsibilities of the state agency or HCFA Medicare contractor in collecting and transmitting the information to HCFA, and set forth rules concerning the privacy of patient identifiable data generated by OASIS, all of which were required in order to create a PPS for HHAs.

Since October 2000, OASIS data has served as the basis for the PPS for reimbursing home health services. Since 2003, data collected through the OASIS instrument have been used by CMS to support home health care quality initiatives. OASIS data are also used by CMS to assess compliance with the Pay for Reporting requirements of the DRA of 2005. CMS views the use of the same data to support both quality monitoring and payment as their way of ensuring HHAs are not maximizing reimbursement at the expense of quality outcomes. In March 2009, CMS published a request for comments in the *Federal Register* regarding the use of a revised OASIS, and in July 2009 received the OMB approval to use OASIS-C. In August 2009 CMS published the final rule which established January 1, 2010 as the required date for HHAs to begin using OASIS-C.

Creation and Development of OASIS

In the late 1980s, the HCFA, along with the Robert Wood Johnson Foundation and later the New York State Department of Health, provided funding to the Center for Health Services and Policy Research at the University of Colorado to assess the feasibility and usefulness of measuring the outcomes of home health care.

The OASIS data set, which allowed HHAs who were already collecting assessment data to do so in a more precise form, was developed over a period of years. The original 73-item data set was first published in a report by the Research Center in 1994. The data set has gone through several iterations of expanding and refining since then, as it was anticipated at the time of initial implementation that OASIS would evolve to reflect changes in quality measurement, health research, health policy, reimbursement, and standards of care. Shortly after the data set was first published, a task force of home care experts convened by HCFA reviewed the items and recommended additional items considered essential for patient assessment. In 1995, incorporating input from the task force, the Research Center revised and rearranged the items into a data set that was called OASIS-A. This data set was used and tested in two demonstration programs in 1995 and 1996. The demonstration programs suggested select refinements which resulted in OASIS-B. Subsequently, OASIS-B was modified slightly to take into account HCFA's needs for data management and administration. The version containing these modifications was released in 1998 and was referred to as OASIS B-1. Further revisions were made to OASIS B-1 in 2007 to support the revised PPS effective January 1, 2008.

As of December 31, 2005, the Colorado Outcome Reporting and Enhancement (CORE) Research Partnership, which appears to have been an extension of the Research Center's (now the Center for Health Services Research) work with OASIS, ceased operations.¹⁰¹

Development of modifications to the OASIS-B1 instrument began in 2005 following input from a variety of stakeholders that included industry feedback, recommendations from the National Quality Forum (NQF), and an expert panel who identified best practice process measures. In September 2006, CMS contracted with Abt Associates and subcontractors from the University of Colorado Health Sciences Center and Case Western University to help CMS refine the OASIS data set.¹⁰² Earlier recommendations, along with a major effort to align OASIS measures with those of other assessment instruments, including the Minimum Data Set (MDS) and the Continuity of Care Record Evaluation (CARE) tool, formed the basis of the OASIS revisions. CMS viewed the revision as an opportunity to address quality of care across the health care continuum as patients moved among health care settings.

OASIS-C testing was completed in 2008 and a revised instrument revision posted in November 2008. After a comment period that ended in January 2009, a revised final version was submitted to the OMB in compliance with the Paperwork Reduction Act, and after receiving OMB approval, posted to the CMS web site August 12, 2009.¹⁰³

Intellectual Property Issues

Prior to 2008, rights to the OASIS instrument were retained by the Center for Health Services and Policy Research in Denver, Colorado. The Research Center, however, granted the right to use the OASIS tool freely, as evidenced by the copyright notice on the CMS web site,¹⁰⁴ and previous agreements that were reached with the NLM¹⁰⁵ and LOINC.¹⁰⁶

The OASIS implementation manual was originally developed in 1999 and has been revised several times to reflect changes to the OASIS data set. A revised manual was released in September 2009 as part of the project to upgrade the instrument to OASIS-C.

The designation for the OASIS in the UMLS is LNC221_OASIS_2002 -- the OASIS. The owner of the data set is the University of Colorado Center for Health Services Research (UCHSC) in Denver, Colorado. Contact information for the OASIS is Andrew Kramer, MD at UCHSC. Use of the OASIS through the UMLS is subject to category 3 restrictions, referenced in the section on the MDS, above.

The OASIS is also represented in the LOINC database. The text of the agreement concerning third party content in the LOINC database is referenced in the section on the MDS, above.

RELMA provides the following language concerning the OASIS copyright claim:

RIGHT TO COPY, REPRINT, AND USE OASIS.

The Outcome and ASsessment Information Set (OASIS) is the intellectual property of the Center for Health Services Research, Denver, Colorado, and may not be copyrighted by any other party. It is our intent to permit the free use of OASIS by home care providers and related organizations, businesses, and individuals, to be incorporated into patient or client assessment forms or software. To this end we grant all such organizations or individuals the nonexclusive right to copy or reprint the contents of the OASIS and to incorporate OASIS items into printed forms, software, or other products. No royalty or use fee is required, but acknowledgement of authorship is expected.¹⁰⁷

As of late 2007, Copyright information on the CMS OASIS web site indicated that OASIS B-1 was now in the public domain. Copyright information on the CMS web site reads: "The Outcome and ASsessment Data Set (OASIS) B1 (1/2008) is in the public domain and may not be copyrighted. No permission is needed to copy and use the data set." Similar text is in the OASIS Implementation Manual: Appendix B, dated January 2008.¹⁰⁸ There is no information with regard to copyright and OASIS-C on the CMS web site, and the issue is not addressed in the OASIS-C guidance manual.

CMS requires that state health agencies transmit encoded OASIS data in a format conforming to the CMS standard electronic record layouts, edit specifications, and data dictionary. The HAVEN system, developed by CMS, supports the data transmission requirements, but other software programs conforming to CMS requirements have also incorporated OASIS into their programs for the purpose of transmitting the data to CMS. There is no indication IP issues were ever a barrier.

Samples of paper assessment forms sold by the Briggs Medical Services Company over the years claim copyright to the forms, but also note that the OASIS data set is the IP of the Center for Health Services and Policy Research, and was being used with permission.¹⁰⁹

INPATIENT REHABILITATION FACILITY - PATIENT ASSESSMENT INSTRUMENT (IRF-PAI)

The IRF-PAI is a data collection instrument used to document the effectiveness and efficiency of rehabilitation care. It is used in IRFs and in distinct rehabilitation units of acute care facilities. IRF-PAI was developed for the CMS and is based in large part on the Functional Independence Measure (FIM), a tool comprised of eighteen assessment items related to motor activities and cognitive skills, each item being accompanied by a rating scale of one to seven, designating level of dependence.¹¹⁰ The sum of item scores describes severity of disability and reflects how much assistance is required to complete activities of daily living (ADLs). As severity of disability changes during rehabilitation, FIM[®] data can be used to track changes and analyze outcomes of treatment. The FIM[®] tool, by design, includes a minimum number of items. It was originally created to support research and to improve the quality of care in rehabilitation facilities. However, as described in more detail below, in 1995, HCFA entered into a licensing agreement that gave HCFA permission to use the FIM in the IRF-PAI, and for classifying patients into case-mix groups for reimbursing IRFs for Medicare Part A-covered services. Since the scale rates patients according to their need for assistance to perform a particular activity, the need for assistance translates to the time and energy another individual must spend to serve the needs of the functionally-impaired individual.

Admission FIM[®] scores must be collected during the first three calendar days after admission to an IRF. Scores are based on activities performed during the entire three-day period. The discharge assessment includes activities performed on the day of discharge and two days preceding.

Both admission and discharge IRF-PAI items must be completed before data records are transmitted to the CMS.¹¹¹ Completion of all items in the IRF-PAI, except the sections for Medical Needs and Quality Indicators, is mandatory. For reimbursement, federal regulations require that patient data be collected within the facility and submitted electronically using the free software (IRVEN[†]) available from the CMS web site. The data collected by CMS are used also to develop an analytical database for monitoring and assessing the implementation of the payment system.

Regulatory Background¹¹²

The Tax Equity and Fiscal Responsibility Act (TEFRA) of 1982 amended the Medicare statute by placing limits on payments for patients discharged from IRFs. Amendments to the Social Security Act in 1983 established a PPS for hospitals, but specifically excluded most PAC settings. TEFRA remained the payment system for

[†] Refer to http://www.cms.hhs.gov/InpatientRehabFacPPS/06_Software.asp#TopOfPage.

IRFs from 1982 to 2001. TEFRA reimbursed PAC providers on a cost basis, based on reasonable costs incurred while providing services. However, costs were limited to a base-line facility-specific target amount per discharge, which sometimes led to disparities in reimbursements between older and newer rehabilitation facilities.

Significant congressional action affecting reimbursement for IRFs since TEFRA includes the BBA of 1997, the BBRA of 1999, the BIPA of 2000, all of which are referenced in the Introduction and Background section of this report, and the Medicare, Medicaid, and SCHIP Extension Act (MMSEA) of 2007.

The BBA of 1997 (Public Law 105-33) required the development of PPS for PAC settings, including implementation of a PPS for medical rehabilitation hospitals by October 1, 2000. The BBRA of 1999 (Public Law 106-113) required the Secretary of HHS to use the discharge as the payment unit for IRFs and to establish classes of patient discharges by Functional Related Groups (FRGs). The BIPA of 2000 (Public Law 106-554) allowed rehabilitation facilities to elect how they wanted to be paid during the transition period between TEFRA and the IRF PPS.¹¹³

The IRF PPS utilizes information collected in the IRF-PAI to classify patients into distinct groups based on clinical characteristics and expected resource needs. Separate payments are calculated for each group, with adjustments for case and facility level.¹¹⁴ CMS' goal for facilities to qualify as an IRF under the PPS was that by July 1, 2008, at least 75% of the inpatients in the facility had to be being treated for at least one of a number of qualifying medical conditions.¹¹⁵ However, the Medicare, Medicaid, and SCHIP Extension Act of 2007 stipulated that CMS could set the compliance rate at no higher than 60%.

The Proposed Rule establishing the IRF PPS was published in the November 3, 2000 *Federal Register*. At the time the rule was published, HCFA entered into agreements with both the UBFA and CareData.com, Inc. to obtain UDSMR[®] and Clinical Outcomes System patient assessment data, both based on the Functional Independence Measure (FIM). In the Final Rule, published in the August 7, 2001 *Federal Register*, the agency, now the CMS, referred to this assessment data collectively as "FIM data."¹¹⁶ In the proposed rule, HCFA had proposed adoption of the MDS-PAC as the instrument to be used for patient assessment. However, following a comparison study of MDS-PAC with the FIM, and responding to concerns expressed about the length of time it took to complete the MDS-PAC and the burden of collecting data using a separate instrument, given that some facilities were already using the FIM for accreditation purposes, CMS announced in the Final Rule that the assessment instrument would be based on the FIM. The instrument was termed "a slightly modified version of the UDSMR patient assessment instrument", which was to be incorporated into the IRF-PAI to serve as the data collection instrument on which the PPS would be based.¹¹⁷

The Final Rule for a Prospective Payment System for Inpatient Rehabilitation Facilities was published August 7, 2001. In the rule, along with the announcement that

the assessment instrument would be based on the Functional Independence Measure, HCFA wrote: "We have by no means abandoned our goal of ultimately establishing a common system to assess patient characteristics and care needs for all post-acute care services and pursuing [sic] more integrated approaches to their payment and delivery."¹¹⁸

Electronic submission of data, using software provided by HCFA, was also required in the final rule. Assessment data was to be submitted via the Medicare Data Collection Network (MDCN). In compliance with the Paperwork Reduction Act, the "Notice of New System of Records," for the IRF PAI was published in the *Federal Register* on November 9, 2001.¹¹⁹

Creation and Development of the IRF-PAI

The IRF-PAI was created for use by facilities subject to CMS's payment system for Medicare inpatient rehabilitation services. The Functional Independence Measure (FIM), on which it is largely based, was developed prior to that, as a standardized way of measuring the progress of patients undergoing medical rehabilitation.

In 1983, the American Congress of Rehabilitation Medicine (ACRM) and the American Academy of Physical Medicine and Rehabilitation (AAPM&R) appointed a national task force of experts in the medical rehabilitation field to develop a uniform medical rehabilitation data system for documenting outcomes and costs of medical rehabilitation.¹²⁰ The work of the task force was originally funded by the National Association of Rehabilitation Facilities (NARF). In order to facilitate the mission of the task force, ACRM and AAPM&R endorsed applying for a development grant from the National Institute of Handicapped Research of the U.S. Department of Education.¹²¹ The grant for developing and field-testing a functional independence measure was applied for and coordinated through the State University of New York at Buffalo. The grant work was supported by 12 national organizations in various rehabilitation specialties who either sponsored, endorsed, or participated in the development of the data system.¹²²

Since the aim was to create a uniform medical rehabilitation data "system," the grant was intended to support both the development of the assessment instrument and the creation of a data management service.

Although the assessment instrument was designed primarily to measure functional status to inform rehabilitative care, it was envisioned that the data system would be useful for purposes beyond clinical care. The project overview read:

The principal uses of such data are expected to be justification for payment of services, accreditation, quality assurance, evaluation of service innovations based on research and development, estimation of cost benefit and cost effectiveness of rehabilitation services, and more uniform and objective education and training of rehabilitation practitioners.¹²³

The task force identified and reviewed both published and unpublished existing functional assessment instruments in order to come to a consensus on a common data set and measure of disability.¹²⁴ From the beginning, there were concerns about the proprietary nature of existing tools, because acceptance of the instrument by rehabilitation facilities and a willingness on their part to submit data to a centralized location for storage and analysis was vital to the vision of a uniform national data system."¹²⁵ The task force and representatives from the sponsoring organizations concurred on a need for a common repository to store information supplied by individual facilities, but how this was to be accomplished and regulated was a concern.

NARF, the American Hospital Association, and the National Easter Society co-authored a letter to project staff expressing their concern over the development of another proprietary software system, although they understood that without the means for collecting the data in a centralized location, it would be impossible to implement a uniform national data system. The task force was also concerned about the issues of public domain, access to data, impact on the industry, and copyrights to the data management system.¹²⁶

In the grant proposal, it was envisioned that a sub-contractor for the data management service would be identified through a Request for Proposal (RFP). However, instead of putting out an RFP, the Task Force recommended that the project office for the grant proposal at the State University of New York at Buffalo create the data management system.¹²⁷ It was anticipated that it would be three years before the data system could operate independently of grant support, at which time care facilities would bear the costs of maintaining the data service. The grant proposal stated: "It is likely that successful long-term maintenance of the national data system will be best achieved when one of several appropriate advocacy or regulating bodies assumes sponsorship of the system."¹²⁸

Although there is significant dispute about whether the Task Force or researchers at the University of Buffalo "authored" the Functional Independence Measure, many accounts, as reflected by the literature in the rehabilitation field, as well as evidence produced in an the trademark case for the FIM, attribute a key role to the members of the task force.¹²⁹ The minutes from the February 26, 1984 meeting of the Joint Task Force read: "At this point the Task Force split into three groups. The first group worked on identifying the demographics and supplemental measures to be collected, and coding system and instructions.... The second group of the Task Force members met to review available published functional assessment instruments, determine the most common functional status items and recommend items for a national data system, decide on how the functional status items should be grouped and whether additional optional items could be added, and to review functional status rating scales and recommend a common rating scale."¹³⁰ Testimony in support of the Applicant (UBFA, Inc.) in the FIM trademarks case before the Trademark Trial and Appeal Board of the U.S. Patents and Trademarks Office, appears to contradict the meeting notes: "The National Advisory Committee was made up of representatives within the field of rehabilitation medicine selected and invited by UDSMR to function solely in an advisory

capacity. The National Advisory Committee had no relationship with UB Foundation Activities, Inc. UDSMR is a division of UB Foundation Activities, Inc."¹³¹

Testimony on behalf of the Foundation in the trademark case credited Dr. Granger with being the primary creator and developer of the assessment instrument and the person who coined the term FIM. The American Medical Rehabilitation Providers Association (AMRPA), the Opposer in the trademark case to granting trademark status to the FIM, disputed the claims that the task force served only an advisory role.¹³²

Text in the grant proposal read: "The proposed Uniform National Data System for Medical Rehabilitation will be developed by a Task Force of recognized experts in rehabilitation care, administration, research and evaluation, and coordinated through the resources of the State University of New York at Buffalo." Dr. Carl Granger, of the University at Buffalo was the Project Director, and Dr. Byron Hamilton, of the Rehabilitation Institute in Chicago was the Principal Investigator. The grant proposal stated that Dr. Granger and Dr. Hamilton "will draft, pilot, and field test the instrument and then refine it based on consultation in Chicago with the panel of experts." The grant proposal also stated that "The ACRM/AAPM&R Task Force (of which Dr. Granger was co-chair) and the ASIA/Spinal Cord Injury Model System consultants ... will be responsible for developing the instrument and for subsequent revisions."¹³³

The grant and its extension for the development and implementation of the Functional Independence Measure and the creation of a data management service ran from September 30, 1984 to September 29, 1987. The development of the software and the data management system were envisioned to take place during the second and third years of the project, but staff at the University of Buffalo had already begun working on the software prior to the end of the first year of the contract.¹³⁴ The data management system created was originally called the Uniform Data System (UDS), and subsequently became UDSMR[®].

As with other PAC assessment instruments, the history of the FIM is closely entwined with the history of the PPS for the care setting. For a quick summary, the Functional Independence Measure was developed in the middle 1980s, with funding from the U.S. Department of Education, to address the functional status of patients in rehabilitation facilities. In 1987, under contract to HCFA, RAND and the Medical College of Wisconsin investigated UDSMR[®] data and found that functional status instead of diagnoses alone did a better job of explaining total costs of caring for rehabilitation patients. In 1993, FRGs were developed by researchers at the VA Medical Center in Los Angeles as a possible basis for a PPS.¹³⁵ In 1994, researchers at the University of Pennsylvania refined the FRGs by applying them to a large database of patient rehabilitation data maintained by UDSMR[®].¹³⁶ In 1995, RAND, again under contract to HCFA, used UDSMR[®] data to study the FRGs and found that they remained stable over time and could be used as a case mix methodology for a PPS.¹³⁷ In 1997, HCFA published the criteria for a IRF PPS, and the Secretary of HHS established case mix groups, required IRFs to submit data to establish and administer the PPS, provided a computerized data system for group patients for payment, and provided software for

data transmission. In 1999, the BBRA refined the PPS for IRFs, amending the Social Security Act to require the Secretary of HHS to base the case-mix groups on criteria deemed "appropriate to improve the explanatory power of functional independence measure-function related groups."¹³⁸ Also in 1999, MedPAC issued a report urging Congress to implement an IRF-PPS as soon as possible and recommended that the PPS be based on the "FIM-FRG classification system."¹³⁹

Intellectual Property Issues

UDS (later UDSMR[®]), a division of UBFA, was formed on October 1, 1987. UBFA, a New York not-for-profit corporation, claims exclusive ownership of the Functional Independence Measure (FIM[®] instrument). The Research Foundation of the State University of New York (SUNY) originally claimed ownership of the FIM, with rights being transferred to UBFA "in order to facilitate proper protection and licensing of the FIM System."¹⁴⁰ UDSMR[®] provides teaching workshops and data management services through their FIM[®] System. Most IRFs in the United States subscribe to UDSMR[®] services.¹⁴¹

Any use of the FIM, other than for reimbursement from CMS authorized through license agreements signed between UBFA and HCFA (in 1995) and CMS (in 2002), requires a license agreement with UDSMR[®]. Vendors who incorporate the FIM[®] portions of the IRF-PAI into products may do so only with a license agreement with UDSMR[®].¹⁴² UDSMR[®] offers a number of different kinds of licenses for use of the FIM[®] instrument, all of which, including use of the FIM for research purposes, require a license fee. Academics who want to use the FIM for research or educational purposes need to sign research licenses with UDSMR[®], identify the FIM as required by UDSMR[®], and present the results of their research to UDSMR[®] for review. Research letters of agreement are available for students, as well as for large-scale or collaborative research projects carried out by researchers in the field. In order to qualify for a research license to use the FIM for research or educational purposes, UDSMR[®] requires the individual or entity to complete and return to UDSMR[®] a research tracking form, including an abstract or description of the project along with the proposed use of the FIM in the project. If the request is approved by the UDSMR[®] research committee, the licensee:

will be asked to conform to established criteria regarding use of service marks and trademarks, as well as established standards with respect to references to materials copyrighted or registered by UDSMR. The entity will also be required to sign a written agreement that serves to protect intellectual property rights as well as formally establish responsibilities of both parties with respect to use and dissemination of UDSMR data and copyrighted materials.

A licensing fee is assessed for each research request approved. Also, licensees using the FIM are required when reporting results to indicate whether they have taken and passed the UDSMR mastery level test.¹⁴³

UDSMR[®] offers annual licenses to health care facilities for use of the FIM[®] instrument and data collection software. A limited license for a defined period of time is also available to facilities not currently subscribing to UDSMR[®] services, with the expectation that a long-term relationship would develop. This license allows a facility to test the FIM[®] System to determine clinical usefulness. There are fees associated with license agreements for these pilot projects. Subscribers are required to acknowledge that UDSMR[®] owns the FIM.¹⁴⁴

Geographical areas also can license the FIM[®] system. Territorial licenses include training and distribution agreements for marketing and distributing FIM[®] materials and for provision of FIM[®] training for UDSMR[®] subscribers in that region. Licensing arrangement with countries also may include a database license for the purpose of using the FIM[®] instrument for aggregating data and providing statistical reports within the country.¹⁴⁵

Software companies who have licensed the FIM for use have been given permission to use the FIM as long as software screen pages properly incorporate the FIM[®] service and trademarks. A typical letter agreement between UDSMR[®] and a software company states:

You have asked for UDSMR's permission to incorporate descriptive and definitional elements of the FIM System. UDSMR is willing to grant to you permission to use and incorporate the FIM System into your software upon the terms and conditions set forth in this letter agreement...

1. UDSMR hereby grants to you the right to incorporate some or all of the description, definitional and other terms comprising the FIM System...
2. In consideration of and as a condition to the rights granted to you pursuant to this letter agreement, you shall take all steps reasonable and necessary to acknowledge UDSMR's ownership rights to the FIM System. Without limiting the generality of the preceding sentence, a notice substantially in the form set forth should be incorporated into and appear (a) on introductory screen displays as well as any screens which make specific reference to or which introduce any sub-routines that incorporate any elements of the FIM System and (b) in any manuals or documentation relating to said software.... "The Uniform Data Set and the Functional Independence Measure are proprietary products of UB Foundation Activities, Inc."
3. You shall provide to UDSMR upon request, samples of proposed screen layouts and other portions of text containing elements of the FIM[®] System or containing the foregoing notice.¹⁴⁶

The requirement regarding furnishing UDSMR[®] with screen displays of the acknowledgments of copyright, trademarks, and service marks continues to be part of the License Agreement with UDSMR[®] for incorporation of the FIM into software.

In a 2002 Addendum to the 1995 License Agreement with HCFA, UDSMR[®] agreed to develop and update on a periodic basis the IRF-PAI Training Manual. UDSMR[®] claims

compilation rights to the manual, and also provides training and help desk support for IRF-PAI issues, presumably under contract with CMS.¹⁴⁷

The “FIM[®] system,” including the data set, definitions, documentation, and software for storing and analyzing the data, is maintained by UDSMR[®], which has licensed the system since 1994. The number of subscribers in 1994 was 622, which by 2009 had grown to 1400. Revenues for use of the FIM and “the FIM[®] System” goods and services are in the seven million dollar range.¹⁴⁸

UDSMR[®] requires that in order to be called “FIM[®] data,” the data must be collected by trained clinicians and sent to UDSMR[®] for analysis.

Data management services are performed by UDSMR. To include facility data in the aggregate reports, UDSMR requires that the data be credentialed through a two-step process that requires clinicians who are reporting data to demonstrate understanding of rating with the FIM instrument by passing a mastery test and by subjecting the data to analysis of each subscribing facility for outlier variables.¹⁴⁹

Facilities retain ownership in the data they send to UDSMR[®], but there are limitations to the uses they can make of UDSMR[®]-analyzed data:

When facilities subscribing to UDSMRSM compare results of their own programs with those of the national aggregate, they should be aware that the aggregated regional and national data from their UDSMR reports are copyrighted and owned by the University at Buffalo Foundation Activities, Inc., State University of New York at Buffalo, and must be used according to the UDSMR service agreements and contracts.¹⁵⁰

Unlike the MDS and OASIS, neither the FIM[®] data set nor the IRF-PAI assessment instrument is represented in either UMLS or LOINC.

Intellectual Property Notices Displayed by the CMS

CMS accepts the assertion by the University at Buffalo Foundation Activities, Inc. (UBFA) that they own the Functional Independence Measure (FIM). UBFA’s copyright notice appears in the final rule for the IRF PPS published in the *Federal Register* August 7, 2001. The copyright notice also appears on the CMS web site.¹⁵¹ The text of the copyright notice reads as follows:

The FIM data set, measurement scale and impairment codes incorporated or referenced in the IRF PAI are the property of UB Foundation Activities, Inc.[©]
1993, 2001 UB Foundation Activities, Inc. The FIM mark is owned by UBFA, Inc.

UBFA's copyright notice also appears on every page of the 244-page training manual available for download from the UDSMR web site.¹⁵² The text of the copyright notice in the training manual reads as follows:

Copyright © 2001-2004 UB Foundation Activities, Inc. (UBFA, Inc.) for compilation rights; no copyrights claimed in U.S. government works included in Section I, portions of Section IV, Appendices I and K, and portions of Appendices B, C, E, G, H and J. All other copyrights are reserved to their respective owners. Copyright © 1993-2001 UB Foundation Activities, Inc. for the FIM Data Set, Measurement Scale, Impairment Codes, and refinements thereto for the IRF-PAI, and for the Guide for the Uniform Data Set for Medical Rehabilitation, as incorporated or referenced herein. The FIM mark is owned by UBFA, Inc.

Intellectual Property Notices Displayed by UDS_{MR}[®]

The UDS_{MR}[®] web site displays the following copyright notice:

The Uniform Data System for Medical Rehabilitation, a division of UB Foundation Activities Inc., is the developer and sole owner of the copyrighted assessment tool known as the FIM[™] Instrument. As the owner, UDS_{MR} only grants permission to use the FIM[™] instrument through a variety of licensing arrangements. The intended use of the instrument dictates the level of licensure and the associated rights and fees.¹⁵³

UBFA License Agreements with HCFA and CMS

In September 1995, UBFA and HCFA entered into an agreement that allowed HCFA to study the Functional Independence Measures as a basis for the IRFs PPS. Addenda to the September agreement were signed in November 1995, and again in February 2002. The license had two distinct phases -- one was to evaluate the FIM[®] System as the basis for the PPS. The second phase covered the terms of the agreement should HCFA decide to use the FIM for the PPS.

The license agreement gave HCFA the right to use the FIM[®] instrument and related materials in the development, design, and evaluation of the PPS. As interpreted by UBFA, the agreement permitted "HCFA to sublicense hospitals to use the FIM[™] instrument and related materials 'without fee or obligation to UDS_{MR}' as part of the Medicare-payment system."¹⁵⁴

The agreement did not limit the use of the FIM to reimbursement, but the use had to be related to the payment system. Clause 2(b)(iv) gave HCFA the right "to use the Licensed System for other HCFA program needs related to the Payment System, including quality assurance, hospital certification and research." In the agreement, the parties also agreed "that discharge data, provider data, or other data and products derived from and specifically related to the Payment System, including but not limited to data or other products relating to quality assurance, hospital certification, or research derived from or relating to the Payment System, shall be subject to public disclosure and use for purposes of the Payment System, notwithstanding that such data or products incorporate any portion of the Licensed System."¹⁵⁵

UDS_{MR}[®] viewed the agreement as giving HCFA the "right to use the FIM instrument and related materials and to license one or more third-parties to use UDS

system 'in connection with the development, design, implementation, maintenance, operation, and evaluation of the [Medicare] Payment System.' Specifically, the License Agreement permits HCFA to sublicense hospitals to use the FIM™ instrument and related materials 'without fee or obligation to UDSMR' as part of the Medicare-payment system." [emphasis theirs]¹⁵⁶

In a 2002 clarification letter to an employee at HHS/ASPE regarding legitimate use of the FIM, the Director of UDSMR® wrote:

Under the License Agreement, the only authorized users of the portions of the Training Manual contributed by UDSMR are CMS, UDSMR and the inpatient rehabilitation facilities subject to the payment system. UDSMR has made these materials available to CMS and the facilities on a completely royalty-free basis. However, the right to use them does not extend to the 'regulatory community' in general, as AMRPA erroneously states.¹⁵⁷

The letter continued:

As you may be aware, UDSMR worked closely with CMS's attorneys to develop the copyright notice for the Training Manual. It has been carefully crafted to indicate that some sections and appendices of the Training Manual have been wholly developed by either UDSMR or CMS, while others reflect contributions from both and/or other parties.

The AMRPA had suggested that the copyright notice was confusing and that it was not necessary to put it on every page of the training manual.

In response, the Director of UDSMR® wrote:

AMRPA's letter highlights the need for a brief explanation of the ownership issues relating to the Training Manual and the related Inpatient Rehabilitation Assessment Instrument on CMS's website. We have made this suggestion to CMS on numerous occasions. We believe that many of AMRPA's concerns would be addressed if CMS were to place a notice similar to the following on its website:

"The Inpatient Rehabilitation Facility-Patient Assessment Instrument (IRF-PAI) and the IRF-PAI Training Manual were created for use by facilities subject to CMS's payment system for Medicare inpatient rehabilitation services. The IRF-PAI and the Training Manual contain proprietary material that was incorporated with the express permission of the owners. Anyone other than a facility subject to the payment system who wishes to use the IRF-PAI or the Training Manual should contact such owners prior to any such use."¹⁵⁸

Portions of the license agreements between HCFA (and subsequently CMS) and UBFA, which limited how and for what purposes the FIM could be used, appear to be in direct contradiction to the *Code of Federal Regulations* and OMB Circular A-110 grant rules under which the FIM was developed, and rules to which UDSMR® points as justification of their copyrights.¹⁵⁹

The 1995 license gave HCFA the right to modify the instrument. The amended license signed in 2002 limited CMS's (HCFA's successor) rights to modify the instrument without first consulting with UDSMR[®], and asserted that "any such modification shall only be for the purpose of carrying out CMS's tasks relating to the Payment System...."¹⁶⁰

The IP rights section of the 1995 agreement outlines how HCFA must acknowledge UDSMR[®] ownership of the FIM:

5. Intellectual property

(a) HCFA acknowledges that all right, title and interest in and to the Licensed System, the Marks, and all copyrights shall remain the sole and exclusive property of UDSMR. To the extent permitted by federal law, HCFA's use of the Licensed System and the Marks shall inure to the benefit of UDSMR, and this Agreement shall not operate to transfer or convey to HCFA or to any Third Party any ownership interest whatsoever in the Licensed System, the Marks or any derivative works thereof created by UDSMR.

(b) HCFA shall take all steps reasonable and necessary to acknowledge UDSMR's ownership and copyright rights to the Licensed System and the Marks. Without limiting the generality of the preceding sentence, notices substantially in the forms set forth below or any successor notices shall be incorporated into and appear in any printed or published documentation or other tangible materials relating to or resulting from the exercise by HCFA of its rights and licenses under this Agreement insofar as any such materials refer to or incorporate any portion of the Licensed System.

"The FIMSM data set, measurement scale and impairment codes incorporated or referenced herein are the property of UB Foundation Activities, Inc."

"The FIMSM service mark is owned by UB Foundation Activities, Inc.

In addition, any such materials which substantially reproduce the Data Set, the Adult FIM Scale or the Impairment Codes from the Guide, or any other copyrighted UDSMR materials, shall contain the following copyright notice:

"Copyright 1993 UB Foundation Activities, Inc.", or any successor notice.

(c) To the extent HCFA has the requisite right and license, and the authority to grant such right and license, HCFA agrees to grant to UDSMR an unconditional, irrevocable and nonexclusive right and license to use, to modify and to sublicense others to use and modify any modifications, enhancements, improvements or other derivative works made to, or based upon, the Licensed System by HCFA or any of its sub licensees."¹⁶¹

The 2002 addendum to the agreement added the following sentence to Section 5(b) of the 1995 license. "CMS shall also include the copyright notice contained in the Training Manual in any reproduction of the Training Manual in whole or in part, regardless of the medium in which such reproduction is made."¹⁶²

Between the time that UDSMR[®] and HCFA signed the 1995 license agreement, and while awaiting the report from RAND, with whom CMS contracted to analyze the

Functional Independence Measure and Function Related Groups (FRGs) for use in the PPS, UDSMR[®] issued a position statement, prompted by concerns expressed by the rehabilitation community that UDSMR[®] was standing in the way of a PPS based on the FIM and the FIM/FRGs. UDSMR[®] was reticent to let the RAND study be published without UDSMR[®] edits, based on what they saw as the unauthorized publication of proprietary information:

The present issue with HCFA over publication of the RAND reports involves the protection of UDSMR's **intellectual property rights under its agreements with HCFA**. The premature dissemination of the **draft reports** without UDSMR's consent has already led to improper commercial exploitation by third parties of the information contained in those reports, and UDSMR seeks only to avoid further breaches of its proprietary rights. UDSMR has requested deletion of certain information for purposes of general publication, and **had agreed to make the full reports available subject to appropriate terms and conditions**. [emphasis theirs]¹⁶³

In the position statement, UDSMR[®] writes:

Although Dr. Granger has always believed strongly in the free flow of ideas among researchers and others, UDSMR has had no choice but to take steps to protect the FIM instrument and data so valuable to the field and to UDSMR's subscribers.

Analysis of IRF-PAI Intellectual Property Issues

Sorting out the IP issues with respect to the IRF-PAI is not easy. The IRF-PAI is a government document, based largely on the Functional Independence Measure (FIM) of which UBFA claims ownership. Whether the claim is legitimate or not is a matter of dispute. HCFA's agreement to "license" the FIM and to print UBFA's copyright claims on their web site, in the *Federal Register* final rule, and on every page of the IRF-PAI user's manual, lends legitimacy to the ownership claims. As Trosow writes, "once copyright attaches to a work, there can be significant negative consequences for downstream access to that work."¹⁶⁴

On the coding form, UBFA claims copyrights to all parts of the IRF-PAI except for the medical needs and quality indicators sections. The copyrighted portions include Identification Information, Admission Information, Payer Information, Medical Information, Function Modifiers, FIM[™] Instrument, and Discharge Information.

Ownership of the FIM has been challenged in at least two legal cases. A challenge to the trademarking of FIM was settled by the Trademark Trial and Appeal Board of the U.S. Patent and Trademark Office in UBFA's favor, giving them the right to trademark FIM[®] and the FIM system[®].¹⁶⁵ A dispute before the Federal District Court in Western New York has been ongoing since 2003 and, barring an unlikely settlement between the parties, is slated to come to a jury trial in 2010. The original defendant in the case (there has been a countersuit) claims UBFA has admitted they don't own the copyright to the FIM, although it is not clear that has been stipulated by the plaintiff.

The dispute now appears to be focused more on restraint of trade and monopolization issues, but ownership of the FIM is a key issue. Part of the problem in these cases appears to be an expanding definition of what is being claimed as IP, whether it was the data collected and analyzed using the FIM[®] instrument, the software used to collect and store the data, the user and training manuals (which at some point began adding "including the FIM[®] instrument" to the title), the "FIM system[®]," or the FIM[®] data set itself. Over the years, the definition appears to have grown to include all of the above.¹⁶⁶ A 2006 study by the Division of Health Care Policy and Research at the University of Colorado at Denver and Health Sciences Center described the system as such: "The UDSMR[®] consists of four components: (1) a data set used to assess disability severity and medical rehabilitation outcomes; (2) computer software; (3) a data management service for subscribing facilities; and (4) a training program for users."¹⁶⁷

From the beginning, a complicating factor was the fact that one of the co-chairs of the Task Force was the project director on the grant and also a faculty member in the Department of Rehabilitation Medicine at the State University of New York at Buffalo, the recipient of the grant from the U.S. Department of Education. Another complicating factor was the intention in the grant proposal to issue an RFP for a software company to create software designed for locating, interpreting, and reporting the data. However, the RFP was never issued because the task force decided that the University at Buffalo was equipped to carry out the task.¹⁶⁸ As the assessment tool was accepted, data accumulated, and software developed, the analysis of which became a profitable business, ownership rights to the software and analyzed data became entangled with ownership rights to the FIM itself, since the FIM was not only integral to the software and related documentation, but also to derivative products created by UDSMR[®] (e.g., FIMware[®], weeFIM[®]).¹⁶⁹

Also confusing the issue were conflicting statements from UDSMR[®] concerning who owned the tool and whether it was in the public domain. Reviewing contemporary correspondence and other materials produced as evidence in the Trademarks case, it is unclear when UBFA began to assert their IP rights, but it is clear that, from the beginning, this was an issue hovering below the surface. In the grant extension proposal in 1985, under the "Inventions and Copyrights" section, the proposal states: "It was too early to consider copyrighting the National Data Set."¹⁷⁰

An undated draft of a UDSMR brochure entitled "Why Uniform Data Now?" stated:

With the development of the Uniform Data System for Medical Rehabilitation (UDSMR) clinicians are now able to document the severity of patient disability and results of the medical rehabilitation process. The national task force which created the much-needed system is co-sponsored by the American Congress of Rehabilitation Medicine and American Academy of Physical Medicine and American Academy of Physical Medicine and Rehabilitation.¹⁷¹

Other statements made during this period include a 1986 letter by Carl Granger in which he wrote:

I certainly confirm that the coding sheet of the Uniform Data System (UDS) is in the public domain. We have worked very diligently to obtain national consensus regarding the assessment items and have a detailed and scientifically rigorous method for evaluating the reliability, validity, and precision of the Functional Independence Measure (FIM) component. Therefore, we have copyrighted the coding sheet to preserve its integrity while we promote its use as widely as possible.¹⁷²

In correspondence with a company called Formations in Health care, Inc., UDSMR[®], through their attorney wrote:

With respect to the "FIM" mark, it is neither descriptive nor generic, but rather a coined phrase which UDSMR has adopted and is using in connection with its business. This is legally protectable trademark use which UDSMR intends to enforce as its exclusive right for its business purposes. There are no barriers to its claim to ownership. ...With respect to copyrightability of the Functional Independence Measure itself, it is clear under the Copyright Act that the measurement device, and the manner of its definition, including the instrument and item definitions are copyrightable subject matter under Section 102 of that Act, as original works of authorship in the category of literary works. It is equally clear that ownership of those copyrights is properly and legitimately claimed by the Research Foundation of the State University of New York and/or by the UDSMR division of the UB Foundation Activities, Inc., as their respective rights may appear.¹⁷³

A document presented for exhibit in the case before the Trademark Trial and Appeal Board, stated:

All copyrights, service marks and trademarks relating to the FIM SystemSM are owned by UBFA and none of the FIM SystemSM is or has ever been in the public domain. Any unauthorized or unlicensed incorporation of portions of copyrighted works relating to the FIM SystemSM into other works, any modification of any such modified works by third parties and any unauthorized or unlicensed use of any such copyrighted works or of the UDSMR or FIM service marks or trademarks are and remain improper and in violation of UDSMR 's intellectual property rights. (Trademark dispute case, p.207 OPP-47.)

Correspondence between Kenneth Aitchinson, chair of an AMRPA PPS Task Force and Carl Granger in April 1998 included this exchange:

Aitchinson: "We are in a very critical period in the development of a PPS for rehab and AMRPA is, as you know, mounting a major campaign to influence the outcome. We need to be sure that there be no misunderstanding...." At the Task Force meeting on January 19, Jim [Phillips, of UDSMR] was asked specifically... whether [UDS] would assert proprietary rights to the FIM or portions thereof if it was used by HCFA, in whole or in part, as an element of a new MDS instrument. Jim assured us that there was no problem... and the HCFA had complete license to use the FIM or items therefrom. Based on those assurances AMRPA developed the policy position set forth in the attachment."¹⁷⁴

Granger's response was: "We are in communication with John Morris, the HCFA contractor, for the MDS-PAC and these issues are being discussed and analyzed. He understands that no barriers exist under the license agreement between UDSMR and HCFA."¹⁷⁵

In a 1999 letter, UDSMR[®] made the statement that:

...the FIM[™] instrument and all other aspects of the FIM system is owned by UDSMR, and that no part of the FIM system is or ever has been in the public domain. UDSMR has entered into numerous licensing arrangements granting licensees the right to use the FIM instrument and related materials for a variety of purposes. Unfortunately, UDSMR must from time to time take action with respect to researchers and service providers who are ignorant of, or choose to ignore, UDSMR's ownership rights in the FIM System.¹⁷⁶

E-mail correspondence between the VA and UDSMR[®] with the subject line "copyright question," indicates that the VA was confused about the proprietary nature of the FIM. A response from UDSMR[®] to an e-mail inquiry from the VA with the subject line "Copyright question" read:

I am sending this email to you in response to a question you had given to Dr. Carl Granger regarding UDSMR's ownership in the IRF-PAI. In answer to your concerns, CMS (formerly HCFA) has a license agreement with UDSMR under which CMS has UDSMR's permission to use elements of the FIM[™] instrument in connection with the IRF-PAI. UDSMR, however, retains all ownership rights in and to the FIM[™] instrument.¹⁷⁷

The VA Medical System subscribes to the FIM[®] instrument and UDSMR[®].¹⁷⁸ However, the VA User's Manual for the FIM, developed for use with the the VA's electronic health care system, VistA, dated May 2003, makes no mention of the copyright issue, or of UDSMR[®] or UBFA, Inc.¹⁷⁹

The Functional Independence Measure (FIM) is likely copyrightable, but it is unclear that UDSMR[®] has exclusive rights as to how the FIM can be used. If UBFA has legitimately copyrighted the FIM, based on rules published in the OMB circular (A-110) and title 34 of the *Code of Federal Regulations* concerning "intangible property" created through government grants (in this case, the U.S. Department of Education), it is unclear, based on the same rules, how they have justified the restrictions they have placed on HCFA's and CMS's use, unless it is simply a technical matter that the grant was through the U.S. Department of Education and not the HHS.

UBFA, Inc. has not had an easy time asserting their exclusive rights to the FIM. That being the case, it is hard to surmise whether they would be inclined to permit the creation and dissemination of HIT-coded versions of the FIM, simply because the policing of unauthorized use could prove to be burdensome. Despite the ubiquitous copyright notices, it appears that many continue to be unaware, or doubtful of the legitimacy of UBFA's claims to the FIM, even though most people in the rehabilitation field are likely familiar with UDSMR[®] and their data services.

While it is not possible with currently available documentary evidence to sort out the ownership claims and counterclaims to determine the IP issues that will arise if standards organization wish to apply HIT standards to the instrument and disseminate a standardized IRF-PAI, some further analysis of where we have been and how we got here as described in "Medicare Funding for Inpatient Rehabilitation: How Did We Get to This Point and What Do We Do Now?" may be informative.¹⁸⁰ It should be noted however, that the work underway in CMS to develop a new patient assessment instrument, the CARE instrument, may eliminate the need to rely on the FIM[®] data elements for Medicare payment purposes if the data elements in the CARE instrument are found to support appropriate Medicare payment algorithms for IRFs.

FOLLOW UP AND ADDITIONAL RESEARCH

Additional discussions and research may provide further insight into the various IP issues addressed above. Conversations with the leadership at the NLM, the Regenstrief Institute, the interRAI consortium, UDSMR[®], and the Center for Health Services Research at the University of Colorado, may prove helpful for future development and standardization of federally-required assessment instruments. It would be instructive to understand how the Regenstrief Institute was able to address interRAI's international licensure constraints when incorporating the MDS into LOINC and whether any other IP issues remain in applying and disseminating accepted HIT standards to MDS patient assessments. Further, these conversations could shed light on issues that will likely be faced should there be an effort to apply CHI standards to the IRF-PAI. These discussions may suggest useful steps that could be taken to minimize or eliminate IP issues in the development of future assessment instruments.

The terms of past contracts under which assessment instruments and related documentation were developed may inform how future contracts could be written so that data collection instruments developed for government use remain in the public domain. In particular, incorporating the "special works" clause of the Federal Acquisitions Regulations (FAR) into contracts would give the government the ability to limit the contractor's rights to claim ownership in content first produced through the contract. It would also allow the contracting agency to direct the contractor to establish a copyright claim and assign the copyright to the government, which would give the government unlimited rights in how the instruments are released and used.¹⁸¹

Preliminary conversations indicate that CMS is fully aware of many of the issues that can arise when federally-required assessment instruments are not freely available in the public domain, including concerns that IP claims may constrain the application of HIT standards to these instruments and limit the dissemination of HIT-enabled standardized assessments. Obtaining guidance from those with expertise in applying and disseminating CHI-accepted standards to current assessment instruments developed under federal contracts or grants will facilitate the application and dissemination of HIT standards to emerging assessment instruments, and support the goal of health information exchange and system interoperability.

A number of organizations have commented to CMS on the non-interoperable nature of the specifications for the electronic transmission of patient assessment data, and have recommended that code formats be consistent across the various assessment instruments, encouraging CMS, for example, to adopt the HL7 Patient Assessment Questionnaire and Clinical Document Architecture (CDA) instead of using a custom-designed data transmission tool, stating "Rather than developing a custom based data transmission process,... CMS [should] reevaluate the benefits and usage of CDA for the MDS 3.0 including the applicable content standards (LOINC and SNOMED-CT).¹⁸²

Efforts are underway to create a system for all PAC assessments using consistent terminology. The instrument being developed is the CARE which aims to harmonize data elements across the three assessment tools CMS currently requires. The National Quality Forum is also calling for harmonization of assessment items in the areas they are addressing as part of their quality initiatives.

A major piece of legislation from 2009 with broad implications for health care delivery and health information exchange was the ARRA, also known as the “stimulus bill.” Provisions in the HITECH section of the Act address incentives for the adoption of HIT by health care providers. Although care assessments are not addressed specifically in the wide-ranging act, the Act is likely to significantly impact health information exchange and the use of certified EHRs. The stimulus plan provides significant funding for EHR adoption by some healthcare providers. While ARRA's definition of health care providers includes SNFs, nursing facilities, home health entities and other LTC facilities, these providers are not yet slated to receive the same incentive payments physicians and hospitals will be eligible for if they are able to demonstrate "meaningful use" of HIT. However, with the ONC investigating how to expand HIT adoption incentives to other providers and industry movement towards certification of PAC electronic records, significant opportunities exist to leverage federally mandated functional assessment tools to drive the interoperability required in the stimulus bill. Standardizing the data sets in these assessments is an important first step towards achieving that interoperability.

ACRONYM LIST

AAPM&R	American Academy of Physical Medicine and Rehabilitation
ACRM	American Congress of Rehabilitation Medicine
AMRPA	American Medical Rehabilitation Providers Association
ARRA	American Recovery and Reinvestment Act
ASIA	American Spinal Injury Association
ASPE	Office of the Assistant Secretary for Planning and Evaluation of the U.S. Department of Health and Human Services
BBA	Balanced Budget Amendment of 1997
BBRA	Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999
BIPA	Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000
CAM	Confusion Assessment Method
CARE	Continuity Assessment Record and Evaluation
CFR	<i>Code of Federal Regulations</i>
CHI	Consolidated Health Informatics Initiative
CIHI	Canadian Institute for Health Information
CMS	Centers for Medicare and Medicaid Services of the U.S. Department of Health and Human Services (formerly HCFA)
CoP	Medicare Conditions of Participation
CPS	Cognitive Performance Scale
DRA	Deficit Reduction Act of 2005
EHR	Electronic health record
FAR	Federal Acquisition Regulations
FHA	Federal Health Architecture
FIM [®]	Functional Independence Measure
FR	<i>Federal Register</i>
FRGs	Functional Related Groups
HCFA	Health Care Financing Administration (predecessor to CMS)
HHA	Home health agency
HHS	U.S. Department of Health and Human Services
HIT	Health information technology
HITPC	Health IT Policy Council
HITSP	Healthcare Information Technology Standards Panel
HL7	Health Level Seven
HRCA	Hebrew Rehabilitation Center for Aged

IHE	Integrating the Healthcare Enterprise (HIMSS)
interRAI	inter[national]RAI. These are the developers of the MDS.
IOM	Institute of Medicine
IP	Intellectual property
IRF	Inpatient Rehabilitation Facility
IRF-PAI	Inpatient Rehabilitation Facility-Patient Assessment Instrument
LOINC	Logical Observation Identifiers Names and Codes
LTC	Long-term care
LTCH	Long-term care hospital
LTCI	Long-term care insurance [Japan]
MDS	Minimum Data Set
MDS-PAC	Minimum Data Set-Post-Acute Care
NARF	National Association of Rehabilitation Facilities
NCVHS	National Committee on Vital and Health Statistics
NLM	National Library of Medicine
OASIS	Outcome and ASsessment Information Set
OBQI	Outcome-Based Quality Improvement
OBRA	Omnibus Budget Reconciliation Act of 1987
OMB	U.S. Office of Management and Budget
ONC	Office of the National Coordinator for Health Information Technology
PAC	Post-acute care
PHQ	Patient Health Questionnaire
PPS	Prospective Payment System
RAI	Resident Assessment Instrument
RAI-MH	Resident Assessment Instrument for Mental Health
RAI-NH	Resident Assessment Instrument for Nursing Homes [Spain]
RAP	Resident Assessment Protocol
RELMA	Regenstrief LOINC mapping assistant
RFP	Request for Proposal
RTI	Research Triangle Institute
RUG	Resource Utilization Group
SDO	Standards development organization
SNF	Skilled nursing facility
SNOMED-CT	Systematized Nomenclature of Medicine-Clinical Terms
TEFRA	Tax Equity and Fiscal Responsibility Act of 1982

UBFA	University of Buffalo Foundation Activities, Inc.
UDS	Uniform Data System (later became UDSMR)
UDSMR	Uniform National Data System for Medical Rehabilitation
UMLS	Unified Medical Language System
USPTO	U.S. Office of Patents and Trademarks
VA	U.S. Veteran's Administration

COPYRIGHTS AND TRADEMARKS

Please note that failure to register a copyright does not mean forfeiture of rights in copyrightable works.

MDS/RAI

Copyrights:

A number of individuals and publishers have claimed copyrights to what appear to be derivative works that include or reference the MDS (e.g., forms, compilations with added texts, training and reference manuals). The following are the only copyrights registered by interRAI.

InterRAI. (1995) *Long Term care Resident Assessment Instrument User's Manual: Version 2.0*. (Authorship on application: coauthors: John N. Morris, Katherine M. Murphy, Brant E. Fries... et al.; Basis of Claim: New Matter: revisions, additions.)

InterRAI. (1997) *RAI-home care (RAI-HC) Assessment Manual*. (Authorship on application: co-authors of text: John N. Morris, Brant E. Fries, Roberto Bernabei, R. Knight Steel, pseud., Naoki Ikegami, G. Iain Carpenter & Ruedi Gilgen; Basis of Claim: New Matter: substantial text added to preexisting assessment program.)

Trademarks:

To date, it does not appear that interRAI has sought trademark or service mark protection for any of their instruments.

OASIS

Copyrights:

The following are copyrights registered by the Center for Health Policy Research:

Center for Health Policy Research. (1994a). *Measuring Outcomes of Home Health Care: Vol. 1: Final Report, September 1994*. Denver: Center for Health Policy Research.

Center for Health Policy Research. (1994b). *Objective Review Criteria for Abstracting Data for Clinical Record Review of Home Health Care: Vol. 3, Final Report*.

Center for Health Policy Research. (1994c). *Technical Appendices to the Report on Measuring Outcomes of Home Health Care: Final Report, September 1994*.

Trademarks:

Registrant: Center for Health Services and Policy Research. Word Mark: OASIS GENIE. Goods and Services: "Computer software for use to enter and track information on patient demographics, functional status, and health status, and instruction manuals used in connection therewith." Type of Mark: Trademark. Date of Registration: July 23, 2002.

IRF-PAI

Copyrights:

The following are copyrights registered by University of Buffalo Foundation Activities, Inc. (UBFA):

Guide for the Uniform Data Set for Medical Rehabilitation. (1995).

Guide for the Uniform Data Set for Medical Rehabilitation & 2 Other Titles. (1995).

The UDS-PRO System Software and Software Guide, Version 2.0.

UB Foundation Activities, Inc. (1997). *Guide for the Uniform Data Set for Medical Rehabilitation (adult FIM[®]): Ver. 5.1.*

UB Foundation Activities, Inc. (1999). *Revised appendices A and B for the Guide for the uniform data set for medical rehabilitation (Adult FIM[®]): Version 5.1.* (Registration Number/Date: TX0005665330/2002-10-21)

UDSPRO Source.txt.

UDS-PRO System Software and Software Guide 3.01.

UDS-PRO: Software.

Uniform Data System for Medical Rehabilitation. (1998). *LIFeware Software.*

Uniform Data System for Medical Rehabilitation. (2005). *UDS-PRO HL7.*

Uniform Data System for Medical Rehabilitation, UB Foundation Activities, Inc., & UB Foundation Activities, Inc. Uniform Data System for Medical Rehabilitation. (2002). *IRF-PAI Training Manual.*

Uniform Data System for Medical Rehabilitation, UB Foundation Activities, Inc., & UB Foundation Activities, Inc. Uniform Data System for Medical Rehabilitation. (supplement to item registered in 2002). *IRF-PAI Training Manual.*

Uniform Data System for Medical Rehabilitation, UB Foundation Activities, Inc., & UB Foundation Activities, Inc. Uniform Data System for Medical Rehabilitation. (2005). *The UDS-PRO System Software and Software Guide, Version 1.1.*

Uniform Data System for Medical Rehabilitation, & UB Foundation Activities, Inc. Uniform Data System for Medical Rehabilitation. (2003). *The UDS-PRO Software Data Specification Guide.*

University at Buffalo Foundation Activities, Inc. (1994). *Guide for the Uniform Data Set for Medical Rehabilitation (adult FIM[®]): Version 4.0.*

US [sic] Foundation Activities, Inc. (2001). *The UDS-PRO System (including the FIM[®] Instrument): Clinical Guide, Version 1.0.* (Registration Number/Date: TX0005877639/2002-05-27)

WeeFIM[®] II Software

Trademarks:

Trademark for the mark "FIM". Originally, the registration of FIM was turned down by the U.S. Office of Patents and Trademarks. When UDSMR[®] provided further evidence, the USPTO approved the registration of FIM. Subsequently, the American Medical Rehabilitation Providers Association (AMRPA) challenged the trademarking of FIM, but the USPTO ruled in UDSMR's favor in 2009. UBFA claims the following trademarks:

AlphaFIM[®], AlphaFIM Analyzer[®], FIM[®], FIM-PAI[™], FIMware[®], The FIM System[®], Mini-FIM[™], LIFEware[®], LIFEwareSM, PAR-PRO[™], PAR-PROSM, Piece of the PAI[®], UDSMR[®], UDS Central[™], UDS-FIMI[™], UDSFIM Central[™], UDSPRO Central[™], UDS-PRO[®], UDS-PROi[®], UDS-PROiSM, WeeFIM[®], WeeFIM[®], WeeFIM II[®], WeeFIMware[™]

<http://www.udsmr.org/Documents/Trademark-service%20mark.pdf>

MDS STAKEHOLDER LETTERS

July 25, 2003

Barbara Paul, MD
Director
Quality Measurement and Health Assessment Group
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Dr. Paul:

The undersigned organizations, representing key constituencies in the Resident Assessment Instrument (RAI) process, would like to request a meeting with you and any staff members you choose to include.

We believe it is critical that we discuss a number of issues regarding revision of the MDS as soon as possible. From our vantage point, the current direction for the instrument's evolution appears to be leading toward a tool that is increasingly driven primarily by program support needs. We firmly believe that the MDS must retain a resident focus and that the paramount objective in redesign must be to improve the quality of information to facilitate accurate, comprehensive resident assessment and care planning, consistent with the law, current regulations, current standards of practice and the best available science on quality care for the populations served in nursing homes.

While keeping this goal primary in our minds, we must also strive to ensure that the critical information is being collected not only to support current quality measurement and payment needs, but also to ensure that revisions to the system give us the capacity to improve and strengthen these systems in the future through the collection of better data that provides more robust information for these purposes.

Specifically, we would like to address the following issues with you:

- The need to re-assess the major goals for the instrument and engage with key stakeholder groups in a clear articulation of a unified vision and objectives for the MDS.
- The need to assess the current charge for the contract team engaged to work with CMS on this effort, in light of a clear consensus on vision and direction, as well as whether the resources devoted to this effort and the timeline for its completion are realistic.

- The need to coordinate this activity with the rapidly unfolding HHS efforts to facilitate improved information technology capacity and the widespread adoption of electronic health information systems.

We are very concerned that if these key issues are not addressed prior to finalizing major MDS 3.0 design decisions, the new instrument will fall short of its potential and lack stakeholder support. Given the investment of significant resources on the part of all concerned parties to make this transition, it would be most unfortunate if this historic opportunity to significantly improve the process were lost.

We are eager to meet with you prior to the planned August 25-26 meeting of the Technical Expert Panel that will be advising the contract team on their work. We would like to suggest a date sometime during the weeks of August 4th or 11th.

Please contact Ruta Kadonoff at (202) 508-9450, rkadonoff@aaahsa.org or, during the week of July 28-August 1, Evvie Munley at (202) 508 9478, emunley@aaahsa.org, who will be happy to work with you or a member of your staff to coordinate a mutually convenient date and time. We look forward to your response.

Sincerely,

American Association of Homes and Services for the Aging
American Association of Nurse Assessment Coordinators
American Hospital Association
American Health Care Association
Catholic Health Association
National Association of Directors of Nursing Administration in Long-Term Care
National Association of Subacute and Post-Acute Care
National Citizens Coalition for Nursing Home Reform
National Hospice and Palliative Care Association

Cc: Tom Scully, CMS Administrator

May 21, 2004

Sean Tunis, MD
Chief Clinical Officer and Director, Office of Clinical Standards and Quality
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Dr. Tunis:

The undersigned organizations, representing key constituencies in the Resident Assessment Instrument (RAI) process, would like to express our continuing concerns about plans for development of the Minimum Data Set (MDS), version 3.0. We would appreciate the opportunity to meet with you and key staff working on this project as soon as possible.

As you are likely aware, we approached CMS in August of last year to voice our concerns with regard to the direction of the MDS 3.0 development process and to make recommendations on revising the project in order to better meet the needs of key stakeholders.

We appreciate the update that was provided on April 7th of this year, detailing CMS work since August, primarily on one of the key issues that was raised in our August meeting. We are pleased with the extensive efforts to better coordinate the MDS revision process with concurrent work on development of electronic medical records technology and standards. Ultimately, the seamless integration of the MDS with electronic medical records systems will greatly reduce the paperwork burden on professional nursing care staff and improve quality of care for residents as well as accurate information for CMS program objectives. CMS efforts to ensure that the next iteration of the MDS helps to begin moving providers in the direction of this ultimate goal are critical to fostering these evolving technologies and their diffusion in the long-term care setting.

We remain concerned, however, that other key issues that we raised in our August meeting do not seem to be figuring prominently in the current plans, as conveyed to us on April 7th.

We reiterate our firm belief that the MDS must be resident-focused and that the paramount objective in making revisions must be to improve the quality of information collected to facilitate accurate, comprehensive resident assessment and care planning, consistent with the law, current regulations, current standards of practice and the best available science on quality care for the populations served in nursing homes.

While keeping this goal primary in our minds, we must also strive to ensure that the critical information is being collected not only to support current quality measurement and payment needs, but also to ensure that revisions give us the capacity

to improve and strengthen these systems in the future through the collection of better data that provides more robust information for these purposes.

In particular, the following three issues, which we raised with CMS last August, do not appear to be a part of the current work plans as we understand them.

- The vision, goals and objectives for the MDS must be clearly defined. Objectives must be prioritized, in order to ensure that decisions about items that are/are not to be included are based on a clear and rational set of criteria specifying how competing priorities are to be reconciled. The methodology that will be used for achieving and maintaining the clinical relevance of the MDS in accordance with evolving standards of care must also be defined.
- The current effort fails to take into account and prioritize all of the purposes that the MDS data are expected to serve. The first step in the process of re-design should be to pose open-ended questions about what information, if collected, could improve the instrument's utility for one or more of its primary or secondary purposes -- assessment, care planning, quality measurement, payment, support of regulatory activities, and research.
- We must strive to improve the instrument's ability to meet the needs of specific types of residents (e.g., long-term, post-acute, end-of-life/palliative care, non-elderly adults, pediatric) by targeting specific questions through the use of skip patterns or a modular approach to the form. The diverse residents in nursing homes are not well-served by a one-size-fits-all approach to assessment.

Finally, we would like to see CMS working in greater collaboration with key stakeholders. The time span between our initial meeting in August of 2003 and the first follow-up in April of 2004 concerns us, as does the latest communication we received from Bob Connolly. In his recent e-mail to our group, Connolly notes that an every-other-month or quarterly schedule of calls/meetings had been proposed by many of the stakeholders on the April 7th call. He went on to state that, "we likely won't have much to report in the next 2-3 months," and that CMS would not yet be scheduling another follow-up.

We urge CMS to engage more directly with our groups and other stakeholders as *partners* in this effort. We would appreciate being a part of design and planning efforts, with an opportunity to engage in dialogue and planning with CMS rather than merely reacting to reports on the work completed. We believe this would also be to CMS' advantage, in that it would help to guide this effort in a direction that will be more likely to achieve the support and buy-in from the ultimate users and beneficiaries of this work, which will be critical to its acceptance.

We continue to be very concerned that if the key issues we have raised are not addressed prior to finalizing major decisions about the design of MDS 3.0, the new instrument will fall short of its potential and lack support. Given the investment of

significant resources on the part of all concerned parties to make this transition, it would be most unfortunate if this historic opportunity to significantly improve the process were lost.

Accompanying this letter are our thoughts on proposed vision and mission statements for MDS, as well as a copy of the memo we provided at our August meeting, which summarizes our issues and makes specific recommendations as to how they might be addressed. We continue to believe that these recommendations outline critical steps that must take place prior to investment in field testing of an instrument. Key questions remain unaddressed in the process as we have seen it unfold to date -- what information do we need, about which residents, for what purposes? We need experts in clinical care, quality measurement and payment/resource utilization to come to consensus on answers to these questions first, then identify how each of the needed elements should ideally be collected -- via the MDS, via some other data collection tool (e.g., an independent, quality of life/satisfaction resident survey), or via electronic health records at a point when they are widely adopted.

We would appreciate the opportunity to meet with you as soon as possible to discuss these issues and develop plans for how they might be addressed. Please contact Ruta Kadonoff at (202) 508-9450, rkadonoff@aaahsa.org, who will be happy to work with you or a member of your staff to coordinate a mutually convenient date and time. We look forward to your response.

Sincerely,

American Association of Homes and Services for the Aging
American Association of Nurse Assessment Coordinators
American Health Care Association
American Hospital Association
American Medical Directors Association
Catholic Health Association
National Association of Directors of Nursing Administration in Long-Term Care
National Citizens' Coalition for Nursing Home Reform
National Hospice and Palliative Care Organization

Cc: Trent Haywood
Lisa Hines

REFERENCES

- Baker, L. (2000, April 27). Rehab Outcomes Stored at UB: Database Could Set the Standard for Medicare Reimbursement. *University at Buffalo Reporter*, 31(29). Accessed January 2008 at <http://www.buffalo.edu/reporter/vol31/vol31n29/n2.html>.
- Berg, Katherine, et al. (2001). *Identification and Evaluation of Existing Quality Indicators that are Appropriate for Use in Long-Term Care Settings. Final Report*. Washington, DC: CMS. Accessed January 2008 at <http://www.cms.hhs.gov/NursingHomeQualityInits/Downloads/NHQIYear2002Archives.zip>.
- Braddom, Randall L. (2005, July). "Medicare funding for inpatient rehabilitation: How did we get to this point and what do we do now?" *Archives of Physical Medicine and Rehabilitation*, 86(7): 1287-1292. PubMed link <http://www.ncbi.nlm.nih.gov/pubmed/16003652>.
- Buchanan, J.L., Andres, P.L., Haley, S.M., Paddock, S.M., & Zaslavsky, A.M. (2004). "Evaluating the planned substitution of the minimum data set-post acute care for use in the rehabilitation hospital prospective payment system." *Medical care*, 42: 155-63. PubMed link <http://www.ncbi.nlm.nih.gov/pubmed/14734953>.
- Buchanan, J.L., Andres, P.L., Haley, S.M., Paddock, S.M., & Zaslavsky, A.M. (2003). "An assessment tool translation study." *Health Care Financing Review*, 24: 45-60. PubMed link <http://www.ncbi.nlm.nih.gov/pubmed/12894634>.
- Continuity Assessment Record and Evaluation [CARE] Tool (2007, October 23). CMS-10243 [OMB#:0938-NEW]. Appendix A: Data Collection for Administering the Medicare Continuity Assessment Record and Evaluation (CARE) Instrument. Available for download from the CMS Paperwork Reduction Act web site at <http://www.cms.hhs.gov/PaperworkReductionActof1995/PRAL/itemdetail.asp?filterType=none&filterByDID=0&sortByDID=1&sortOrder=descending&itemID=CMS1201543> or <http://www.cms.hhs.gov/PaperworkReductionActof1995/downloads/CMS-10243.zip>.
- CARE Tool (2007, October 29). CMS-10243 [OMB#:0938-NEW]. Appendix B: Master Document (Core and Supplemental Items). Available for download from the CMS Paperwork Reduction Act web site at <http://www.cms.hhs.gov/PaperworkReductionActof1995/PRAL/itemdetail.asp?filterType=none&filterByDID=0&sortByDID=1&sortOrder=descending&itemID=CMS1201543> or <http://www.cms.hhs.gov/PaperworkReductionActof1995/downloads/CMS-10243.zip>.
- Carpenter, G.I. (2006). "Accuracy, validity and reliability in assessment and in evaluation of services for older people: The role of the interRAI MDS assessment system." *Age and ageing*, 35(4): 327-9. PubMed link <http://www.ncbi.nlm.nih.gov/pubmed/16788075>.
- Carter, G.M., Relles, D.A., Ridgeway, G.K., & Rimes, C.M. (2003). "Measuring function for Medicare inpatient rehabilitation payment." *Health Care Financing Review*, 24(3): 25-44.
- Carter, G.M., Relles, D.A., Wynn, B.O., et al. (2000). *Interim Report on an Inpatient Rehabilitation Facility Prospective Payment System*. Santa Monica, CA: RAND, MR-1503-CMS. Accessed at <http://www.rand.org/pubs/drafts/DRU2309/>.

- Carter, G.M., Beeuwkes Buntin, M., Hayden, O., Kawata, J., Paddock, S.M., Relles, D.A., Ridgeway, G.K., Totten, M.E., & Wynn, B.O. (2001). *Analyses for the Initial Implementation of the Inpatient Rehabilitation Facility Prospective Payment System*. Santa Monica, CA: RAND, MR-1500-CMS. Accessed January 2008 at http://www.rand.org/pubs/monograph_reports/MR1500/.
- Carter, J., et al. (2006). *Making the "Minimum Data Set" Compliant with Health Information Technology Standards*. Washington, DC: HHS Office of Disability, Aging and Long-Term Care Policy. Accessed January 2008 at <http://aspe.hhs.gov/daltcp/reports/2006/MDS-HIT.htm>.
- CENDI Copyright Task Group (2002). *Frequently Asked Questions About Copyright: Issues Affecting the U.S. Government*. Oak Ridge, TN: CENDI Secretariat, Information International Associates, Inc. Accessed at <http://www.cendi.gov/publications/04-8copyright.html#41>.
- Centers for Medicare & Medicaid Services [CMS] (2007, October 23). *Data Collection for Administering the Medicare Continuity Assessment Record and Evaluation (CARE) Instrument*. OMB Clearance Package Supporting Statement Part A.
- CMS (2007, July 17). *Data Collection for Administering the Medicare Continuity Assessment Record and Evaluation (CARE) Instrument*. OMB Clearance Package Supporting Statement-Part A. Accessed January 2008 at <http://www.cms.hhs.gov/PaperworkReductionActof1995/Downloads/CMS-10243.zip>.
- CMS (2006, July 31). *Draft Minimum Data Set, Version 3.0 (MDS 3.0) For Nursing Home Resident and Care Screening*. Accessed at <http://www.cms.hhs.gov/NursingHomeQualityInits/Downloads/MDS30Draft.pdf>.
- CMS. Home Health Quality Initiatives. Accessed December 2007 at <http://www.cms.hhs.gov/HomeHealthQualityInits/>.
- CMS. IRF Patient Assessment Instrument. Accessed January 2008 at <http://www.cms.hhs.gov/InpatientRehabFacPPS/>.
- CMS. MDS 2.0 for Nursing Homes. Accessed January 2008 at http://www.cms.hhs.gov/NursingHomeQualityInits/20_NHQIMDS20.asp.
- CMS. MDS 3.0 for Nursing Homes: Minimum Data Set (MDS) 3.0. Accessed at http://www.cms.hhs.gov/NursingHomeQualityInits/25_NHQIMDS30.asp.
- CMS (2005, April). MDS 3.0 Update. Accessed at <http://www.cms.hhs.gov/NursingHomeQualityInits/downloads/MDS30MDS30Update.pdf>.
- CMS. [MDS 3.0]: Phase 1 -- 2003 Stakeholder and Expert Review. Accessed at http://www.cms.hhs.gov/NursingHomeQualityInits/25_NHQIMDS30.asp.
- CMS. [MDS 3.0]: Phase 2 -- VA Validation Protocol Research. Accessed at http://www.cms.hhs.gov/NursingHomeQualityInits/25_NHQIMDS30.asp.

- CMS (2005, December 23). Medicare and Medicaid Programs: Reporting Outcome and ASessment Information Set Data as Part of the Conditions of Participation for Home Health Agencies. Final Rule (70 FR 76199). Accessed at <http://a257.g.akamaitech.net/7/257/2422/01jan20051800/edocket.access.gpo.gov/2005/05-24389.htm>.
- CMS (2007, August 29). Medicare Program; Home Health Prospective Payment System Refinement and Rate Update for Calendar Year 2008; Final Rule (72 FR 49761). Accessed at <http://a257.g.akamaitech.net/7/257/2422/01jan20071800/edocket.access.gpo.gov/2007/07-4184.htm>.
- CMS. Nursing Home Quality Initiatives: MDS 2.0 for Nursing Homes. Accessed January 2008 at http://www.cms.hhs.gov/NursingHomeQualityInits/20_NHQIMDS20.asp.
- CMS. OASIS User Manual. Accessed December 2007 at http://www.cms.hhs.gov/HomeHealthQualityInits/14_HHQIOASISUserManual.asp.
- CMS. OASIS web site. Accessed December 2007 at <http://www.cms.hhs.gov/OASIS>.
- CMS (2001, December 27). Privacy Act of 1974; Report of a Modified or Altered System (66 FR 66903). Accessed at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=2001_register&docid=01-31546-filed.
- CMS (2002, December; revised March 2007). *Revised Long-Term Care Facility Resident Assessment Instrument User's Manual. Version 2.0*. Accessed at http://www.cms.hhs.gov/NursingHomeQualityInits/20_NHQIMDS20.asp.
- CMS (2002, December; revised January 2008). *Revised Long-Term Care Facility Resident Assessment Instrument User's Manual. Version 2.0*. Accessed January 2008 at <http://www.cms.hhs.gov/NursingHomeQualityInits/Downloads/MDS20RAIUsersManual.zip>.
- CMS (2008, January 24). Special Open Door Forum on Minimum Data Set 3.0 (MDS 3.0). Transcript accessed at http://www.cms.hhs.gov/OpenDoorForums/05_ODF_SpecialODF.asp.
- Choi, J., Jenkins, M.L., Cimino, J.J., White, T.M., & Bakken, S. (2005). "Toward semantic interoperability in home health care: Formally Representing OASIS items for integration into a concept-oriented terminology." *Journal of the American Medical Informatics Association*, 12: 410-417. PubMed link <http://www.ncbi.nlm.nih.gov/pubmed/15802480>.
- Code of Federal Regulations*. Accessed at <http://www.gpoaccess.gov/cfr/index.html>.
- Code of Federal Regulations*. CFR 42 §484 Public Health. Chapter IV-Health Care Financing Administration, Department of Health and Human Services. Part 484 -- Conditions of Participation: Home Health Agencies. Accessed December 2007 at http://www.access.gpo.gov/nara/cfr/waisidx_06/42cfr484_06.html.
- Connolly, Robert (2007, October). MDS 3.0 Implementation Plans. Presented at the National Academy for State Health Policy's 20th Annual State Health Policy Conference in Denver, CO.

- Consolidated Health Informatics (2006). Standards Adoption Recommendation -- Functioning and Disability. Accessed at <http://www.ncvhs.hhs.gov/061011p2b.pdf>.
- Cotterill, P.G., & Gage, B.J. (2002). "Overview: Medicare post-acute care since the Balanced Budget Act of 1997." *Health Care Financ Rev*, 24: 1-6. Accessed January 2008 at http://www.cms.hhs.gov/HealthCareFinancingReview/Downloads/Winter_2002_Post_Acute_Care.zip.
- Deficit Reduction Act of 2005. Public Law 109-171 (Section 5008). Accessed at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=109_cong_public_laws&docid=f:publ171.109.
- Dellefield, M.E. (2007). "Implementation of the resident assessment instrument/minimum data set in the nursing home as organization: Implications for quality improvement in RN clinical assessment." *Geriatric Nursing*, 28: 377-386. PubMed link <http://www.ncbi.nlm.nih.gov/pubmed/18068821>.
- Department of Health & Human Services (2007, December 17). Additional Consolidated Health Information (CHI) Health Information Technology Standards. 72 *Federal Register* 71413-14. Accessed at <http://a257.g.akamaitech.net/7/257/2422/01jan20071800/edocket.access.gpo.gov/2007/07-6058.htm>.
- Dougherty, Michelle (2001). "Documentation in the Long Term Care Record," In *Long Term Care Health Information Practice and Documentation Guidelines*. Chicago, IL: Foundation of Research and Education of the American Health Information Management Association. Accessed January 2008 at http://library.ahima.org/xpedio/groups/public/documents/ahima/bok2_001235.hcsp.
- Dougherty, Michelle, & Mitchell, Sue (2004, November/December). "Getting better data from the MDS: Improving diagnostic data reporting in long-term care facilities." *Journal of AHIMA*, 75(10): 28-33. PubMed link <http://www.ncbi.nlm.nih.gov/pubmed/15559836>.
- Federal Register*. Access at <http://www.gpoaccess.gov/fr/index.html>.
- Fiedler, Roger C., Granger, Carl V. & Russell, Carol F. (2000, March/April). "UDSMRSM: Follow-up data on patients discharged in 1994-1996." *American Journal of Physical Medicine & Rehabilitation*, 79(2): 184-192. PubMed link <http://www.ncbi.nlm.nih.gov/pubmed/10744194>.
- Fries, Brant. Curriculum Vitae. Accessed January 2008 at <http://www.sph.umich.edu/faculty/pdf/bfries.pdf>.
- Fries, B.E. (2005, July 22). Testimony: [Building Great Assessment Systems: Lessons from the interRAI Collaborative], Public Hearing, Reports and Testimony, National Commission for Quality Long-Term Care. Accessed at: <http://www.qualitylongtermcarecommission.org/meetings/722PH/pdf/txstmtRQlfries07-18-05.pdf>.

- Fries, Brant E., Morris, John N., Bernabei, Roberto, Finne-Soveri, Harriet, & Hirdes, John (2007, July). "Rethinking the resident assessment protocols." *Journal of the American Geriatrics Society*, 55(7): 1139-1140. PubMed link <http://www.ncbi.nlm.nih.gov/pubmed/17608893>.
- Fries, B.E., Simon, S.E., Morris, J.N., Flodstrom, C., & Bookstein, F.L. (2001). "Pain in U.S. nursing homes: Validating a pain scale for the minimum data set." *The Gerontologist*, 41(2): 173-9. PubMed link <http://www.ncbi.nlm.nih.gov/pubmed/11327482>.
- Gage, B., & Green, J. (2006). "The State of the Art: Current CMS PAC Instruments." In *Uniform Patient Assessment for Post-Acute Care*. Aurora, CO: Division of Health Care Policy and Research, University of Colorado at Denver, and Health Sciences Center. Accessed at <http://www.bu.edu/hdr/documents/QualityPACFullReport.pdf>.
- General Accounting Office (2001, January). "Appendix II: Development and Testing of the OASIS Data Set." In *Medicare Home Health Care: OASIS Data Use, Cost, and Privacy Implications*. Washington, DC: General Accounting Office. Accessed at <http://www.gao.gov/new.items/d01205.pdf>.
- Government Accountability Office (2005, April). *Medicare: More Specific Criteria Needed to Classify Inpatient Rehabilitation Facilities*. Report to the Senate Committee on Finance and the House Committee on Ways and Means. Accessed at <http://www.gao.gov/new.items/d05366.pdf>.
- Granger, Carl V. (2008). Quality and Outcome Measures for Rehabilitation Programs. eMedicine <http://emedicine.medscape.com/article/317865-overview>.
- Granger, C.V. (2007, September 17). UDSMR Comment Letter re: CMS CARE Tool and PAC-PRD Demonstration.
- Granger, C.V., Deutsch, A., Russell, C., Black, T., & Ottenbacher, K.J. (2007). "Modifications of the FIM[®] instrument under the inpatient rehabilitation facility prospective payment system." *Am J Phys Med Rehabil*. PubMed link <http://www.ncbi.nlm.nih.gov/pubmed/17873825>.
- Granger, C., et al. (2007). "Modifications of the FIM[®] instrument under the inpatient rehabilitation facility prospective payment system." *Am J Phys Med Rehabil*, 86(11): 883-892. PubMed link <http://www.ncbi.nlm.nih.gov/pubmed/17873825>.
- Hamilton, B.B., Granger, C.V., Sherwin, F.S., Zielezny, M., & Tashman, J.S. (1987). "A Uniform National Data System for Medical Rehabilitation." In *Rehabilitation Outcomes: Analysis and Measurement*. Baltimore, MD: Brookes (pp. 137-47).
- Harada, N.D., Kominski, G., & Sofaer, S. (1993). "Development of a resource-based classification for rehabilitation." *Inquiry*, 30(1): 54-63. PubMed link <http://www.ncbi.nlm.nih.gov/pubmed/8454315>.
- Harris, M., Chute, C.G., Harvell, J., et al. *Toward a National Health Information Infrastructure: a Key Strategy for Improving Quality in Long-Term Care*. Washington, DC: HHS Office of Disability, Aging and Long-Term Care Policy. Accessed at <http://aspe.hhs.gov/daltcp/reports/toward.htm>.

- Harris, Y., & Clauser, S.B. (2002). "Achieving improvement through nursing home quality measurement." *Health Care Financ Rev*, 23: 5-18. PubMed link <http://www.ncbi.nlm.nih.gov/pubmed/12500467>.
- Hawes, C., Mor, V., Phillips, C.D., Fries, B.E., Morris, J.N., Steele-Friedlob, E., et al. (1997). "The OBRA-87 nursing home regulations and implementation of the resident assessment instrument: Effects on process quality." *J Am Geriatr Soc*, 45: 977-85. PubMed link <http://www.ncbi.nlm.nih.gov/pubmed/9256852>.
- Hawes, C., Morris, J.N., Phillips, C.D., Fries, B.E., Murphy, K., & Mor, V. (1997). "Development of the nursing home resident assessment instrument in the USA." *Age Ageing*, 26: 19-25. PubMed link <http://www.ncbi.nlm.nih.gov/pubmed/9464550>.
- Health Care Financing Administration [HCFA] (1999, January 25). *Medicare and Medicaid Programs: Reporting Outcome and ASsessment Information Set (OASIS) Data as Part of the Conditions of Participation for Home Health Agencies and Comprehensive Assessment and Use of the OASIS as Part of the Conditions of Participation for Home Health Agencies*. Interim Final Rule with Comment (64 FR 3748-3763). Accessed at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=1999_register&docid=99-1448-filed.
- HCFA (1999, January 25). *Medicare and Medicaid Programs: Comprehensive Assessment and Use of the OASIS as Part of the Conditions of Participation for Home Health Agencies*. Final Rule (64 FR 3764-3784). Accessed at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=1999_register&docid=99-1449-filed.
- HCFA (1999, June 18). *Medicare and Medicaid Programs: Mandatory Use, Collection, Encoding, and Transmission of Outcome and ASsessment Set (OASIS) for Home Health Agencies and Privacy Act of 1974; Report of New System; Notices* (64 FR 32983). Accessed at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=1999_register&docid=99-15529-filed.
- HCFA (1999, June 18). *Privacy Act of 1974; Report of New System* (64 FR 32992). Accessed at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=1999_register&docid=99-15530-filed.
- Herndon, R.M. (2006). *Handbook of Neurologic Rating Scales*. New York, NY: Demos Medical Publishing. Google Books link <http://books.google.com/books?id=w1yPmehSZ2cC&pg=PP1&dq=Handbook+of+Neurologic+Rating+Scales&sig=-Wq74yickQK8AsUDrddXMRbY7DE>.
- Hirdes, J.P. (2006). "Addressing the health needs of frail elderly people: Ontario's experience with an integrated health information system." *Age Ageing*, 35: 329-331. Accessed at <http://ageing.oxfordjournals.org/cgi/content/full/35/4/329>.
- Hirdes, Smith, Rabinowitz, Yamauchi, Pérez, Telegdi, et al. (2002). "The resident assessment instrument-mental health (RAI-MH): Inter-rater reliability and convergent validity." *Journal of Behavioral Health Services and Research*, 29: 419-432. PubMed link <http://www.ncbi.nlm.nih.gov/pubmed/12404936>.

- Holthaus, Danielle, & Kramer, Andrew Kramer (2006). "Introduction, Background, and Objectives." In *Uniform Patient Assessment for Post-Acute Care*. Aurora, CO: Division of Health Care Policy and Research, University of Colorado at Denver and Health Sciences Center, 2006. Accessed at <http://www.bu.edu/hdr/documents/QualityPACFullReport.pdf>.
- Ikegami, N., Hirdes, J.P., & Carpenter, I. (2002). "Measuring the Quality of Long-Term Care in Institutional and Community Settings." In *Measuring Up: Improving Health System Performance in OECD Countries*. Paris: OECD (pp. 277-293). Accessed at <http://www.ikwilwerken.nl/pdf/eu/8102011ehealthsystem.pdf>.
- Implementing the Resident Assessment Instrument: Case Studies of Policymaking for Long-Term Care in Eight Countries* (2003, May). Milbank Memorial Fund Electronic Reports. Accessed at http://www.milbank.org/reports/interRAI/ResidentAssessment_Mech2.pdf.
- Inouye S.K. (2003). *The Confusion Assessment Method (CAM): Training Manual and Coding Guide*. New Haven, CT: Yale University School of Medicine. Accessed at <http://elderlife.med.yale.edu/pdf/The%20Confusion%20Assessment%20Method.pdf>.
- The Inpatient Rehabilitation Facility -- Patient Assessment Instrument (IRF-PAI) Training Manual: Effective 4/01/04* (2004). UB Foundation Activities, Inc. Accessed January 2008 at [http://www.udsmr.org/pdfs/irfpaimanual040104%20\(1\).pdf](http://www.udsmr.org/pdfs/irfpaimanual040104%20(1).pdf).
- Integrating the Healthcare Enterprise (IHE) wiki. Functional Status Assessments (FSA) Integration Profile Supplement. Accessed at [http://wiki.ihe.net/index.php?title=Talk:Functional_Status_Assessments_\(FSA\)_Integration_Profile_Supplement](http://wiki.ihe.net/index.php?title=Talk:Functional_Status_Assessments_(FSA)_Integration_Profile_Supplement).
- interRAI web site. Accessed at <http://www.interrai.org/>.
- interRAI. Licensing with interRAI. Accessed January 2008 at <http://www.interrai.org/section/view/?fnode=32>.
- interRAI. Long Term Care Facility. Accessed January 15, 2008 at <http://www.interrai.org/section/view/?fnode=17>.
- Jette, A.M., Haley, S.M., & Ni, P. (2003). "Comparison of functional status tools used in post-acute care." *Health Care Financ Rev*, 24: 13-24. PubMed link <http://www.ncbi.nlm.nih.gov/pubmed/12894632>.
- Keillor, Ann, & Nutten, Sandra (1999). "Post-acute prospective payment: What you should know." *Journal of AHIMA*, 70(6): 24-30. PubMed link <http://www.ncbi.nlm.nih.gov/pubmed/10537621>.
- KPMG LLP (2006). *University at Buffalo Foundation, Inc. and Affiliates Consolidated Financial Statements, June 30, 2006 and 2005*. Accessed August 21, 2007 at <http://www.ubfoundation.buffalo.edu/z/node/360.pdf>.
- Kramer, A. (2004). *Case Studies of Electronic Health Records in Post-acute and Long-term Care*. Washington, DC: HHS Office of Disability, Aging and Long-Term Care Policy. Accessed at <http://aspe.hhs.gov/daltcp/reports/ehrpaltc.htm>.

- Liu, Korbin, Gage, Barbara, Harvell, Jennie, Stevenson, David, & Brennan, Niall (1999). *Medicare's Post-Acute Care Benefit: Background, Trends, and Issues to be Faced*. Washington, DC: HHS Office of Disability, Aging and Long-Term Care Policy. Accessed at <http://aspe.hhs.gov/daltcp/reports/1999/mpacb.htm>.
- LOINC. LOINC and RELMA Terms of Use. Accessed at <http://www.regenstrief.org/medinformatics/loinc/terms-of-use>.
- Matherlee, K. (1999). "Implementing the BBA: The challenge of moving Medicare post-acute services to PPS." *Issue Brief Natl Health Policy Forum*, 743: 1-8. Accessed at http://nhpf.ags.com/pdfs_ib/IB743_BBA_7-7-99.pdf.
- Medicare Conditions of Participation. Access available through the *Code of Federal Regulations* at 42 CFR 482 (Hospital -- http://www.access.gpo.gov/nara/cfr/waisidx_07/42cfr482_07.html); 42 CFR 483 (Long Term Care -- http://www.access.gpo.gov/nara/cfr/waisidx_07/42cfr483_07.html); 42 CFR 484 (Home health -- http://www.access.gpo.gov/nara/cfr/waisidx_07/42cfr484_07.html); 42 CFR 412 (Inpatient Rehabilitation Facilities -- http://www.access.gpo.gov/nara/cfr/waisidx_07/42cfr412_07.html).
- Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999. Public Law 106-113 (Appendix F). Accessed at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=106_cong_public_laws&docid=f:publ113.106.
- Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000. Public Law 106-554 (Appendix F). Accessed at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=106_cong_public_laws&docid=f:publ554.106.
- Medicare Payment Advisory Commission (2005). "Payment for Post-Acute Care." In *Report to the Congress: Issues in a Modernized Medicare Program*. Washington, DC: MedPAC (pp. 103-133). Accessed at http://www.medpac.gov/publications/congressional_reports/June05_ch5.pdf.
- Medicare Payment Advisory Commission (1999, March). "Post-Acute Care Providers: Moving Toward Prospective Payment." In *Report to Congress: Medicare Payment Policy*. Washington, DC: MedPAC (pp. 79-98). Accessed in http://www.medpac.gov/publications/congressional_reports/Mar99%20Ch5.pdf.
- Mor, V. (2004). "A comprehensive clinical assessment tool to inform policy and practice: Applications of the minimum data set." *Medical Care*, 42: 50-59. PubMed link <http://www.ncbi.nlm.nih.gov/pubmed/15026672>.
- Morris, J.N., Hawes, C., Fries, B.E., Phillips, C.D., Mor, V., Katz, S., et al. (1990). "Designing the national resident assessment instrument for nursing homes." *The Gerontologist*, 30: 293-307. PubMed link <http://www.ncbi.nlm.nih.gov/pubmed/2354790>.
- Murphy, Katharine M., & Morris, John N. (1995). "The resident assessment instrument: Implications for quality, reimbursement and research." *Generations*, 19(4): 43-46.

- National Library of Medicine [NLM] (2002). *Appendix to the License Agreement for Use of the UMLS® Metathesaurus*. LNC_OASIS_2002 (new) -- The Outcome and ASsessment Information Set (OASIS). Denver, CO: Center for Health Services Research, UCHSC. Accessed at <http://www.nlm.nih.gov/research/umls/metaa1.html>.
- NLM. UMLS web site. Accessed January 2008 at <http://www.nlm.nih.gov/research/umls/>.
- Office of Management & Budget (1999). Circular A-110 (revised November 19, 1993; as further amended September 30, 1999). Accessed at <http://www.whitehouse.gov/omb/circulars/a110/a110.html>.
- Ontario Joint Policy and Planning Committee (2002). *Evaluation and Selection of a Classification/Assessment Tool for Rehabilitation Care in Ontario*. Summary Report from the JPPC Rehabilitation Advisory Group. Accessed at http://www.jppc.org/new/files/acrobat/rd9_6.pdf.
- Patent & Trademark Office web site. Accessed December 2007 at <http://www.uspto.gov/>.
- RAND Health (2003, June 2,). "Evaluating Revisions to the Minimum Data Set for Nursing Homes." Presentation at CMS Town Hall Meeting on the MDS 3.0.
- RAND Health (2008, January 24). "The MDS 3.0: Improving Assessment." Special Open Door Forum.
- Reynolds, M. (2001). "Final inpatient rehabilitation PPS rule improves on proposed rule." *Healthc Financ Manage*, 55: 68-70. PubMed link <http://www.ncbi.nlm.nih.gov/pubmed/11588870>.
- Shaughnessy, P.W., Crisler, K.S., Schlenker, R.E., & Arnold, A.G. (1997). "Outcomes across the care continuum: Home health care." *Medical Care*, 35(11): NS115-NS123. PubMed link <http://www.ncbi.nlm.nih.gov/pubmed/9424484>.
- Shaughnessy, Peter W., Crisler, Kathryn S., Schlenker, Robert E., & Hittle, David F. "Medicare's OASIS: Standardized Outcome and ASsessment Information Set for Home Health Care -- July 1999." In *OASIS Implementation Manual 1/2008 Appendix B*. Accessed at <http://www.cms.hhs.gov/HomeHealthQualityInits/Downloads/HHQIOASISAppendices.zip>.
- Shaughnessy, Peter W., et al. (2002, March). Summary of the Report on OASIS and Outcome-Based Quality Improvement in Home Health Care: Research and Demonstration Findings, Policy Implications, and Considerations for Future Change. Denver, CO: Center for Health Services Research, University of Colorado Health Sciences Center. Accessed December 2007 at <http://www.cms.hhs.gov/HomeHealthQualityInits/Downloads/HHQIOASISReportSummary.pdf>.
- Spector, W.D., & Drugovich, M.L. (1989). "Reforming nursing home quality regulation: Impact on cited deficiencies and nursing home outcomes." *Medical Care*, 27: 789-801. PubMed link <http://www.ncbi.nlm.nih.gov/pubmed/2755219>.

- Spector, William D., Potter, D.E.B., & De La Mare, Jan (2000, October). *Future Directions for Residential Long-Term Care Health Services Research. Expert Meeting Summary*. Rockville, MD: Agency for Healthcare Research and Quality, AHRQ Publication No. 01-0007. Accessed at <http://www.ahrq.gov/research/futureltc/summary1.htm>.
- Stineman, M.G., Escarce, J.J., Goin, J.E., Hamilton, B.B., Granger, C.V., & Williams, S.V. (1994). "A case-mix classification system for medical rehabilitation." *Medical Care*, 32: 366-379. PubMed link <http://www.ncbi.nlm.nih.gov/pubmed/8139301>.
- Stineman, M.G., Tassoni, C.J., Escarce, J.J., Goin, J.E., Granger, C.V., Fiedler, R.C., et al. (1997). "Development of function related groups version 2.0: A classification system for medical rehabilitation." *Health Services Research*, 32: 529-548. PubMed Central link <http://www.pubmedcentral.nih.gov/articlerender.fcgi?tool=pubmed&pubmedid=9327817>.
- Tesio, L., Granger, C.V., Perucca, L., Franchignoni, F.P., Battaglia, M.A., & Russell, C.F. (2002). "The FIM[®](TM) instrument in the United States and Italy: A comparative study." *Am J Phys Med Rehabil*, 81: 168-176. PubMed link <http://www.ncbi.nlm.nih.gov/pubmed/11989512>.
- Trela, Patricia (2002). "Inpatient rehabilitation PPS presents new challenges, opportunities." *Journal of AHIMA*, 73(1): 48A-D. PubMed link <http://www.ncbi.nlm.nih.gov/pubmed/12469663>.
- Trela, Patricia (2007, May). "IRF PPS coding challenges." *Journal of AHIMA*, 78(5): 70-71. PubMed link <http://www.ncbi.nlm.nih.gov/pubmed/17552328>.
- Trosow, S.E. (2003). *Copyright Protection for Federally Funded Research: Necessary Incentive or Double Subsidy?*. Accessed at http://publish.uwo.ca/~strosow/Sabo_Bill_Paper.pdf.
- UDSMR web site. Accessed January 2008 at <http://www.udsmr.org/> and <http://www.fimsystem.com/>.
- U.S. Copyright Office. Accessed December 2007 at <http://www.copyright.gov/>.
- U.S. District Court, Western District of New York. "UB Foundation Activities, Inc., plaintiff v. IT Healthtrack, Inc. and Dr. Pamela Smith, Defendants." Docket report and filed documents. Case Filed June 14, 2004. Accessed December 2007 at <http://pacer.psc.uscourts.gov>.
- University of Colorado, Center for Health Services and Policy Research. Right to Copy, Reprint, and Use Oasis. Accessed December 2007 at <http://www.cms.hhs.gov/HomeHealthQualityInits/downloads/HHQIOASISDataSetPermit.pdf>.
- University of Colorado, Center for Health Services Research, Division of Health Care Policy and Research. Accessed December 2007 at <https://www2.uchsc.edu/chsr/index.shtml>.
- University of Michigan. U-M Researcher Leads Development of Health Care Standards (Press release). Accessed at <http://www.umich.edu/news/index.html?Releases/2005/Apr05/r041805c>.

- Velozo, C.A., Byers, K.L., & Joseph, B.R. (2007). "Translating measures across the continuum of care: Using Rasch analysis to create a crosswalk between the Functional Independence Measure and the Minimum Data Set." *Journal of Rehabilitation Research and Development*, 44(3): 467-478. PubMed link <http://www.ncbi.nlm.nih.gov/pubmed/18247243>.
- Wark, C.G., Insley, M.L., Tillery, L.S., & Orvis, N.J. (2004). "Government issue: CHI lays the groundwork for federal data exchange." *Journal of AHIMA/American Health Information Management Association*, 75: 36-8. PubMed link <http://www.ncbi.nlm.nih.gov/pubmed/15455567>.
- Wunderlich, Gooloo S., & Kohler, Peter O., eds. (2001). *Improving the Quality of Long Term Care*. Committee on Improving Quality in Long-Term Care, Division of Health Care Services, Institute of Medicine. Washington DC: National Academies Press. Accessed December 2007 at http://www.nap.edu/catalog.php?record_id=9611.

ENDNOTES

1. Wark, Cynthia G., et al. "Government Issue: CHI Lays the Groundwork for Federal Data Exchange." *Journal of AHIMA* 75, no.8 (September 2004): 36-38.
2. Consolidated Health Informatics (2006). Standards Adoption Recommendation -- Functioning and Disability. <http://www.ncvhs.hhs.gov/061011p2b.pdf>; NCVHS's letter to the Secretary and Secretary Leavitt's response are available on the NCVHS web site at <http://www.ncvhs.hhs.gov/sssmemb.htm>.
3. U.S. Department of Health and Human Services. "Additional Consolidated Health Information (CHI) Health Information Technology Standards" 72 *Federal Register* 71413-14 (December 17, 2007) Accessed January 2008 at <http://a257.g.akamaitech.net/7/257/2422/01jan20071800/edocket.access.gpo.gov/2007/07-6058.htm>.
4. For purposes of this report, post-acute care services are defined as services received after patients are discharged from hospital stays to a skilled nursing facility (SNF), a home health agency (HHA), and/or a rehabilitation hospital/unit -- inpatient rehabilitation facility (IRF).
5. Kramer, Andrew, et al. *Case Studies of Electronic Health Records in Post-Acute and Long-Term Care*. Washington, DC: U.S. Dept. of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation, Office of Disability and Long-Term Care Policy, 2004. <http://aspe.hhs.gov/daltcp/reports/ehrpaltc.htm>.
6. Kramer. *Case Studies*. (2004).
7. Gage, Barbara, and Jeremy Green. "The State of the Art: Current CMS PAC Instruments" *Uniform Patient Assessment for Post-Acute Care* (Aurora, CO: Division of Health Care Policy and Research, University of Colorado at Denver and Health Sciences Center, 2006), accessed at <http://www.bu.edu/hdr/documents/QualityPACFullReport.pdf>.
8. Wang, 2008.
9. 74 *Federal Register* 10050 (March 9, 2009) and 74 *Federal Register* 22208 (May 12, 2009).
10. 74 FR 10050 (March 9, 2009).
11. See <http://www.nasl.org/files/members/IT/mds3-1-15-09.pdf>.
12. National Association for Home Care and Hospice, AAHSA, AHIMA, CAST, National Association for the Support of Long Term Care. Response re: Information Collection -- Medicare and Medicaid Programs OASIS Collection Requirements as Part of the CoPs for HHAs and Supporting Regulations in 42 CFR, Sections 484.55, 484.205, 484.245, 484.250 [74FR10050] (April 8, 2009) accessed online at

- <http://www.ahima.org/dc/documents/AHIMArespondstoOMBreviewrequestforCMSOASISCollectionRequirements.pdf>. AHIMA. Comments on the Centers for Medicare & Medicaid Services' (CMS) proposed changes to the Skilled Nursing Facilities Inpatient Prospective Payment Systems (SBF-PPS) as published in the May 12, 2009 *Federal Register* [74FR22208].
13. AHIMA. Comments on the Centers for Medicare & Medicaid Services' (CMS) proposed changes to the Skilled Nursing Facilities Inpatient Prospective Payment Systems (SBF-PPS) as published in the May 12, 2009 *Federal Register* [74FR22208].
 14. 74 *Federal Register* 40287 (August 11, 2009).
 15. Chan, Leighton, Thomas D. Koepsell, Richard A. Deyo, Peter C. Esselman, Jodie K. Haselkorn, Joseph K. Lowery, and Walter C. Stolov. 1997. The Effect of Medicare's Payment System for Rehabilitation Hospitals on Length of Stay, Charges, and Total Payments. *N Engl J Med* 337, no. 14: 978-985.
<http://content.nejm.org/cgi/content/abstract/337/14/978>.
 16. Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999, Pub.L. 106-113.
 17. Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, Pub.L. 106-554.
 18. Deficit Reduction Act of 2005 (DRA 2005). Pub.L. 109-171.
 19. Matherlee, Karen. "Implementing the BBA: the Challenge of Moving Medicare Post-Acute Services to PPS." *National Health Policy Forum Issue Brief No.743* (Washington, DC: The George Washington University, 1999).
 20. Pub.L. 106-554. Appx F -- Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000. Section 545.
 21. DRA 2005. Accessed at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=109_cong_public_laws&docid=f:publ171.109.
 22. U.S. Office of Management and Budget. "Data Collection for Administering the Medicare Continuity Assessment Record and Evaluation (CARE) Instrument" Clearance Package Supporting Statement Part A. (Washington, DC: Centers for Medicare and Medicaid Services, July 17, 2007).
 23. Avalere Health LLC. (2009). *Post-acute and Long-term Care Reform: Estimating the Federal Budgetary Effects of the AHCA/NCAL/Alliance Proposal*. Retrieved July 16, 2009, from <http://post-acute.org/bundling/Avalere%20Report%20prepared%20for%20AHCA-NCAL-Alliance%20on%20Post-acute%20and%20Long-term%20Care,%20April%202009.pdf>.

24. Talk: Functional Status Assessments (FSA) Integration Profile Supplement (IHE wiki) accessed at [http://wiki.ihe.net/index.php?title=Talk:Functional Status Assessments \(FSA\) Integrati on Profile Supplement](http://wiki.ihe.net/index.php?title=Talk:Functional_Status_Assessments_(FSA)_Integrati_on_Profile_Supplement).
25. Granger, Carl V. "UDSMR Comment Letter re: CMS CARE tool and PAC-PRD Demonstration". (September 17, 2007).
26. Testimony of Brant E. Fries, Professor, Department of Health Management and Policy, University of Michigan School of Public Health, Public Hearing, Reports and Testimony, July 22, 2005. (Washington, DC: National Commission for Quality Long-Term Care) accessed at <http://www.qualitylongtermcarecommission.org/meetings/722PH/pdf/txstmtRQlfries07-18-05.pdf>.
27. U.S. Office of Management and Budget Circular A-110 (revised November 19, 1993; as further amended September 30, 1999), codified at 45 CFR §74.36 and 45 CFR §92.34 for the Department of Health and Human Service and 34 CFR §74.36 and 34 CFR §80.34 for the U.S. Department of Education, applies to grants awarded to nonprofit institutions; Federal Acquisition Regulation 52.227 (Rights in Data clauses begin with 227-14), codified at 48 C.F.R. §52.227-14-18 applies to data rights in the performance of contracts with federal agencies.
28. CENDI Copyright Task Group. *Frequently Asked Questions About Copyright: Issues Affecting the U.S. Government*. (Oak Ridge, TN: CENDI Secretariat, Information International Associates, Inc., 2002; updated August 2007) accessed at <http://www.cendi.gov/publications/04-8copyright.html#41>.
29. OMB Circular A-110 is codified at 45 CFR §74.36 and 45 CFR §92.34 for the Department of Health and Human Service and 34 CFR §74.36 and 34 CFR §80.34 for the U.S. Department of Education.
30. U.S. Office of Management and Budget. Circular A-110 (revised November 19, 1993; as further amended September 30, 1999) <http://www.whitehouse.gov/omb/circulars/a110/a110.html#36>. Text from earlier versions of Circular A-110, in affect at the time of the contract or grant awards, is available in the relevant sections of the *Code of Federal Regulations*, referenced above. See also "The Federal Grant and Cooperative Agreement Act" (31 USC 6301-08), available at http://www.access.gpo.gov/uscode/title31/subtitlev_chapter63_.html for further guidance on the use of contracts, grants, and cooperative agreements.
31. Federal Acquisition Regulation. 48 CFR §27 (Patents, Data, and Copyrights). Solicitation provisions and contract clauses are addressed at 48 CFR §52.227-14 (Rights in Data -- General); §52.227-17 (Rights in Data -- Special Works); §52.227-18 (Rights in Data -- Existing Works).
32. FAR 52.227-17(c)(1).

33. Trosow, Samuel E.I. *Copyright Protection for Federally Funded Research: Necessary Incentive or Double Subsidy?* (draft paper September 7, 2003). Accessed at http://publish.uwo.ca/~strosow/Sabo_Bill_Paper.pdf.
34. 72 *Federal Register* 71413-14 (December 17, 2007).
35. U.S. Centers for Medicare & Medicaid Services (CMS). *Data Collection for Administering the Medicare Continuity Assessment Record and Evaluation (CARE) Instrument*. (OMB Clearance Package Supporting Statement Part A. (October 23, 2007).
36. U.S. Centers for Medicare & Medicaid Services (CMS). *Revised Long-Term Care Facility Resident Assessment Instrument User's Manual: version 2.0* (December 2002, revised March 2007).
37. CMS. *RAI 2.0 User's Manual*.
38. Wunderlich, G.S., & Kohler, P.O. "Information Systems for Monitoring Quality" *Improving the Quality of Long-Term Care* (Washington, DC: National Academies Press, 2001).
39. Information about RAVEN software is accessible at http://www.cms.hhs.gov/MinimumDataSets20/07_RAVENSoftware.asp.
40. Regulations are available on the *Federal Register* web site at <http://www.gpoaccess.gov/fr/index.html>. These regulations have been codified at 42 CFR 483.20 (Public Health, Requirements for States and Long Term Care Facilities, Resident Assessment). CFR 483.75 covers the confidentiality issues. Other relevant legislation affecting the MDS includes the Omnibus Budget Reconciliation Act of 1987. P.L. 100-203. Subtitle C: Nursing Home Reform. (OBRA 1987) and the Balanced Budget Act of 1997 (BBA 1997) (establishing the PPS system). Section 1819 of the Social Security Act contains the regulations for skilled nursing facilities participating in the Medicare program and section 1919 contains the regulations for nursing facilities participating in the Medicaid program. Annual updates to the prospective payment system (PPS) rates for skilled nursing facilities (SNFs) are required by section 1888(e) of the Social Security Act, added by section 4432 of the Balanced Budget Act of 1997 (BBA), and amended by the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA), the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA).
41. Smith vs. O'Halloran, 55i F Supp. 289 (Denver, Colorado Circuit, in 1983.), reversed subnom. Smith vs, Heckler, i37 F2nd 583 (10th Cir 1984) see Spector, W.D., & Drugovich, M.L. (1989). "Reforming Nursing Home Quality Regulation: Impact on Cited Deficiencies and Nursing Home Outcomes." *Medical Care*, 27, 789-801.
42. Morris, J.N., Hawes, C., Fries, B.E., Phillips, C.D., Mor, V., Katz, S., et al. (1990). "Designing the national resident assessment instrument for nursing homes." *The Gerontologist*, 30, 293-307.
43. Institute of Medicine. Committee on Nursing Home Regulation. *Improving the Quality of Care in Nursing Homes*. (Washington, DC: National Academy Press, 1986).

44. Hawes, C., Mor, V., Phillips, C.D., Fries, B.E., Morris, J.N., Steele-Friedlob, E., et al. (1997). "The OBRA-87 nursing home regulations and implementation of the Resident Assessment Instrument: effects on process quality." *J Am Geriatr Soc*, 45, 977-85.
45. U.S. Centers for Medicare & Medicaid Services. "Minimum Data Set (MDS) 3.0 Timeline" accessed at <http://www.cms.hhs.gov/NursingHomeQualityInits/downloads/MDS302010ImplementationTimeline.pdf>.
46. Cotterill, P.G., & Gage, B.J. (2002). "Overview: Medicare post-acute care since the Balanced Budget Act of 1997." *Health Care Financ Rev*, 24, 1-6.
47. 63 FR 26252-26316 (May 12, 1998).
48. "Development of Resident Assessment System and Data Base for Nursing Home Residents," Health Care Financing Administration (#500-88-0055); October 1988; 4 years, \$3.5 million (extended to 6 years, \$4.9 million) to Research Triangle Institute, with Brown University, Hebrew Rehabilitation Center for the Aging and The University of Michigan. See Fries, Brant. "Curriculum Vitae" Accessed January 2008 at <http://www.sph.umich.edu/faculty/pdf/bfries.pdf>.
49. Morris (1990).
50. "Revision of Resident Assessment Instrument (RAI) and Development of Resident Assessment Protocols (RAPs)," Centers for Medicare and Medicaid Systems (#500-94-0058); September 30, 1994; 6 years, \$465,000 to Hebrew Rehabilitation Center for Aged; Principal Investigator: J. Morris; Co-Principal Investigator [Brant Fries]. Refine Version 2 and develop Version 3 of the National Nursing Home Resident Assessment Instrument, develop the RAI-PAC assessment instrument for post-acute care, and evaluate the nursing home population under age 65." See Fries, "Curriculum Vitae".
51. interRAI web site. "Long Term Care Facility". Accessed January 2008 at <http://www.interrai.org/section/view/?fnode=17>.
52. See Fries et al. letter to the editor, *Journal of the American Geriatrics Society*, July 2007.
53. The letter to the editor from Lisa Hines at the Office of Clinical Standards and Quality of the Health Care Financing Administration objected to the use by the authors, who were also investigators associated with contractors or subcontractors on the HCFA MDS contracts, of the designation "InterRAI-HCFA" in describing the work that was being done under contract to HCFA. The author of the letter wanted to make it clear that the contract was not with interRAI, and that whatever relationship the authors had with interRAI, their work on the contract had nothing to do with that relationship but due to the fact that they were experts in the field. Hines, L. (2001). Response to "Pain in U.S. nursing homes: validating a pain scale for the Minimum Data Set". *The Gerontologist*, 41(4), 553.

54. U.S. Centers for Medicare & Medicaid Services. MDS 3.0 Town Hall Meeting Conference Call. Transcript (June 3, 2003) Accessed at http://www.cms.hhs.gov/NursingHomeQualityInits/25_NHQIMDS30.asp.
55. U.S. Centers for Medicare & Medicaid Services. [MDS 3.0]: Phase 1 -- 2003 Stakeholder and Expert Review. Accessed at http://www.cms.hhs.gov/NursingHomeQualityInits/25_NHQIMDS30.asp.
56. U.S. Centers for Medicare & Medicaid Services. *Draft Minimum Data Set, Version 3.0 (MDS 3.0) For Nursing Home Resident and Care Screening*. (July 31, 2006) <http://www.cms.hhs.gov/NursingHomeQualityInits/Downloads/MDS30Draft.pdf>.
57. RAND Health. "The MDS 3.0: Improving Assessment." Special Open Door Forum, January 24, 2008.
58. U.S. CMS [MDS 3.0]: Phase 1 -- 2003 Stakeholder and Expert Review.
59. RAND Health. "Evaluating Revisions to the Minimum Data Set for Nursing Homes" Presentation at CMS Town Hall Meeting on the MDS 3.0 (June 2, 2003).
60. U.S. Centers for Medicare & Medicaid Services. [MDS 3.0]: Phase 2 -- VA Validation Protocol Research. Accessed at http://www.cms.hhs.gov/NursingHomeQualityInits/25_NHQIMDS30.asp.
61. RAND Corporation. (April 2008). *Development & Validation of a Revised Nursing Home Assessment Tool: MDS 3.0*.
62. Dougherty, Michelle, and Sue Mitchell. "Getting Better Data from the MDS: Improving Diagnostic Data Reporting in Long-term Care Facilities." *Journal of AHIMA* 75, no.10 (Nov-Dec 2004): 28-33. PubMed link <http://www.ncbi.nlm.nih.gov/pubmed/15559836>.
63. Letter to Barbara Paul, MD, Director, Quality Measurement and Health Assessment Group at CMS. Signees were the American Association of Homes and Services for the Aging, the American Association of Nurse Assessment Coordinators, the American Hospital Association, the American Health Care Association, the Catholic Health Association, the National Association of Directors of Nursing Administration in Long-Term Care, the National Association of Subacute and Post-Acute Care, the National Citizens Coalition for Nursing Home Reform, and the National Hospice and Palliative Care Association.
64. Apelon Inc., Making MDS 3.0 Compliant with CHI Standards: Project Summary (August 2005). Accessed at <http://aspe.hhs.gov/daltcp/reports/MDSprjsum.htm>.
65. 72 *Federal Register* 71413-14 (December 17, 2007).
66. *PPS Alert for Long-Term Care*, May 2009, p.7.
67. 74 *Federal Register* 22208 (May 12, 2009).

68. MDS 3.0 RAI Manual (November 2009).
<http://www.cms.hhs.gov/NursingHomeQualityInits/Downloads/MDS30RAIManual.zip>.
69. See <https://www.qtso.com/strive.html>.
70. U.S. Centers for Medicare & Medicaid Services. "Special Open Door Forum on Minimum Data Set 3.0 (MDS 3.0)." Transcript, January 24, 2008. Accessed at http://www.cms.hhs.gov/OpenDoorForums/05_ODF_SpecialODF.asp.
71. Connolly, Robert. "MDS 3.0 Implementation Plans." Presented at the National Academy for State Health Policy's 20th Annual State Health Policy Conference in Denver, Colorado (October 2007).
72. U.S. Centers for Medicare & Medicaid Services. "Nursing Home Quality Initiatives: MDS 2.0 for Nursing Homes" accessed January 2008 at http://www.cms.hhs.gov/NursingHomeQualityInits/20_NHQIMDS20.asp.
73. Morris, John N., Katharine Murphy, and Sue Nonemaker. *Long Term Care Facility Resident Assessment Instrument (RAI) User's Manual*. (HCFA, October 1995).
74. U.S. Centers for Medicare & Medicaid Services. *Revised Long-Term Care Facility Resident Assessment Instrument User's Manual: Version 2.0*. (December 2002; revised March 2007).
75. Murphy, Katharine M., and John N. Morris. "The resident assessment instrument: Implications for quality, reimbursement and research." *Generations*, Winter95, Vol. 19 Issue 4, p43-46.
76. Testimony of Brant E. Fries, Professor, Department of Health Management and Policy, University of Michigan School of Public Health, Public Hearing, Reports and Testimony, July 22, 2005. (Washington, DC: National Commission for Quality Long-Term Care) accessed at <http://www.qualitylongtermcarecommission.org/meetings/722PH/pdf/txstmtRQlfries07-18-05.pdf>.
77. *Implementing The Resident Assessment Instrument: Case Studies Of Policymaking For Long-Term Care In Eight Countries* (New York: Milbank Memorial Fund, 2003). Accessed at <http://www.milbank.org/reports/interRAI/030222interRAI.html>.
78. interRAI. "Licensing with interRAI." Accessed January 2008 at <http://www.interrai.org/section/view/?fnode=32>.
79. interRAI. "Licensing".
80. interRAI. "Licensing".
81. Hirdes, John P. et al., "The Resident Assessment Instrument-Mental Health (RAI-MH): Inter-Rater Reliability and Convergent Validity" *The Journal of Behavioral Health Services & Research* 2002, 29(4), 419-432.

82. Fries, B. E. (2005, July 22). Testimony of Brant E. Fries, Professor, Department of Health Management and Policy, University of Michigan School of Public Health. Public Hearing, Reports and Testimony, National Commission for Quality Long-Term Care. Accessed at:
<http://www.qualitylongtermcarecommission.org/meetings/722PH/pdf/txstmtRQIfries07-18-05.pdf>.
83. Hirdes, J. P. (2006). "Addressing the health needs of frail elderly people: Ontario's experience with an integrated health information system." *Age Ageing*, 35, 329-331.
84. Canadian Institute for Health Information. (2005) Resident Assessment Instrument (RAI) -- MDS 2.0[®] and RAPs Canadian Version, Second Edition, March 2005. Ordering information available at
http://secure.cihi.ca/cihiweb/dispPage.jsp?cw_page=bl_ccrs_29apr2005_e.
85. See http://www.kent.ac.uk/chss/interrai/develop/what_is_interrai.htm, <http://www.interrai-au.org/authorisation.htm>, and <http://ageing.hku.hk/interrai/index.html>.
86. Integrating the Healthcare Enterprise (IHE) wiki. "Follow-ups to 2/15 call from Tom White"
[http://wiki.ihe.net/index.php?title=Talk:Functional_Status_Assessments_\(FSA\)_Integration_Profile_Supplement#Follow-ups_to_2.2F15_call_from_Tom_White](http://wiki.ihe.net/index.php?title=Talk:Functional_Status_Assessments_(FSA)_Integration_Profile_Supplement#Follow-ups_to_2.2F15_call_from_Tom_White).
87. U.S. National Library of Medicine. National Institutes of Health. (2007) "License Agreement for Use of the UMLS[®] Metathesaurus[®]." Accessed January 2008 at
<http://wwwcf.nlm.nih.gov/umlslicense/snomed/license.cfm>.
88. LOINC. "LOINC and RELMA Terms of Use." Accessed January 2008 at
<http://www.regenstrief.org/medinformatics/loinc/terms-of-use>.
89. Copyright information concerning sources in the LOINC database is available from the full RELMA download available at
<http://www.regenstrief.org/medinformatics/loinc/downloads/files/loinc-and-relma-complete-download/gotoCopyrightedFile>. In the loincdb MS Access database, see the Source Organization table.
90. interRAI web site accessed at <http://www.interrai.org/section/view/?fnode=32>.
91. LTCQ, Inc. ["MDS Scales"] accessed January 2008 at
<http://www.ltcq.com/MDS%20Scales.pdf>.
92. CMS. Open Door Forum, held December 9, 2009.
93. See <http://elderlife.med.yale.edu/pdf/The%20Confusion%20Assessment%20Method.pdf>.
94. See http://www.qualitymeasures.ahrq.gov/summary/summary.aspx?ss=1&doc_id=369.
95. Personal communication between staff at the Regenstrief Institute and the Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services.

96. U.S. Centers for Medicare and Medicaid Research. U.S. Department of Health and Human Services. "OASIS Background". Accessed December 2007 at http://www.cms.hhs.gov/OASIS/02_Background.asp.
97. Shaughnessy, P.W., Crisler, K.S., Schlenker, R.E., & Arnold, A.G. (1997). "Outcomes across the Care Continuum: Home Health Care" *Medical Care*, 35(11), NS115-NS123.
98. U.S. Centers for Medicare & Medicaid Services. "OASIS: HAVEN." Accessed at http://www.cms.hhs.gov/OASIS/045_HAVEN.asp.
99. U.S. Centers for Medicare & Medicaid Services. "Home Health Quality Initiatives." Accessed December 2007 at <http://www.cms.hhs.gov/HomeHealthQualityInits/>.
100. Regulations published are available at the *Federal Register* web site: 64 FR 3748 (January 25, 1999), 64 FR 3764 (January 25, 1999), 64 FR 32983 (June 18, 1999), 64 FR 32992 (June 18, 1999), 66 FR 66903 (December 27, 2001), 70 FR 76199 (December 23, 2005), and 72 FR 49761 (August 29, 2007). Regulations have been codified at: CFR 42 §484 Public Health. Chapter IV-Health Care Financing Administration, Department of Health and Human Services. Part 484 -- Conditions of Participation: Home Health Agencies http://www.access.gpo.gov/nara/cfr/waisidx_06/42cfr484_06.html and CFR 42 §488 Public Health. Chapter IV-Health Care Financing Administration, Department of Health and Human Services. Part 488 -- Survey, Certification, and Enforcement Procedures. Sections relevant to OASIS include: CFR 42 §484.20 - Reporting OASIS Information; CFR 42 §484.11 -- Release of patient identifiable OASIS information; CFR 42 §484.55 -- Comprehensive Assessment of Patients, and CFR 42 §488.68 -- State agency responsibilities for OASIS collection and data base requirements. Other relevant legislation includes: the Social Security Act §1861(o) which required the establishment of a Home Health Prospective Payment System (HHPPS); the Social Security Act §1891(d) which required the Secretary of HHS to designate an assessment instrument for home health agencies to use; the Balanced Budget Act of 1997, which authorized the Secretary of HHS to require that home health agencies submit information for the purpose of implementing a prospective payment system (PPS) for HHAs, and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), which temporarily suspended the requirements in CFR §484.55 requiring comprehensive assessments for non-Medicare/non-Medicaid patients.
101. Center for Health Services Research. Division of Health Care Policy and Research. University of Colorado Health Sciences Center. Accessed December 2007 at <https://www2.uchsc.edu/chsr/index.shtml>.
102. "Home Health Quality Measures and Data Analysis". Contract # HHSM 500-2005-000181 T.O. #2. (Awarded September 2006).
103. U.S. Centers for Medicare & Medicaid Services. *Outcome and ASsessment Information Set : OASIS-C Guidance Manual*. September 2009. Accessed at http://www.cms.hhs.gov/homehealthqualityinits/14_hhqioasisusermanual.asp.

104. Center for Health Services and Policy Research. "Right to Copy, Reprint, and Use Oasis". Accessed December 2007 at <http://www.cms.hhs.gov/HomeHealthQualityInits/downloads/HHQIOASISDataSetPermit.pdf>.
105. Appendix to the License Agreement for Use of the UMLS[®] Metathesaurus LNC_OASIS_2002 (new) -- The Outcome and Assessment Information Set (OASIS), 2002, Center for Health Services Research, UCHSC, Denver, CO. Accessed at <http://www.nlm.nih.gov/research/umls/metaa1.html>.
106. LOINC. "LOINC and RELMA Terms of Use." Accessed January 2008 at <http://www.regenstrief.org/medinformatics/loinc/terms-of-use>.
107. Copyright information concerning sources in the LOINC database is available from the full RELMA download available at <http://www.regenstrief.org/medinformatics/loinc/downloads/files/loinc-and-relma-complete-download/gotoCopyrightedFile>. In the loincdb MS Access database, see the Source Organization table.
108. U.S. Centers for Medicare & Medicaid Services. OASIS Data Set. Accessed February 2008 at http://www.cms.hhs.gov/HomeHealthQualityInits/12_HHQIOASISDataSet.asp.
109. "Comprehensive Adult Nursing Assessment Including SOC/ROC Elements with CMS 485 Information" (Briggs Medical Service Company, 2003). Accessed December 2007 at <http://shop.briggscorp.com/pdf/3491P.pdf>.
110. Carter, G.M., & et al. (2002). *Analyses for the Initial Implementation of the Inpatient Rehabilitation Facility Prospective Payment System*. Retrieved from http://www.rand.org/pubs/monograph_reports/MR1500/.
111. "Item-by-Item IRF-PAI Coding Instructions" *The Inpatient Rehabilitation Facility -- Patient Assessment Instrument (IRF-PAI) Training Manual: Effective 4/01/04*. (Buffalo, NY: UB Foundation Activities, Inc., 2004), p. II-1. Accessed February 2008 at [http://www.udsmr.org/pdfs/irfpaimanual040104%20\(1\).pdf](http://www.udsmr.org/pdfs/irfpaimanual040104%20(1).pdf).
112. Regulatory notices can be found at "Medicare Program; Prospective Payment System for Inpatient Rehabilitation Facilities; Proposed Rule" 65 FR 66303-66442 (November 3, 2000) and "Medicare Program; Prospective Payment System for Inpatient Rehabilitation Facilities; Final Rule" 66 FR 41316-430. Updates to the Medicare Conditions of Participation for Inpatient Rehabilitation Facilities have been codified at 42 CFR, sections 412.610, 412.614 and 412.602. In order to participate in the Medicare program, hospitals must comply with Medicare Conditions of Participation, which are found at CFR 42 482 and subparts. Before performing an assessment using the IRF-PAI, a patient must be given several documents outlining their privacy rights, based on the Privacy Act of 1974 and HIPAA (1996).
113. 66 FR 41317 (August 7, 2001).
114. U.S. Centers for Medicare & Medicaid Services. (2002) *IRF-PAI Training Manual*. "Appendix J: Relative Weights for Case-Mix Groups (CMGs)".

115. A list of qualifying conditions is available at http://www.cms.hhs.gov/InpatientRehabFacPPS/Downloads/IRF_PPS_75_percent_Rule_060807.pdf. This requirement has been one of the most controversial aspects of the IRF PPS. Implementation of the 75 percent rule was delayed several times and is being gradually phased in. For the last extension of the phase-in period for the 75 percent rule, see 44292 FR 72 (August 7, 2001) accessible at <http://a257.g.akamaitech.net/7/257/2422/01jan20071800/edocket.access.gpo.gov/2007/07-3789.htm>.
116. 66 FR 41323 (August 7, 2001).
117. 66 FR 41326 (August 7, 2001).
118. 66 FR 41325 (August 7, 2001).
119. 66 FR 56681-56687.
120. Trela, Patricia. "IRF PPS Coding Challenges." *Journal of AHIMA* 78, no.5 (May 2007): 70-71.
121. ACRM/AAPM&R Task Force, Uniform National Data System, Meeting Minutes (Las Vegas, NV, February 26, 1984).
122. Hamilton BB, Granger CV, Sherwin FS, Zielezny M, Tashman JS. "A uniform national data system for medical rehabilitation," in Fuhrer MJ (ed): *Rehabilitation Outcomes: Analysis and Measurement*. Baltimore, MD: Paul H Brookes Publishers, 1987, pp 137-147.
123. The Research Foundation of State University of New York, SUNY at Buffalo. "Proposal for Field Initiated Research Project: Development of a Uniform National Data System for Medical Rehabilitation." Submitted to the National Institute of Handicapped Research, Office of the Assistant Secretary for Special Education and Rehabilitative Services, U.S. Department of Education by the State University of New York at Buffalo, Department of Rehabilitation Medicine, Carl V. Granger, M.D., Project Director, Byron B. Hamilton, M.D., Principal Investigator. (May 21, 1984).
124. ACRM/AAPM&R Task Force, Uniform National Data System, Meeting Minutes (Las Vegas, NV, February 26, 1984).
125. A letter from Carl Granger to the American Hospital Association Section for Rehabilitation Hospitals and Programs suggesting how to respond to developers of existing assessment instruments included the text: "Several developers of disability assessment and rehabilitation outcome instruments and/or reporting systems have recommended that the Task Force adopt their products as a national system. The Task Force has noted the recommendations and implications of these requests and as a result has developed a position statement (appended) intended for wide dissemination concerning proprietary interests and development of the National Data System for Medical Rehabilitation.... The Task Force is attempting to anticipate the needs of the marketplace by developing an unbiased, valid, and reliable minimum data set." [Letter

from Forer and Granger, signed only by Granger; no copy of the position statement found.] The Task Force rejected a system in place at the University of Pittsburgh, saying "Although the HUP system is perhaps the best available patient data base for medical rehabilitation, it has some shortcomings. It is an abstracting service with the usual reports to each hospital, but many rehabilitation units do not want to subscribe to such a service even if they are willing to contribute data for the purpose of establishing national norms." (Research Foundation, SUNY-Buffalo. "Proposal," 1984.)

126. The National Task Force on a Uniform National Data System for Medical Rehabilitation, Minutes September 28-29, 1985, Kansas City, MO.
127. The National Task Force on a Uniform National Data System for Medical Rehabilitation, Minutes for Meeting held in Baltimore, MD, October 20, 1986.
128. Research Foundation, SUNY-Buffalo. "Proposal," 1984.
129. The dispute over FIM ownership is at the heart of the FIM trademark case, in which UBFA, Inc. is the claimant and AMRPA the opposer. AMRPA argues in their opposition: "Applicant is aware that others in the field contributed to the research and development of the assessment tool known as the FIM, and that the assessment tool was not developed solely by or for Applicant but was the product of an industry-wide Task Force." ("Notice of Opposition" American Medical Rehabilitation Providers Association, Opposer v UB Foundation Activities, Inc., Applicant" In The United States Patent and Trademark Office Before the Trademark Trial and Appeal Board, November 7, 2003). The UBFA applicant-respondent's trial brief (September 21, 2007) reads: "Dr. Carl Granger, the Director of Uniform Data System for Medical Rehabilitation ("UDS" or UDSMR") and a physician with an extensive background and experience in rehabilitation medicine, began to develop a medical-rehabilitation-assessment tool in 1970. In early 1984, Dr. Granger became a member of a task force to look at rehabilitation tools. Three months later, in May 1984, the Research Foundation of the State University of New York applied for a grant to the National Institute of Handicapped Research within the U.S. Department of Education. The grant's purpose was to develop a uniform national-data system for medical rehabilitation. Dr. Granger was the grant's Project Director. Contrary to repeated statements in AMRPA's Brief, the Task Force did not apply for or receive the grant; indeed the Task Force is explicitly identified in the grant application as nothing more than a consultant. As Dr. Granger testified, the Task Force played an advisory role. In 1985, the Research Foundation of the State University of New York filed a further application to continue the grant. The FIMTM instrument was developed as part of the work under the grant; it was *not* completed before the grant was completed. All rights in the FIMTM instrument were owned by the Research Foundation of the State University of New York, and were assigned to University at Buffalo Foundation Activities, Inc." ("Applicant-Respondent's Trial Brief" American Medical Rehabilitation Providers Association, Opposer-Petitioner, v UB Foundation Activities, Inc., Applicant-Respondent" The United States Patent and Trademark Office Before the Trademark Trial and Appeal Board, September 21, 2007).
130. ACRM/AAPM&R Task Force minutes (February 26, 1984).

131. American Medical Rehabilitation Providers Association, Opposer-Petitioner, v UB Foundation Activities, Inc., Applicant-Respondent" The United States Patent and Trademark Office Before the Trademark Trial and Appeal Board.
132. The grant extension proposal also suggested a greater role for the task force: "The AAPM&R Task Force reviewed a draft of the demographic characteristics and functional behavior items at the October 20 meeting held in conjunction with the annual meeting in Boston... Over the course of a full day's deliberations, decisions were made with respect to the items. A major decision was to measure functional behavior on a four-point rather than a five-point scale. The instrument is called the Functional Independence Measure." "Steven Forer [task force co-chair] developed the demographic items for review by the project personnel as well as a code sheet. Both were adopted with some modifications." ("Continuation of Field Initiated Research Project; Development of a Uniform National Data System for Medical Rehabilitation". Submitted to: The National Institute of Handicapped Research, Office of the Assistant Secretary for Special Education and Rehabilitation Services. Submitted by: The State University of New York at Buffalo, Department of Rehabilitation Medicine, Carl V. Granger, MD, Project Director, Byron B. Hamilton, MD, Principal Investigator, January 18, 1985).
133. Research Foundation, SUNY-Buffalo. "Proposal," 1984.
134. Research Foundation, SUNY-Buffalo. "Continuation of Field Initiated Research Project," 1985.
135. Harada, N.D., G. Kominski, and S. Sofaer (1993). "Development of a Resource-Based Classification for Rehabilitation" *Inquiry*. 30(1): 54-63.
136. Stineman, M.G. et al. (1994) "A Case Mix Classification System for Medical Rehabilitation." *Medical Care* 32 (4):366-79.
137. Carter, G.M., D.A. Relles, B.O. Wynn, et al., (2000) *Interim Report on an Inpatient Rehabilitation Facility Prospective Payment System*, Santa Monica, CA: RAND, MR-1503-CMS. Accessed at <http://www.rand.org/pubs/drafts/DRU2309/>.
138. P.L. 106-113.
139. Medicare Payment Advisory Commission: Post-Acute Care Providers: Moving Toward Prospective Payment. Report to Congress: Medicare Payment Policy. Washington, DC. March 1999.
140. UDSMR. "Statement of Ownership of the FIM System." (n.d.) The Statement went on to read: "Any incorporation of portions of the Guide or other copyrighted works relating to the FIM System into other works, any modification of any such modified works by third parties, and any use of any such copyrighted works of the FIM service marks owned by UDSMR, without a license from UDSMR, is and remains improper and in violation of UDSMR's intellectual property rights."
141. Tesio L, Granger CV, Perucca L, Franchignoni FP, Battaglia MA, Russell CF: "The FIM(TM) instrument in the United States and Italy: A comparative study." *Am J Phys Med Rehabil* 2002;81:168-176.

142. Letter from Kathleen Wall, Partner HodgsonRuss Attorneys LLP (counsel to UDSMR) to Mr. John Shinn, President, PPS Plus Software (December 5, 2002). [interestingly, this letter goes on to say that there is no comparison to MDS and OASIS, because those two, unlike the FIM, are not proprietary.]
143. UDSMR. Center for Functional Assessment Research. "Research Policy: Use of Instruments" <http://www.UDSMR.org/instruments.php>. [Note December 21, 2009: the research policy is no longer available on the UDSMR web site. A view of an archived edition of the policy is available here -- <http://web.archive.org/web/20050930205127/http://www.udsmr.org/instruments.php>.]
144. "UDSMR International: General Information".
145. UDSMR states that countries, including Italy, Sweden, Finland, Israel, and Japan have implemented parts of the FIM system under license and standards developed by UDSMR. (Tesio, "The FIM Instrument".)
146. License Agreement Letter between UDSMR and Integrated Voice Solutions, dated July 12, 1994.
147. *The Inpatient Rehabilitation Facility -- Patient Assessment Instrument (IRF-PAI) Training Manual: Effective 4/01/04*. (UB Foundation Activities, Inc. 2004). Accessed at [http://www.udsmr.org/pdfs/irfpainmanual040104%20\(1\).pdf](http://www.udsmr.org/pdfs/irfpainmanual040104%20(1).pdf).
148. UB Foundation Activities, Inc. "Briefs on Merits for Defendant" before the Trademark Trial and Appeal Board, in the U.S. Patent and Trademark Office. (September 21, 2007); KPMG LLP. University at Buffalo Foundation, Inc. and Affiliates. Consolidated Financial Statements, June 30, 2009 and 2008 (With Independent Auditor's Report Theron). (October 30, 2009). Accessed at <http://www.ubfoundation.buffalo.edu/drpl/node/456>.
149. Tesio. "The FIM Instrument" (2002).
150. Fiedler, Roger C., Granger, Carl V. and Carol F. Russell. (2000) "UDSMRSM: Follow-Up Data on Patients Discharged in 1994-1996" *American Journal of Physical Medicine & Rehabilitation* 79:2, March/April 2000, pp. 184-192.
151. 66 FR 41334; U.S. Centers for Medicare & Medicaid Services. "IRF Patient Assessment Instrument" accessed at http://www.cms.hhs.gov/InpatientRehabFacPPS/04_IRFPAI.asp#TopOfPage.
152. See <http://www.cms.hhs.gov/InpatientRehabFacPPS/downloads/irfpainmanual040104.pdf>.
153. UDSMR. "UDSMR International: General Information" accessed at http://www.udsmr.com/WebModules/International/int_About.aspx.
154. UB Foundation Activities, Inc. "Briefs on Merits for Defendant" before the Trademark Trial and Appeal Board, in the U.S. Patent and Trademark Office. (September 21, 2007) License Agreement between UBFA, Inc. and HCFA, dated September 21, 1995.

155. License Agreement between UBFA, Inc. and HCFA, dated September 21, 1995.
156. American Medical Rehabilitation Providers Association, Opposer-Petitioner, vs. UB Foundation Activities, Inc., Applicant-Respondent. "Applicant-Respondent's Trial Brief". Trademark Trial and Appeal Board, U.S. Patent and Trademark Office, deposited September 21, 2007. <http://ttabvue.uspto.gov/ttabvue/ttabvue-91158512-OPP-70.pdf>.
157. Letter from Richard T. Linn, Director, UDSMR, to Christy Schmidt, Executive Coordinator, Regulatory Reform Initiative, ASPE, dated April 17, 2002. ASPE apparently had put out a request for input to which AMRPA had responded.
158. Richard Linn letter, April 17, 2002.
159. The text of the OMB circular at the time of the FIM grants was slightly different from what it is currently, but basically states the same thing. As codified in 34 CFR 74.145 (revised as of July 1, 1984), the text read: "Copyrights. (a) *Works under grants*. Unless otherwise provided by the terms of the grant, when copyrightable material is developed in the course of or under a grant, the grantee is free to copyright the material or permit others to do so... (c) *ED rights*. If any copyrightable material is developed in the course of or under an ED grant or subgrant, ED shall have a royalty-free, nonexclusive, and irrevocable right to reproduce, publish, or otherwise use, and to authorize others to use, the work for Federal Government purposes."
160. "Addendum to September 21, 1995 License Agreement Between Uniform Data System for Medical Rehabilitation and Department of Health and Human Services, the Centers for Medicare & Medicaid Services, dated February 1, 2002.
161. 1995 License Agreement.
162. 2002 License Agreement Addendum.
163. UDSMR Position Statement Concerning HCFA/RAND Reports on the Development of a Prospective Payment System for Medical Rehabilitation (dated September 1997).
164. Trosow, Samuel E. I. Copyright Protection for Federally Funded Research: Necessary Incentive or Double Subsidy? (draft paper September 7, 2003).
165. U.S. Patent and Trademark Office. Trademark Trial and Appeal Board. *American Medical Rehabilitation Providers Association v. UB Foundation Activities, Inc.* September 23, 2008. Accessed at <http://ttabvue.uspto.gov/ttabvue/ttabvue-91158512-OPP-78.pdf>.
166. For example, Herndon, in the *Handbook of Neurologic Rating Scales* 2nd ed.(Demos Medical Publishing, 2006) indicates that the 7-point scale is under copyright, but later writes that "The FIM has become proprietary."
167. Holthaus, Danielle, and Andrew Kramer. "Introduction, Background, and Objectives" *Uniform Patient Assessment for Post-Acute Care* (Aurora, CO: Division of Health Care Policy and Research, University of Colorado at Denver and Health Sciences Center, 2006). Accessed at <http://www.bu.edu/hdr/documents/QualityPACFullReport.pdf>.

168. The National Task Force on a Uniform National Data System for Medical Rehabilitation, Minutes for Meeting held in Baltimore, MD, October 20, 1986.
169. UDSMR web site.
170. Research Foundation, SUNY-Buffalo. "Continuation of Field Initiated Research Project," 1985.
171. UDSMR. "Why Uniform Data Now?" (n.d.) Document appears to be a draft of a brochure.
172. Letter marked "Draft" from Carl V. Granger, M.D. to Carolyn Zollar (dated August 8, 1986). This letter was in response to a letter from Carolyn Zollar, General Counsel to the National Association of Rehabilitation Facilities (NARF), dated June 29, 1986.
173. Letter re: UDSMR/Formations in Health Care, Inc. dated August 16, 1994, from Tricia T. Semmelhack to Laura Dickinson Lee.
174. Letter from Kenneth W. Aitchison, President, Kessler Rehabilitation Corporation to Carl V. Granger, M.D., UDSMR, dated April 7, 1998. (A copy of the AMRPA position statement was not located.)
175. Letter from Carl V. Granger, Professor Rehabilitation Medicine, and Director, CFAR & UDSMR to Kenneth V. Aitchison, President, Kessler Rehabilitation Corporation, dated April 28, 1998.
176. Letter from Marisa Smith, Paralegal, UDSMR to Robert M. Rowe, Director of Information Services, InterLink Rehab Services, dated October 22, 1999.
177. Email response from Marisa Smith, Legal Services Supervisor at UDSMR to Dr. Michael Yoshida at the VA, dated April 08, 2002.
178. Velozo, C.A., Byers, K.L., & Joseph, B.R. (2007). Translating measures across the continuum of care: Using Rasch analysis to create a crosswalk between the Functional Independence Measure and the Minimum Data Set. *Journal of Rehabilitation Research and Development*. 44(3): 467-478.
179. The VA user's manual for the FIM is available at http://www.va.gov/vdl/documents/Clinical/Func_Indep_Meas/fim_user_manual.pdf.
180. Braddom, Randall L. "Medicare Funding for Inpatient Rehabilitation: How Did We Get to This Point and What Do We Do Now?" *Archives of Physical Medicine and Rehabilitation* Volume 86, Issue 7, July 2005, Pages 1287-1292.
181. 17 U.S.C. §105 <http://www.copyright.gov/title17/92chap1.html#105>.
182. AHIMA Comments on CMS SNF PPS for Skilled Nursing Facilities (June 30, 2009). <http://www.ahima.org/dc/documents/AHIMACommentsonCMSSNFPPSforSkilledNursingFacilities.pdf>.

OPPORTUNITIES FOR ENGAGING LONG-TERM AND POST-ACUTE CARE PROVIDERS IN HEALTH INFORMATION EXCHANGE ACTIVITIES: EXCHANGING INTEROPERABLE PATIENT ASSESSMENT INFORMATION

Files Available for This Report

Main Report	[54 PDF pages] http://aspe.hhs.gov/daltcp/reports/2011/StratEng.htm http://aspe.hhs.gov/daltcp/reports/2011/StratEng.pdf
APPENDIX A: Stakeholder Interview Summary	[13 PDF pages] http://aspe.hhs.gov/daltcp/reports/2011/StratEng-A.htm http://aspe.hhs.gov/daltcp/reports/2011/StratEng-A.pdf
APPENDIX B: Background Report on Intellectual Property Issues and the Dissemination of Standardized Federally-Required Patient Assessments	[89 PDF pages] http://aspe.hhs.gov/daltcp/reports/2011/StratEng-B.htm http://aspe.hhs.gov/daltcp/reports/2011/StratEng-B.pdf
APPENDIX C: Rosetta Stone Mapping Guidelines and Heuristics	[19 PDF pages] http://aspe.hhs.gov/daltcp/reports/2011/StratEng-C.htm http://aspe.hhs.gov/daltcp/reports/2011/StratEng-C.pdf
APPENDIX D: Rosetta Stone MDS and OASIS and Value Sets for MDS Full Appendix	[518 PDF pages] http://aspe.hhs.gov/daltcp/reports/2011/StratEng-D.htm http://aspe.hhs.gov/daltcp/reports/2011/StratEng-D.pdf
Toolkit Overview, Model of Use, Model of Meaning, and Supporting EHR Observation [135 PDF pages]	http://aspe.hhs.gov/daltcp/reports/2011/StratEng-D1.htm http://aspe.hhs.gov/daltcp/reports/2011/StratEng-D1.pdf http://aspe.hhs.gov/daltcp/reports/2011/StratEng-D1.xlsx
MDS Value Sets (Separate Excel files accessible through links within HTMLs and PDFs) [381 PDF pages]	
<i>Alzheimer's Disease through Cirrhosis</i> [184 PDF pages]	http://aspe.hhs.gov/daltcp/reports/2011/StratEng-D2a.htm http://aspe.hhs.gov/daltcp/reports/2011/StratEng-D2a.pdf
<i>Coronary Artery Disease through Wound Infection</i> [197 PDF pages]	http://aspe.hhs.gov/daltcp/reports/2011/StratEng-D2b.htm http://aspe.hhs.gov/daltcp/reports/2011/StratEng-D2b.pdf
APPENDIX E: Rosetta Stone OASIS	[71 PDF pages] http://aspe.hhs.gov/daltcp/reports/2011/StratEng-E.htm http://aspe.hhs.gov/daltcp/reports/2011/StratEng-E.pdf http://aspe.hhs.gov/daltcp/reports/2011/StratEng-E.xlsx
APPENDIX F: Current Standards Landscape for Exchanging Interoperable Patient Assessment Information	[9 PDF pages] http://aspe.hhs.gov/daltcp/reports/2011/StratEng-F.htm http://aspe.hhs.gov/daltcp/reports/2011/StratEng-F.pdf

APPENDIX G: LTPAC Interoperability Toolkit for Exchanging Interoperable Patient Assessment Instruments [9 PDF pages]
Overview <http://aspe.hhs.gov/daltcp/reports/2011/StratEng-G.htm>
<http://aspe.hhs.gov/daltcp/reports/2011/StratEng-G.pdf>

Several attachments are listed separately at the end of this Appendix.

APPENDIX H: Standards Development and Adoption Recommendations [6 PDF pages]
<http://aspe.hhs.gov/daltcp/reports/2011/StratEng-H.htm>
<http://aspe.hhs.gov/daltcp/reports/2011/StratEng-H.pdf>

APPENDIX I: Functional Status Standardization Recommendations [13 PDF pages]
<http://aspe.hhs.gov/daltcp/reports/2011/StratEng-I.htm>
<http://aspe.hhs.gov/daltcp/reports/2011/StratEng-I.pdf>

APPENDIX J: Overview of Patient Assessment Summary [23 PDF pages]
<http://aspe.hhs.gov/daltcp/reports/2011/StratEng-J.htm>
<http://aspe.hhs.gov/daltcp/reports/2011/StratEng-J.pdf>

APPENDIX K: Rosetta Stone MDS Summary [162 PDF pages]
<http://aspe.hhs.gov/daltcp/reports/2011/StratEng-K.htm>
<http://aspe.hhs.gov/daltcp/reports/2011/StratEng-K.pdf>
<http://aspe.hhs.gov/daltcp/reports/2011/StratEng-K.xlsx>

APPENDIX L: Rosetta Stone OASIS Summary [127 PDF pages]
<http://aspe.hhs.gov/daltcp/reports/2011/StratEng-L.htm>
<http://aspe.hhs.gov/daltcp/reports/2011/StratEng-L.pdf>
<http://aspe.hhs.gov/daltcp/reports/2011/StratEng-L.xlsx>

APPENDIX M: Terms and Acronyms [6 PDF pages]
<http://aspe.hhs.gov/daltcp/reports/2011/StratEng-M.htm>
<http://aspe.hhs.gov/daltcp/reports/2011/StratEng-M.pdf>

To obtain a printed copy of this report, send the full report title and your mailing information to:

U.S. Department of Health and Human Services
Office of Disability, Aging and Long-Term Care Policy
Room 424E, H.H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201
FAX: 202-401-7733
Email: webmaster.DALTCP@hhs.gov

NOTE: All requests must be in writing.

RETURN TO:

Office of Disability, Aging and Long-Term Care Policy (DALTCP) Home
http://aspe.hhs.gov/_office_specific/daltcp.cfm

Assistant Secretary for Planning and Evaluation (ASPE) Home
<http://aspe.hhs.gov>

U.S. Department of Health and Human Services (HHS) Home
<http://www.hhs.gov>