DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Part 483

[HCFA–2180–F]

RIN 0938–AE61

Medicare and Medicaid; Resident Assessment in Long Term Care Facilities

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Final rule.

SUMMARY: This final rule establishes a resident assessment instrument for use by long term care facilities participating in the Medicare and Medicaid programs when conducting a periodic assessment of a resident's functional capacity. The resident assessment instrument (RAI) consists of a minimum data set (MDS) of elements, common definitions, and coding categories needed to perform a comprehensive assessment of a long term care facility resident. A State may choose to use the Federally established resident assessment instrument or an alternate instrument that is designed by the State and approved by us. These regulations establish guidelines for use of the data set and designation of the assessment instrument.

The provisions contained in these regulations implement statutory requirements. The resident assessment instrument is intended to produce a comprehensive, accurate, standardized, reproducible assessment of each long term care facility resident's functional capacity.

EFFECTIVE DATE: Except for §§ 483.20(f) and 483.315(h), these regulations are effective March 23, 1998. Sections 483.20(f) Facility computerization requirements and 483.315(h) State computerization requirements are effective June 22, 1998.

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SUPPLEMENTARY INFORMATION:

I. Background

On December 28, 1992, we published in the **Federal Register**, at 57 FR 61614, a proposed rule with an opportunity for public comment, ''Resident Assessment in Long Term Care Facilities,'' which established a resident assessment instrument that all long term care facilities participating in the Medicare and Medicaid programs must use when conducting an assessment of a resident's functional capacity. We proposed that a State may choose to use the Federally established resident assessment instrument or an alternate instrument that is designed by the State and approved by us. We proposed that a facility must enter information from the resident assessment into a computer, in accordance with HCFA-specified formats. At least monthly, the facility must transmit electronically the information contained in each resident assessment to the State.

The resident assessment instrument would consist of a minimum data set (MDS) of screening and assessment elements, including common definitions and coding categories for use by a facility in performing a comprehensive assessment of a long term care facility resident. In addition to containing identifying information such as name, birthdate, and occupation, the MDS consists of standardized items that assess, for example, a resident's communication patterns, cognitive patterns, physical functioning and structural problems, health conditions, and medications. The proposed rule established guidelines for use of the data set, and designated one or more assessment instruments that a State may require a facility to use.

We proposed to add a new § 483.315, which would require a State to specify for use in long term care facilities within the State either the HCFA-designated resident assessment instrument or an alternate instrument. The State would request and receive approval from us before implementing or modifying an alternate instrument. The uniform MDS was included in § 483.315(b). We also provided as attachments to the regulations the utilization guidelines for the resident assessment instrument, MDS common definitions, and resident assessment protocols (RAPs).

II. Analysis of and Responses to Public Comments

We received 146 timely letters in response to our December 28, 1992, proposed regulation. Most were from provider organizations and nursing home staff. We also heard from consumer organizations, professional organizations, nursing home residents and their families, and State and Federal agencies.

Prior to addressing comments on specific regulatory sections, we will provide a summary of public comments on major topics, and discuss some of the general issues raised by these regulations (in the order in which those issues appeared in the preamble to the proposed rule).

Summary of Public Comments

Summary of Public Comments on MDS

During the public comment period, respondents suggested over 70 different additions to the MDS. Many commenters suggested modifying items to increase clarity. For example, the item ''wheeled self'' was divided into two items, ''wheeled self on unit'' and ''wheeled self off unit'' to further differentiate a resident's capabilities. Commenters also suggested the addition of items that provided information needed by clinical staff caring for residents. Data suggest that nursing home residents experience pain on a regular basis, but the MDS items associated with pain did not differentiate the intensity and location of pain (chest, joint, other). We expanded MDS items associated with pain to assist clinicians in determining the nature and scope of pain for care planning purposes.

There was a concern expressed by commenters that the MDS, as originally designed, could not be used for determining nursing home payment or monitoring quality of care, either at the resident and or the facility level. To address this concern, we added items to the MDS that are needed to support a case-mix classification system for long term care facility payment known as, Resource Utilization Groups III, which is a mechanism for determining the level of resources necessary to care for an individual based upon his clinical characteristics as measured by the MDS. This classification system was developed under the auspices of the HCFA-funded Multistate Nursing Home Case-mix and Quality demonstration, whose purpose is to develop, implement and evaluate a case-mix payment system for SNF services under Medicare. The original four States participating in the demonstration began using the MDS+ (an alternate RAI that consists of the original MDS, plus additional assessment items specified by the State for use in all Medicare and Medicaid-certified nursing homes in the State), based on the Resource Utilization Groups III classification system in their Medicaid programs in 1994, as have several other States subsequently.

Section 4432 of the Balanced Budget Act of 1997 (Public Law 105–33), amends section 1888 of the Social Security Act (the Act), by adding a new subsection (e). The Balanced Budget Act and the Prospective Payment System (PPS) will require national implementation in Fiscal Year 1998 of a casemix payment system for Medicare that is based on MDS data. The Secretary determines the manner and

time frames within which resident assessment data are collected at the State and national levels to develop and implement casemix payment rates. The resident assessment data submitted to the State is a resource upon which the Secretary can draw for development and implementation of the PPS system.

We added other items to the original MDS to ensure that key indicators of quality of care, (known as quality measures) could be derived from the MDS and monitored longitudinally at the resident and facility level. The addition of items needed to support payment and quality monitoring programs will also strengthen the clinical relevancy of the MDS by providing important information to facility staff about the resident's potential for achieving the highest level of functioning. One example of such items are nursing care interventions related to rehabilitation and restorative care for the resident, such as range of motion, training and skill practice in walking, transferring, eating, dressing/grooming, and communication.

Commenters were particularly concerned with the ability of the MDS to assist in assessing the quality of life for nursing home residents. Revisions we made within the section on mood and behavior, in particular, have the potential for providing important information regarding the resident's risk for depression, as well as the presence of depression. Nursing home residents have a high risk of developing depression, with clinical experts estimating that at least 60 percent of current nursing home residents have some level of depression. However, analysis of MDS records for a large group of residents showed that the mood and behavior items were checked for only 16 percent of the residents. We found that nursing homes that have clinical staff with expertise in this area identify more residents with mood and behavior problems. Concerned that residents with, or at risk of, depression may not be identified, we have modified the mood and behavior items to help facility staff identify objective behaviors frequently associated with depression. We also added a scale to measure the frequency with which these symptoms occur. An item indicating the use of a behavior management program was modified to allow the assessor to identify specific strategies that were being used with the resident to deal with mood and behavior symptoms.

Finally, commenters expressed concern that the MDS was not appropriate to use with some groups of nursing home residents, such as the non-elderly or short term stay populations. To better understand the changing nursing home population, we have added an item in Section P that identifies different populations often served by nursing homes (for example, pediatric resident, hospice care resident). To address commenters' concerns, we also added items focusing more on short-term nursing and therapy needs, and issues important to terminal residents, such as pain. We also expanded the item on discharge planning to assess the resident's potential for discharge, including the resident's desire to return to the community and the presence of a support person who is positive towards discharge. This item will also be useful in developing a RAP on discharge planning that was suggested by a number of commenters.

Summary of Public Comments on Triggers

Commenters believed that the trigger legend was too complex and needed to be simplified or eliminated. It is substantially revised, and we have reduced the number of triggers for particular RAPs. We have also eliminated the categories of automatic and potential triggers as this had not been well understood and sometimes led to unnecessary work by nursing home staff.

Summary of Public Comments on the RAP Summary Form

We revised the RAP Summary Form and accompanying instructions to reduce confusion regarding their use that was noted by commenters. Specifically, the revised form provides a column for indicating if the RAP was triggered. It provides more specific instruction and direction on the type of information that we would expect a facility to document for each triggered RAP, including rationale to support decision-making regarding whether to proceed with a care plan for a triggered RAP. Additionally, because we consider the RAPs part of the utilization guidelines for the MDS, we designated the RAP Summary form as Section V of the MDS. This will provide nursing home staff and surveyors with more complete information on resident care problems and outcomes. This will also permit surveyors to monitor the completion of the RAPs.

Summary of Public Comments on RAPs

Most of the commenters valued the RAPs as part of the RAI for improving the quality of care. A number of commenters indicated the need for the addition of new RAPs. Specifically, we received comments suggesting the creation of RAPs on discharge planning, pain, terminal care/imminent death, resident rights, bowel incontinence/constipation, abnormal lab values, and foot care. A new RAP on discharge planning is already developed and we expect to develop other RAPs during 1997.

There was also concern that many of the current RAPs do not address the needs of short-stay residents. Work is currently in progress and we expect to publish revised RAP Guidelines that address the needs of this population in 1997.

Comments on MDS and RAPS

Comment: Most commenters asserted that the original MDS did not provide enough information in some areas. These commenters noted that the areas of nursing diagnosis and medical needs, and certain information needed for care planning, were lacking. Some commenters stated that professional nurses are knowledgeable regarding areas that are not addressed on the MDS and automatically incorporate them into the assessment and care plan. Another commenter pointed out that the MDS+ includes additional information that is helpful in care planning.

Response: As discussed elsewhere, we have added a number of items that nursing home staff have identified as useful in assessing a resident's functional capability and medical problems. We have also clarified items that had been confusing for facility staff in the past. Some of the items added to the MDS were previously on the MDS+. We believe that the MDS captures information on most of the areas of concern in assessing nursing home residents. While we agree that there are additional items that would provide necessary information for nursing home staffs' use in care planning, it is not possible for us to design an instrument that covers every potential item that a nursing home needs to know to provide care to residents. The RAI is not intended to replace or substitute for a resident's full clinical record. The facility should document in those clinical records pertinent information whether or not required by the RAI. A facility is responsible for providing care that is necessary to assist a resident in attaining or maintaining his or her highest practicable well-being, regardless of whether the care areas are captured on the MDS. A facility may document additional information regarding the resident's status wherever it chooses in the resident's clinical records.

Comment: One commenter urged that we move cautiously in adding any other

data elements to the MDS, explaining that some States with a non-MDS based case-mix system are having difficulty merging the MDS and their reimbursement system. Other commenters disagreed regarding the need to add items to the MDS at this time. They thought that we should maintain the status quo until the industry and surveyors have more fully understood and integrated the current instrument into their way of doing business. Commenters mentioned that the MDS is a screening tool that already contains most of the relevant items. One commenter stated that the original MDS underwent extensive scrutiny and testing during its development and should be kept as is for at least 10 years in order to maintain consistency for providers, computer companies, research, and case-mix reimbursement.

Response: We disagree regarding the need to maintain the MDS for the next several years in the form it was originally issued in 1990 (not as revised in 1995 in version 2.0). Many of the changes in version 2.0 of the MDS were made to address areas that had been particularly troublesome or poorly understood by clinicians responsible for completing the RAI. Moreover, changes in the MDS have not been frequent enough to cause significant disruption for facilities. Nearly all States began to require use of the original RAI in late 1990 or early 1991, and most did not require facilities to use the new RAI until January 1996 (with some States deferring that requirement to 1997). This means that the original RAI was in place for nearly 5 years before facilities were expected to change to the new instrument. Additionally, it is less burdensome and confusing to incorporate necessary improvements in the RAI at this time than it will be after implementation of requirements in this regulation for facility computerization of MDS information. Overall, the advantages of implementing version 2.0 of the RAI in 1996 far outweigh maintenance of the original assessment system.

If clinically warranted and supported by affected parties, we anticipate reviewing the MDS every 3 to 5 years to determine whether it needs to be revised, and sponsoring the development of a new version of the RAI approximately every 5 years. For all RAI refinement activities, we will seek the input of interested and affected parties.

Comment: Several other commenters expressed the belief that we should conduct more RAI training on a national level and institute a facility support effort, rather than making major changes to the instrument.

Response: We support the need for more RAI training at all levels and have numerous activities underway to strengthen the knowledge of facility staff and surveyors about comprehensive assessment and its linkage to resident care planning and quality of care. The need for additional RAI training has been consistently supported by the States, provider, consumer and professional associations with which we have worked to develop version 2.0 of the RAI. In 1995, we published a new edition of the Resident Assessment Instrument User's Manual for version 2.0 of the RAI that contains new information on the use of the RAPs and linking the RAI to care plans. We have developed ''train the trainer'' materials for use in both provider and surveyor training, and have begun a multi-year effort to develop educational materials for both providers and surveyors at both basic and advanced levels. We train all long term care facility surveyors on the RAI as part of our basic health surveyor course and have offered specialty courses on advanced resident assessment issues for surveyors as well as other State staff on a routine basis. We also offered a full-day program on resident assessment for all long term care facility surveyors during each of the HCFA regional conferences held during 1994. We are committed to working in partnership with providers and States to identify training needs and develop methods to facilitate the dissemination of consistent information and improve providers' use of the RAI in order to improve care outcomes for nursing home residents.

We believe that the industry also shares a responsibility to promote understanding of the RAI within facilities. Provider and professional organizations should offer sessions on resident assessment during their annual meetings or as special continuing education programs held throughout the course of the year. Our staff have participated in a number of national meetings and will continue to do so, as warranted. However, we believe that providers can best learn how to integrate RAI requirements into their daily practice from other providers who have implemented successful programs. We encourage the use of ''peer teaching'' programs in a variety of forms.

Beneficiary organizations have also played an important role in getting information on the RAI out to their members. The organizations have educated residents, families and ombudsmen regarding the role of resident assessment in quality care and how to use the RAI in care planning and conflict resolution. They also provided invaluable input in modifying the RAI.

As part of a contract with us, the Research Triangle Institute evaluated the extent to which facilities had implemented the RAI as well as the accuracy of the assessments being conducted. The Research Triangle Institute compared available assessment information for 23 specific assessment items in facilities both before and after the implementation of the RAI. Their sample consisted of over 260 facilities in 10 States. The Research Triangle Institute's results showed that:

- The percent of residents with no assessment information available for particular health status issues decreased on average by 81 percent;
- The percent of residents with accurate information documented on assessment items increased on average by 24 percent;
- The percent of residents with available information on all 23 items increased by 53 percent.

The Research Triangle Institute's study asserts that facilities are using the RAI, and that the RAI has resulted in the presence of more accurate information on which a facility can base its individualized care plans.

Comment: Commenters addressed the usefulness of the RAPs. Of those who responded to this request for comment, some said that the RAPs are useful and provide a structured framework for making sense of the MDS data through analysis, interpretation, and synthesis, believing that the RAPs tie the assessment process together. A consumer advocacy organization believed that the RAPs assist facility staff in learning causes of problems and identifying potential risks of decline that require further staff attention. A few said that the RAPs have improved the quality of care in nursing homes, or could with the appropriate training and administrative support.

Response: The RAPs are structured decision frameworks which contain guidelines for additional assessment of relevant resident attributes, risk factors, clinical history and other factors. They assist with clinical decision-making and help nursing home staff gather and analyze necessary information to develop an appropriate and individualized care plan.

The Guidelines section of each RAP assists staff to determine whether a problem exists and to identify relevant causal factors that affect the resident's condition. The RAPs also offer suggestions regarding how a facility can eliminate or minimize factors

contributing to the resident's problem, or how a facility can maximize a resident's strengths to achieve the highest practicable well-being. In this way, the RAPs help facility staff to develop an individualized care plan that meets the needs of the resident.

According to the report of the Research Triangle Institute's study, directors of nursing indicated the RAP triggers and guidelines were used routinely in over 90 percent of the facilities participating in the survey. Three-quarters of the directors of nursing stated that they believed that use of the RAP triggers had increased their facility's ability to identify residents' clinical problems, and two-thirds believed that using the RAPs had increased their facility's ability to identify residents' potential for rehabilitation improvement.

Among the 180 directors of nursing who thought the RAP triggers had increased identification of clinical problems, 45 percent were able to identify, without prompting, specific RAPs for which this increase was most pronounced. They most frequently cited cognitive loss/dementia (21 percent), ADL/functional rehabilitation potential (17 percent), delirium (16 percent), and communication (15 percent). Seventy-two percent of the directors of nursing interviewed stated that they did not believe it had been at all difficult for staff to provide necessary care in response to the newly identified clinical problems.

Comment: Some commenters believed that the RAPs are too prescriptive, and that we are ''legislating a cookbook approach.''

Response: RAPs function as resident-care related assessment tools rather than as clinical standards. RAPs do not contain prescriptive mandates to perform particular diagnostic tests or specialized assessments. Rather, RAPs lead facility staff through a process that enables them to gain a better understanding of the resident's status in a particular area.

For each resident, facility staff are required to make decisions regarding whether each RAP that triggered for that resident identifies a problem that requires care planning and intervention. Staff are required to proceed with a care plan only if clinically appropriate. As part of the RAP review process, facilities are required to document key information regarding a particular area or condition that includes objective findings and subjective complaints of the resident. Irrespective of RAI requirements, this type of information should be routinely assessed and documented by a facility as a part of good clinical practice. We do not require that a facility provide documentation that addresses each issue or question raised in a particular RAP guideline. We disagree that the RAPs represent a cookbook approach. The RAPs are tested assessment protocols that lead facility staff through a focused, logically progressive, clinical evaluation of the resident, relative to the particular area addressed by the RAP. The RAPs are not intended to prescribe courses of action for a facility. Rather, they provide a structured, problem-oriented framework for organizing MDS information and additional clinically relevant information that identifies medical problems. Upon completion of the RAPs, the facility staff will have:

- Identified clinical issues unique to the resident that may adversely affect his or her highest practicable level of well-being;
- Identified factors that place the resident's highest practicable functioning at risk;
- Considered whether the identified potential problems could be prevented or reversed, or risk factors minimized, and evaluated the extent to which the resident is able to attain a higher level of well-being and functional independence; and
- Evaluated ongoing care practices for the individual resident.

Comment: One commenter asked that we not mandate standards for care planning until there is better understanding of how the assessment process works. The commenter stated that a great deal of work needs to be done in setting up appropriate standards for care planning.

Response: Neither the RAPs, nor any other component of the RAI contains required standards of care or standards regarding the specific interventions and time frames for evaluation that must be present in care plans. As noted in the responses above, the RAPs are a structured framework that lead the facility through more in-depth assessment; they do not mandate a course of action for care planning. A facility has a great deal of flexibility in developing a care plan to meet a resident's individual needs.

Comment: Some who commented thought that the RAPs are too complex and difficult to use. One expressed the belief that the RAPs are not the only correct criteria for providing good care. Another pointed out that it has been a difficult learning process for facilities to understand that the MDS provides only raw data about a resident. Commenters recommended that some of the RAP items be included in the MDS as core assessment items.

Response: We agree that there has been a steep learning curve in terms of facilities' understanding of the RAPs and their ability to integrate them into day-to-day clinical process. Anecdotally, and more recently supported in the Research Triangle Institute study, facilities report that understanding and use of the RAPs has lagged well behind that of the MDS. Recognizing that the system required a major learning process, we have tried to address the RAPs in newer versions of our train-the-trainer courses offered annually for State RAI coordinators. Initially, our courses and materials focused on use of the MDS, then use of the RAPs, then integration of the RAI in care planning. Many States are still in the process of conducting training sessions for providers on use of the RAPs and care planning.

We also have made revisions to the RAP Summary form and our instructions regarding use of the RAPs in order to make them easier to understand and use. We will continue to refine our training products as well as evaluate facility staffs' ability to use the RAPs. If problems are identified, we are open to exploring ways to revise the RAP format or content in order to make the comprehensive assessment process more meaningful and productive for both facility staff and residents. We have incorporated some additional RAP triggers into the MDS and integrated assessment procedures contained in the RAP Guidelines throughout the instructions contained in the October 1995 edition of the RAI User's Manual.

Comment: A few commenters suggested that we make the RAPs available to facilities on request. Commenters asserted that often there is not a copy at the nurse's station.

Response: We agree that it is important for the RAPs to be available for staff use. In 1990, we sent information to each nursing home administrator regarding the RAI, and this information included a copy of the RAPs. Additionally, in 1990, we provided each State with a camera-ready copy of the original version of the RAI, and in 1995, we provided each State with a camera-ready copy of the new RAI, version 2.0. States were then responsible for providing facilities with a copy of the revised RAI including the RAPs.

We do not believe it is our responsibility to ensure that each nursing home currently has a copy of the RAPs. Facilities could request a copy from States, provider organizations or from other sources. However, we are exploring strategies to improve consistent distribution of RAI

information to nursing homes and ensure that clinical staff have access to the RAI User's Manual. We believe that for the RAPs to be used as intended, a copy of the RAPs should be available at each nursing station. States are responsible for communicating with facilities regarding the State-specified instrument and should, therefore, ensure that the facilities have the most current RAPs.

Comment: Some commenters wanted more flexibility in using the RAPs. They thought the RAPs should be adaptable, and, as professionals, facility staff should be able to pick and choose appropriate interventions from those suggested in the RAPs. Commenters also suggested that we make the RAPs optional. One commenter believed that the final product and process forces health care professionals into a format that stifles flexibility and interferes with the assessment and care planning process. Another suggestion was to allow a facility to use the RAPs as a flexible assistive device in care planning.

Response: We agree that facility staff are capable professionals and, as such, should be able to use the RAPs as is appropriate for each individual resident. This has always been our intent regarding their use. A facility may supplement the RAP assessment.

We believe that negative feelings regarding the utility of the RAPs are associated with lack of understanding of their use. As aforementioned, our training in the past did not focus on the RAPs. It has been our experience that facility staff who have been properly trained on the RAPs and integrated them into their clinical practice are convinced of their utility and positive effects on resident outcomes.

We do not believe that use of the RAPs should be optional, as they reflect necessary components of a comprehensive assessment. The RAPs represent a standard methodology for assessing and analyzing certain aspects of resident status. As part of the utilization guidelines for the RAI, the RAPs ensure consistent identification of medical problems and description of functional capabilities. They supplement the MDS to provide a standardized comprehensive assessment as is required by the Omnibus Budget Reconciliation Act of 1987 (OBRA '87).

Comment: A few commenters suggested that we collaborate with the Department's Agency for Health Care Policy and Research and the industry to make the RAPs more germane to current industry practice, knowledge, and standards. One commenter wanted us to provide actual assessment tools and decision trees. A State provider association recommended that the RAI contain fewer RAPs, and furthermore, that we encourage facilities to develop their own triggers consistent with their care planning system.

Response: We collaborated extensively with the industry in developing the original 18 RAPs. The Department's Agency for Health Care Policy and Research was not yet in existence when we developed the original RAPs. In revising the RAPs, we will seek the input of interested and affected parties. Regarding the comment to develop assessment tools and decision trees, it would be difficult for us to develop decision trees that cover all possible scenarios. We do not wish to require such a methodology for completing the RAPs, as it would limit the flexibility of facilities. Most providers have tended to request that we develop more RAPs, rather than fewer. We have an ongoing process for developing new RAPs by clinical experts and validating the RAPs through testing. Also, we will review the content of the current RAPs to ensure that they contain information pertinent to the changing nursing home population. We do not anticipate issuing changes to the RAPs more frequently than once a year. States may, with our approval, revise their instruments as frequently as they deem necessary.

Triggers are risk factors or strengths that are indicative of a need for additional assessment. They do not automatically flag all problems worthy of care planning. The original triggers were developed using an expert consensus process and have been empirically validated. As such, it is inappropriate to suggest that a facility identify its own triggers based on their care planning systems. A facility may choose to add additional triggers, but must use at least the triggers identified in the State RAI. Facility staff may choose to assess residents using the RAPs even if the RAPs are not triggered.

Comment: Commenters suggested that we emphasize that the RAP process is not limited to the completion of the RAP Summary form. It includes the need to understand why the resident's condition triggered the RAP. The commenter also recommended that the RAI Training Manual contain a set of examples concerning how to use the information in the RAPs as part of the assessment process.

Response: We agree that the RAP process is not merely filling out the RAP Summary form, but is an important link between gathering assessment information and developing the appropriate care plan. In April 1992, we issued guidance to our regional offices and the States regarding the RAP process and other policy issues. We also shared this information with provider and consumer organizations. We have revised the RAI User's Manual to include this guidance and more specific instructions and examples, including RAP documentation and linkages to care planning. In October 1995, we distributed to States and associations ''train the trainer'' materials that included special course content for RAI surveyors and trainers. This included instructions on using the RAPs.

Comment: A commenter urged that we structure the RAPs so that they identify resident problems, complicating conditions and risk factors. The individual stated that some RAPs are currently in this structure and that this would make the RAPs easier to use.

Response: We believe that all RAPs presently contain this information. However, we are open to reviewing the RAPs to ensure that their format is consistent as a part of our ongoing RAP review and refinement process that we began in 1995.

Comments on the Development of a Computerized National Data Base of Assessment Information

Comment: Generally, commenters that supported the proposed requirement to computerize the MDS included State governments and national and State provider organizations. One State expressed the belief that computerization should be optional; they thought that States should determine when and whether participation is feasible given the States' prevailing conditions.

Response: We intend to implement a Federal process for assuring and improving quality in this country's nursing homes which relies on resident-level MDS assessment data reported by nursing homes participating in Medicaid and Medicare. Furthermore, our intention is to improve the Federal long term care survey process by using information derived from MDS data to identify potential quality problems within nursing facilities. The goals of this approach are twofold: to improve care received by beneficiaries by enhancing the timeliness and effectiveness of facility monitoring; and to better utilize survey agency resources by targeting potential problem facilities and by focusing onsite survey activities on specific problem areas within a facility.

We view the collection of MDS data and its use within a standardized survey process, as defined under our State

Operations Manual as being consistent with our current practices. Under the present survey process, the facility must submit specific information to the State survey agency, including data on resident census, facility staffing and ownership status. These facility-specific data, along with other information gathered by the survey team (for example, facility deficiency information) are currently maintained both at State agencies and within a national data base maintained by HCFA. In addition, survey teams review residents' clinical records and other resident-specific information. The submission and use of MDS data within the context of facility regulation is entirely consistent with existing practices and our obligation to collect the information necessary to ensure the quality of care provided to residents of Medicare and Medicaid certified long term care facilities.

Automated data collection is essential to meaningful analysis of the quantity of data collected. The MDS data system would allow us to expand our existing system for gathering data related to quality, and provide us with objective and detailed measures of the health status and care outcomes for residents of a facility. Coupled with facility characteristic and deficiency history data, we expect the MDS system will be more reliable and effective in supporting early identification of potential care problems and directing the survey process towards these identified problem areas.

In their roles as our agents for conducting regulatory survey and quality assurance activities, States will be required to process and analyze MDS data reported by facilities to meet the objectives stated above. MDS information collected by States will also be used to construct a national repository of MDS assessments. The national data base will be used to serve numerous functions: to study and refine the quality measures used to direct survey activities of State agencies (for example, to enhance the ability of these indicators to support survey targeting); to understand the characteristics of the nation's nursing home residents and the services they receive; to measure the impact of regulation and assist in the formulation of national health care policy; and to provide researchers with information needed to evaluate the outcomes of various types of care and to improve standards of clinical practice.

Our authority to require computerization of MDS information is based on our general authority to set health and safety standards for providers under sections 1819(f)(1) and 1919(f)(1) of the Act. We will use the computerized data to establish standards, evaluate a facility's compliance with these standards, and review the standards' effectiveness and their continued appropriateness. For example, analysis of MDS assessments within a national repository might indicate an increase in the number of residents suffering from depression. We may then develop standards to assist facility staff in detecting and treating the disease. Such a standard could then be evaluated and its effectiveness assessed by a process of continually re-analyzing the MDS data base for changes in the prevalence of this characteristic over time.

Computerization of RAI data is also consistent with our authority under sections 1819(h)(3) and 1919(h)(3) of the Act to perform, review and validate facility surveys. As is discussed above, we intend to revise the survey process to utilize computerized assessment data. The new process will be an information-based approach, oriented around quality measures derived from computerized MDS data, as well as other sources of information. Furthermore, sections 1819(g)(2)(A)(I) and 1919(g)(2)(A)(I) of the Act mandate that we subject facilities to a ''standard'' survey. The availability of computerized assessment data will improve our ability to make the survey process more standard and consistently implemented within the across the States.

Currently, part of the standard survey includes an assessment of the status of a sample of residents over time to determine whether the facility has assisted the residents to attain or maintain their highest practicable level of well-being. Computerized assessment data will be instrumental in that it will allow a complete monitoring of characteristics of ''all'' residents, including changes in their functional status over time. Furthermore, under the current survey process, we can only determine changes in resident status and a facility's relative success in maintaining resident well-being cross-sectionally during an annual onsite survey. MDS computerization, on the other hand, provides the ability to monitor resident functional status and other characteristics through a longitudinal process of continuous measurement.

These uses of computerized RAI data also provide justification for requiring computerization under our overall program supervision responsibilities and general rulemaking authority under section 1102 of the Act, to the extent that the information will be used for general monitoring of care and beneficiary needs. This computerized information will ensure that program standards set forth in sections 1819(b) and 1919(b) of the Act are met, that the program is being properly administered, and that beneficiaries are being served, as contemplated generally by the Act. We address elsewhere the further uses of the data for monitoring the Medicaid and Medicare programs.

In addition to the authority cited above, to the extent that the RAI data are collected solely for Medicaid purposes, section 1906(a)(6) of the Act requires State agencies to make reports as required by the Secretary. As discussed above, the RAI data are essential for the Secretary's evaluation and monitoring responsibilities under the Act.

We disagree with suggestions to offer States a choice to participate in the proposed national MDS data base for a number of reasons. First, the processes being regulated by Federal authority via State agencies (healthcare delivery and associated standards of care) do not have varying criteria from one State to the next. In other words, standards of medical care and health service delivery do not vary across States; health standards in New York are the same as those in Alaska. This commonality has reasonably led to the formulation of one national set of regulations to evaluate provider performance with respect to these common health standards. It is our belief that this standard regulatory approach is in the best interest of the nation's healthcare consumers with respect to both ensuring consistent delivery of services across States and with respect to the healthcare industry's reasonable expectation to operate under a single set of rules and requirements. Thus, as this standard approach to facility regulation evolves over time, with its specific objectives for continuous improvement and refinement, it is appropriate for us to require our agents (in other words, States) to adopt the standard processes and mechanisms required to consistently implement these new approaches.

Specifically, allowing States to choose not to adopt a standard system for MDS information will adversely affect our ability to meet the objectives for these data. The following goals cannot be met without consistent implementation of the MDS system and process standards across all States:

- The ability to construct a modern regulatory model provides a reliable and objective means of measuring facility performance. MDS information gathered and maintained by a standard system in each State provides an information structure capable of providing this

alternate approach to measuring quality and creates the foundation for an information-based regulatory model. The ability to successfully implement such an approach is directly tied to process standardization across States.

- If States are allowed to choose not to operate this standard system, then we would not be capable of developing and implementing a facility targeting system or, information-based survey process consistently across States; thus, at best, an environment would exist in which facilities in one State would be subject to different quality monitoring and survey approaches than facilities in a neighboring State.
- Our ability to build a centralized national repository to support our various objectives with respect to quality monitoring, policy, program and regulatory development and evaluation, and to facilitate healthcare research, is dependent on our ability to receive reliable and timely MDS information from each State. Without a standardized MDS collection system in each State, the development of this MDS repository will be severely limited if not entirely impossible due to the prohibitive costs associated with interacting with varying system implementations in each State. Furthermore, without full participation of each State in this program, the general representativeness and usefulness of the information in the data base will likely be skewed or biased, depending on which States choose to participate. This would affect the validity of the information and could seriously limit its application for health resource planning and research of value to State and Federal governments, providers and consumers.
- Finally, States will play a critical role in informing consumers in that States will make aggregate MDS information available. This information will allow potential residents or their family members to select a facility that may best suit their needs. Without a standard approach and system for developing these public information resources, consumers and advocacy groups will not have reliable, consistent and comparable information healthcare providers across States.

Comment: In commenting on what specific uses States would have for the computerized data, commenters discussed using the data in the nursing home survey process. One State believed that the data would assist State survey agencies to focus the survey process and set norms. A consumer advocacy organization pointed out that, based on the strengths and weaknesses of a facility, a State could individualize the composition of the survey team sent to evaluate the facility's regulatory compliance. In other words, the number and type of surveyors sent onsite would be based on the types of potential care problems identified at the facility. For example, if a facility had a high prevalence of antipsychotic drug use, the survey team would include a pharmacist. This approach has the dual benefits of maximizing limited survey agency resources by better targeting them against the most likely problem areas, and for minimizing the general invasiveness of the survey process within the facility by focusing the process on key problem areas.

The MDS data set provides objective and consistent measures of a number of facility care and outcome parameters. By comparing individual providers to ''gold standards'' and other peer group-based norms on each of these parameters, States can identify high and low facility performance outliers on measures associated with the quality of care and the quality of life for residents of these facilities. Commenters also suggested that the data could be used to replace some resident-level information currently collected during the survey process on a form called the Resident Census and Conditions of Residents (HCFA–672), as well as other reporting forms for State and Federal needs, which would reduce facility burden. The MDS assessment contains detailed resident characteristics that can be used to eliminate all other forms and resident-level data collected by facilities to meet State and Federal requirements. One commenter, however, believed that the information should not be collected by the survey agency and used for investigations or enforcement.

Response: As described in prior responses, MDS data will assist State survey agencies in a plethora of ways to achieve greater efficiencies in monitoring quality of care and ensuring the highest levels of quality of care and quality of life for residents of nursing facilities. These examples include:

- *Problem identification:* the capability to reliably target areas for investigation of potential resident care problems prior to and in support of the onsite survey process;
- *Survey targeting and scheduling:* the ability to determine survey frequency and scope based on specific indicators of potential care problems;
- Tailoring survey team composition to specific problem potentials in facilities to most efficiently use limited staff and resources. It is important to note that States currently are not prohibited from considering nursing home characteristics when determining survey team composition, provided that the team includes a registered nurse. The State Operations Manual notes in section 2801 that to the extent practical, the team's composition should reflect the type of facility surveyed; and
- Conducting cost/benefit analysis of care approaches, based on resident outcome data adjusted for case-mix classification categories. This is consistent with the Department's medical treatment effectiveness initiative.

Many software programs currently used by nursing homes to enter MDS information already have the capacity to generate timely resident census information such as that found on the HCFA form 672. Several States are also developing systems to facilitate this activity for providers. The availability of the MDS standard system will provide significantly more detail on resident characteristics than general census information, and will make use of definitions that have been clinically developed and refined to maximize both reliability and validity. As such, the MDS will create a whole new model for understanding and communicating about resident characteristics. This new model will far outperform the limited view of residents that can be derived from information from current sources, such as the Form 672.

We further believe that automated resident status information has much more potential to further decrease the amount of paper work associated with the survey process. We have recently completed an evaluation of the survey process and intend to make ongoing refinements to incorporate new technologies and increase the efficiency of the survey process.

Comment: One commenter stated that using computerized data to target surveys would resemble a ''big brother'' environment and not one conducive to accurate assessments for fear of investigations based upon minimal data.

Response: We disagree that using assessment data to target the survey process would resemble a ''big brother'' environment or that fear of investigations would affect the accuracy of assessments. Facilities already submit significant resident-level information to support both survey agency functions and for claims processing under Medicaid and Medicare. These data have been collected for years without the adverse effects suggested by a ''big brother'' analogy; instead, to the extent that facility information has been made public (for example, release of survey and complaint results and findings), this release has served to provide valuable information to those interested in promoting the quality of life in nursing

facilities. There is no reason to believe that collection and analysis of MDS information will not similarly be used in the interests of the general public with respect to their right to know the quality of healthcare services delivered by Medicaid and Medicare providers.

The MDS simply provides a better, more powerful mechanism than is currently available to observe and report resident condition or to monitor facility quality and safeguard the rights of residents of these facilities. The MDS is a tool for measuring healthcare facility performance, which also creates a foundation for improving the effectiveness of regulatory agencies as well as their operational efficiency.

Having a standard MDS repository available within State and Federal agencies provides a rich information resource to serve many objectives: it will provide access to reliable information and standard measures of resident characteristics for the many groups interested in improving care and quality of life in nursing homes, including consumer advocates and researchers; and, the MDS will support many other programs within States including providing the basis for Medicaid payments as is currently in effect in a number of States.

Clearly, the availability of MDS information within standardized Federal systems maintained by States directly benefits the general public as consumers of healthcare services and generally enhances the public knowledge of the quality of these services.

Furthermore, we expect that the MDS repository will enable HCFA or its State agent, or both, to provide facilities with analytic reports based on aggregated resident characteristics. This is consistent with a quality improvement model, as it allows facilities to compare themselves to other homes that are similar in terms of size and resident demographics. This directly promotes facilities as they seek to develop their own in-house quality assurance programs. Ultimately, facilities may use the data in ways that would analyze allocation of resources, and demonstrate efficiencies in caring for certain types of residents, and in turn, negotiate with managed care organizations for admission of certain types of residents.

We recognize that information contained within the MDS assessment is sensitive and must be safeguarded, and that protecting the privacy of residents is essential. In establishing a system of records for storage of MDS data, both HCFA and the States (as HCFA's contractors in performing survey functions) must comply with the Privacy Act, which applies to Federal systems of records containing individually-identifiable information. While we can make public aggregate summaries of the data, there are strict Federal guidelines for the release of individually-identifiable information by Federal agencies to any individual or organization. We can only release individually-identifiable information if a disclosure provision exists in the Privacy Act System of Records that is published in the **Federal Register**. We review requests on an individual basis, according to the provisions of the Privacy Act. Refer to the more detailed discussion later in this preamble concerning protection of privacy.

In summary, it is clear that the availability of structured analyses derived from MDS information will empower those working with a variety of approaches to improve the lives of residents of nursing homes. Whereas the big brother term suggests a scenario in which the interests of the individual are sacrificed to promote the interests of the State, this is clearly not the case with respect to the objectives for MDS information. Instead, MDS information will be used to directly support the interests of individual nursing home residents by substantially enhancing our understanding of healthcare delivery in nursing homes and by creating a standard framework for monitoring the quality of this care.

Comment: A few commenters noted that computerized assessment data would support a case-mix reimbursement system, and that it would be helpful to be able to compare facilities with similar case-mix levels.

Response: Our Office of Research and Demonstrations began the Nursing Home Case-mix and Quality Demonstration in 1989. One goal of the demonstration is to design, implement and evaluate a nursing home payment and quality monitoring system for Medicare skilled nursing facilities based on resident-level information contained in an expanded set of MDS data. States participating in the demonstration are also using MDS data to calculate reimbursement under Medicaid. Computerized information from the demonstration's data base will provide information on outcomes and processes of care, stratified by case-mix and other characteristics in the six participating States. This will also provide a mechanism by which to evaluate the effect of reimbursement on quality issues.

Several other Medicaid agencies in States not participating in the demonstration have chosen to independently implement an MDS-based case-mix system for setting payment rates for facilities and for determining coverage. Numerous other States are currently studying moving toward a case-mix payment system based on the MDS. Furthermore, States have identified a plethora of other functions to be supported by information contained on the MDS assessment form, these functions include: utilization review, service placement, and improvement in the States' ability to monitor and evaluate the cost-effectiveness and quality of care and services provided under the Medicaid program.

At least two States have already incorporated, or plan to incorporate, MDS information into their Medicaid management information system. West Virginia notes that to do so will allow the State to fine-tune its long term care rate setting and payment methodology. West Virginia integrated its stand-alone long term care payment process into the Medicaid management information system. The system captures monthly data to calculate the resident-specific case-mix index. An electronic billing system was implemented through the Medicaid management information system, which calculates the base rate reimbursement for all Medicaid beneficiaries, as well as the additional payment due based on the case-mix acuity determined from an expanded set of MDS data. The MDS reporting system not only enables the Medicaid agency to conduct utilization review, but also allows the survey agency to use the reports for quality of care issues.

Another State has a legislative mandate to integrate to the fullest extent possible, its MDS system, preadmission screening and annual resident review system, and treatment authorization request system. The State points out that, because it uses a composite per diem rate, the State agency has little ability to comprehensively review and adjust approval or reimbursement systems in order to improve the quality of care, increase efficiency, or control costs in long term care. We believe that integration of the MDS and the Medicaid management information system will support the objectives of its Medicaid program, including provision of the highest practical level of care and management of available funds in a fiscally prudent manner to maximize purchasing power. The State maintains that its system will provide information to facilities, State and Federal agencies, and to the public that will improve the quality and cost effectiveness of care delivered in the State.

Comment: Another use of computerized resident data that

commenters addressed was to support policy analysis and monitoring of trends. One State noted that the data could be used to inform and improve general Medicare and Medicaid policies. Another State gave the example of using the data as a tracking system for prevalence of pressure sores, restraints, and drug therapy. A commenter stated that data could be used by the appropriate quality monitoring personnel in the State to increase the probability of detecting and analyzing State-wide health care problems. Another State commenter suggested using the data at the resident-specific level to determine an individual's needs for assistance with activities of daily living and other required services. The commenter also discussed analyzing aggregate information for residents by facility.

Response: We agree that these data will benefit both the policy and operational components of States and the Federal Government as well as provide valuable information to the consumers of long term care services.

Potential benefits in policy development and evaluation expected from this information include the following:

- Foremost is the added operational efficiency derived from the MDS' ability to support a multitude of applications and programmatic objectives. As a single form designed to capture a comprehensive view of residents and related facility care practices, when submitted within the context of a standardized data management system, it greatly reduces the operational costs of data gathering as compared to current program requirements involving multiple forms and submissions from the facility. For example, many States receive three different categories of resident information from facilities, each requiring separate forms and submission rules: placement determination forms (for example, preadmission screening and resident review), payment-oriented clinical information to support case-mix adjustment (for example, Minnesota's or West Virginia's case-mix assessments), and survey-oriented forms describing resident characteristics. With the breadth of data collected on the MDS, the requirements in each of these examples can easily be met via a single submission of MDS data; thus, the operational overhead and associated costs for both facility and State are reduced.
- At the national level, policy decision-making, development, and evaluation are supported through the creation of a standard means to analyze State differences in the quality of services and resident care outcomes in the nation's 17,000 certified long term care facilities.
- By deriving both payment and quality functions from a single instrument, a framework is developed to closely monitor the relationship between payment and corresponding service delivery, and to provide an objective basis upon which incentives to promote and reward outstanding care patterns and outcomes can be built.

With respect to support for survey agency operations, creation of a standardized MDS repository in State agencies provides the framework for the development of an information-driven survey process by which the frequency and scope of facility review are based on objective measures of a facility's performance in comparison to established standards. This information-based survey concept and its benefits are discussed in prior sections of this regulation.

Comment: We also received other suggestions and examples of ways that States are currently using computerized MDS data. A few States indicated that they are using or could use the data for resident review requirements under the preadmission screening and resident review program (PASRR). Other ideas included:

- Relating to research support, MDS information will support both basic clinical research activities as well as practical applications such as identifying issues for ''best practice'' conferences.
- Using the resident data to identify strengths of each facility, staffing patterns, common diagnoses, and resident characteristics (suggested by a professional organization).
- Using the data for health planning related to long term care services, certificate of need decision-support, projecting nursing home bed need, and determining characteristics and care needs of current residents.
- Identifying industry and surveyor training needs with respect to changing demographics and industry structural delivery mechanisms (for example, as service delivery blends across multiple traditional care settings).

One State commenter expressed the belief that the paperwork burden in that State would be reduced by having MDS data available for a variety of purposes.

Response: We agree that potential benefits exist for all of the above listed uses of automated assessment information. A standardized system for MDS data collection and analysis that we will be providing to States will facilitate States' and facilities' ability to make use of these data by creating an infrastructure for managing, analyzing and distributing information to meet these varying program objectives.

Comment: A commenter did not think that a facility could determine staffing patterns from the MDS data set, which would negate its ability to be used in determining differential rates of payment.

Response: The commenter is partially correct, in that the RAI does not explicitly collect information on staffing. However, staffing standards, staffing mix, and minimum staffing requirements are already well understood with respect to the intensity of care required for a given resident and his or her clinical characteristics. There are, in fact, several commercially available systems that currently use MDS data and derived resident characteristics information to assist facility administrators in setting appropriate staffing levels according to the mix of resident care requirements in their facility.

Furthermore, with respect to State payment and rate setting, States that currently use an MDS-based case-mix payment approach have adopted the resource utilization group methodology for the payment determination. This methodology is based on resource groupings that are created through time studies of facility staff as they carry out their daily care tasks. These time study data are then linked to corresponding resident characteristics data to determine levels of care resource utilization (staff time, supplies, etc.) for given sets of care needs.

Thus, in this approach, staff requirements are implicit in the determination of each distinct care grouping, each of which is then associated with a specific reimbursement rate. Residents with complex care characteristics fall into a higher reimbursement group which directly reflects the additional staff resources required to care for that resident. In more sophisticated States, these models have been extended to allow for staffing pay rate differences across various regions within the State (for example, urban vs. rural staff pay differentials).

The current MDS 2.0 assessment form includes calculations for several of the most common variations of the resource utilization group's scoring in the standard specification for MDS data. Therefore, States that do not currently use case-mix-based reimbursement will still have an implicit and proven method of measuring the relative care and staffing requirements of residents

according to widely accepted norms for such comparisons.

Again, the ability to support this functionality is created by the deployment of the standardized system for managing State MDS data repositories, upon which such resource utilization groups-oriented analyses will be derived.

Comment: We requested public comment on whether to collect a sample or 100 percent of MDS data. Of those who commented, most believed it would be preferable to collect 100 percent of facility data. One State thought that collecting only a sample of data would not produce the necessary level of detail required for a multipurpose data base system. The commenter further stated that operational activities generally focus on specific individuals, which would usually require information on all residents from all facilities. Another noted that 100 percent would be advantageous for rate setting and quality assurance, recognizing that the intended use of the data influences the collection requirements. The commenter said that an aggregate of 100 percent of facility data would serve well for the Federal level data set. A third State believed that having facilities submit data for all residents would make the State survey agency's sampling procedure in the long term care survey process more effective, as well as result in a comprehensive national data base. One State thought that sampled data would be disadvantageous in that it would provide incomplete or inaccurate representation and would be influenced by factors such as population density.

Those opposing collection of 100 percent of the data listed the associated cost, the size of the data base, and the man hours involved in collecting and maintaining the data. Proponents of collecting a sample of facility data noted that current survey protocols determine compliance with State and Federal requirements based on a sample, and that MDS data set required for submission should be no different. A national provider organization said that collecting 100 percent of the data would not meet the underlying intent of the law pertaining to the implementation of comprehensive assessments, the resultant care plans, and improved quality of care. A national provider organization believed that if 100 percent of the data is collected at the facility level, the State should send us a stratified sample on a quarterly basis, while if a sample is gathered at the facility level, the State should send us the entire sample on a quarterly basis.

Response: There are many drawbacks associated with sampling. An incomplete representation or smaller number of records would make estimates of trends more difficult. Problems with resampling would prevent the development of longitudinal measures. Such problems include:

- The retention of any bias in the initial sample that would increase over time and would affect the reliability of the data.
- The unequal burden on facilities in the sample to correct errors, respond to inquiries and provide data.
- The need to develop complex instructions that would direct facilities how to replenish the sample when subjects drop out. We would require other instructions to handle changes of ownership in facilities, facilities that leave the Medicare and Medicaid programs, and facilities that go out of business.

In short, it would be difficult and expensive to construct and maintain a statistically significant sample of residents for whom we would require a facility to transmit its MDS records to the State.

Furthermore, since the facility must obtain the information required by the MDS on each resident for clinical care planning, and given that most facilities today have already automated this process, the added requirement of submission of data adds comparatively little overhead and associated costs to this process. Certainly, there is some fixed cost associated with developing and supporting transmission of a single resident's record to the State, but the marginal cost of transmitting all residents' records is negligible. Therefore, there is no cost saving to the facility to transmit MDS assessments for a sample versus the entire population of residents.

We agree with the comments that support requiring facilities to transmit 100 percent of all required MDS assessments. We are requiring that a facility submit all initial, annual, and quarterly reviews, as well as partial assessments completed upon discharge, transfer, death, or reentry to the facility, for all residents, and that a State submit those assessments to us.

Generally, selection of a statistically representative sample of MDS assessments adds another complicated, costly and unnecessary layer to producing useful, valid data that can be used to inform States, nursing homes, and us about the quality of care and the status of residents in nursing homes.

One hundred percent of the data is necessary for the following reasons:

- It is necessary for longitudinal tracking of residents across time and facility admissions. This will allow us to track special subpopulations of residents such as those with pressure sores or Alzheimer's disease. It will allow the detection of certain trends, such as characteristics of new admissions to nursing facilities, and it will allow the detection of rare but significant events, such as hospitalizations for pneumonia, fractures or other conditions.
- The universe of data is also necessary to link to facility level data bases, such as ASPEN deficiency data in State agencies and the Online Survey, Certification and Reporting System, and to link to Medicare and Medicaid claims files at the national or State level to determine patterns of utilization and resource use pre- and post-admission to nursing homes, and to determine resource utilization in nursing homes.
- It allows for targeting individual and aggregate resident outcomes for use in an information-driven survey process that would be impossible without a universal data base.

The universe of MDS assessments makes possible the analysis of data at any level (for example, resident, unit within a facility, facility, State, regional, national, or for specific resident populations). An incomplete representation or smaller number of MDS assessments, as well as issues associated with resampling that were mentioned above, would limit trend analyses.

Working with the universal population of resident assessments will eliminate the technical difficulty and expense of selecting and maintaining a representative sample such as will be necessary to support longitudinal analyses. Creating and implementing a complex sampling process would be burdensome to facilities and States, and the burden could fall unequally on selected States or selected facilities. If facilities were required to perform sampling, there would be additional cost to upgrade their software and training for this capability. Additionally, some sampling methodologies would require complicated survey analyses to adjust sampling design. This would also be expensive.

In conclusion, the marginal additional cost of obtaining the full universe of assessments will, in fact, be exceeded by the cost and difficulty of maintaining a representative sample of assessments large enough to provide the necessary information for all the uses proposed for the data base.

Comment: A State suggested submitting 100 percent of data to the State, which would then submit only a sample to us. The State contended that it needed the most complete data set possible. The State also noted that its data base would be manageable and would not warrant sampling.

Response: We disagree with the concept of sending a sample of data to us. Our regional offices have many of the same needs as State survey agencies for 100 percent of resident-level data for certified long term care facilities within their States as one method to target and conduct Federal monitoring surveys in nursing homes. Furthermore, we need 100 percent of the data to develop and refine quality measures, which will be an integral part of the data-driven survey process.

All the factors enumerated in the above comment regarding the negative aspects of sampled submissions between facilities and States apply equally to the submission between States and the national data base: there is no advantage in terms of cost saving by using a sampling approach as it is no more costly or complex to transmit assessments for the full population. In fact, managing sampled data sets is actually more costly; and, the ability to meet the objectives for these data at the national level in terms of support for policy decision-making, development and evaluation, as well as for support for research initiatives, requires access to a complete population-based repository of assessments.

Comment: Commenters discussed whether a national data base would provide useful information to States for making comparisons for management, performance, measurement, and research purposes. Of those who addressed this, all agreed that such information would be valuable. One State said that it would be helpful for them to be able to compare their State with others regarding length of stay for residents with certain diagnoses and for utilization rates of special treatments and procedures.

Response: As discussed previously, we agree that there are many useful purposes for information from this proposed national MDS data base. One example of this submitted by a commenter is that the data base could provide information for interstate comparisons of resident lengths of stay according to diagnoses or outcomes.

Fundamentally, the MDS data, represented within the context of a standardized information system, provides the foundation for organizing complex clinical and facility information in ways that can be easily generalized to support numerous current and future objectives at the facility, State, and Federal levels. It provides a common framework for communicating about resident clinical characteristics, care outcomes, and quality, as well as facilities' service delivery and quality. Many of these specific objectives have been identified throughout this regulation.

Finally, the RAI has been translated into at least seven languages and is being used in several European and Asian countries for care planning to improve clinical care and for research purposes. The international development of comparable data sets would facilitate performance of cross-national research studies to examine the effects of differences in care patterns on long term care resident outcomes. These studies may provide a great deal of information on the geriatric long term care population across all countries.

Comment: Of those who addressed how data should flow, the majority of commenters, including a national provider organization, stated that data should flow through the States to us. Some expressed the belief that States should also maintain their own data base. One commenter recommended that data be transmitted to us by the States on an annual basis. A few commenters believed that the States should send summary information to us. One commenter said that initially, facilities will need a great deal of technical assistance, and it would be easiest for that to come from the States. A national provider organization wanted States mandated to devise methods for disseminating computerization information to facilities and for providing technical assistance. One State noted, however, that States should not be required to collect and store information, if there are no expectations about how the data will be used.

Response: We agree that States should have the responsibility to provide some level of general and technical assistance to facilities as relates to our and States' requirements for encoding and transmission of MDS data. We understand that States have varying levels of experience with the use of computerized information systems and data bases. However, several States have already established an MDS data base for case-mix, quality assurance or survey and certification purposes, or both, and have provided necessary training and assistance to facilities which enabled them to successfully implement automated systems.

We have established technical and user groups as part of the systems design process. These groups consist of States, provider and consumer representatives and experts in systems design. Their expertise and knowledge will be used to facilitate provider and State automation. We will also work with States to ensure that personnel have the necessary technical expertise and training to fulfill State automation responsibilities. Also, system specifications and other relevant materials are already available via an internet web-site, initially established to support MDS software vendors, and otherwise available from HCFA.

The pilot testing of the MDS standard system and associated procedures is another step currently undertaken by us to ensure that all aspects of this standard MDS system are fully understood with respect to technical operational requirements, State and facility user support needs, and general issues associated with deployment and system acceptance. Information from this test phase will directly support our ability to assist States in successfully installing and operating this system and ensure that facilities can easily accomplish their assessment submission requirements.

We fully appreciate the magnitude of support and effort that will be necessary to ensure that appropriate training is developed and disseminated to all who will be involved in implementing this data base, and are in the process of developing additional procedures and communication strategies to address this need.

Finally, a central requirement for the MDS standard system design is to ensure that maximum attention is given to understanding and assessing current technologies employed by facilities and States so that the MDS system will best integrate and accommodate these existing systems. We intend that this will both facilitate system acceptance across all user levels, and minimize support and other implementation costs. Also, we will emphasize technologies that lend themselves to ease of use and user-friendliness in the selection process for each level of the standard systems, but especially as this relates to systems used by facilities to submit MDS assessments to their State agency. Also, one of the implicit benefits of the decision to develop a standard system for MDS data management is that this provides the greatest ability to centralize support efforts, and also reduces costs for multi-state facility chains and software vendors by reducing the variation of systems with which they will interface, in that they need only support access to a single standard system across States.

Comment: A few commenters thought that the data should be sent directly to us without being sent to the State first. One said that it would be costly and duplicative if States maintained their own data base. One State agreed that State data bases would be duplicative and suggested that States have access to a HCFA data base through the Online Survey, Certification and Reporting System. The State commenter noted that this could be difficult for States that have adopted an alternate Resident Assessment Instrument, since it would be necessary to remove extraneous data collected by the alternate instrument. A State put forth the idea of creating a single national entity for the centralized collection of MDS data. The commenter suggested that States could then arrange for periodic digital communications with the entity, believing that this method would be more efficient than each State having to develop the capacity to receive facility data.

Response: We support having each facility initially submit 100 percent of the MDS data to the State. This would enable States to maintain a data base for use in Medicare and Medicaid activities that are primarily State responsibilities: quality assurance, longitudinal tracking of care outcomes for survey, certification and licensing, and in some States, case-mix reimbursement classification systems. Several States are already using computerized MDS information for this purpose, having decided that the derived benefits outweigh the costs of establishing and maintaining such a system. Our experience has been that States realize even more programmatic uses for the data once it is available to them.

While we could develop a central mechanism for collecting information from providers, there are significant disadvantages associated with this approach: (1) It would impose an additional layer between facilities and States with associated impact on timeliness and accuracy of information; (2) With so many of the objectives for MDS data being at the State level, direct submission of information to us creates an unnatural information flow which will have an impact on the ability of States to meet these objectives, especially as many of the objectives, such as the information-based survey process, are so dependent on timely access to MDS assessment information; (3) With the many State-specific uses for MDS information, such as case-mix payment, many of which require specialized elements recorded in the State-unique S Section of the MDS, we could not possibly centralize support for these functions or even accommodate all these variations in a central repository; thus, direct submission to us would defeat the goal of supporting unique State objectives; and, (4) States are in a much more appropriate position to support their individual facilities with respect to the MDS assessment, submission and data validation processes.

The information provided by a State-maintained MDS data base is not duplicative of a national data base. States vary with regard to their demographics, licensing policies, quality assurance and reimbursement systems. States are a logical level for maintenance of MDS information since each State performs and must manage its own survey and regulation processes. Information provided by MDS assessments cannot be obtained from our Online Survey, Certification and Reporting System. The Online Survey, Certification and Reporting System itself is not designed to provide the quantity and specificity of the information in the proposed MDS data base. Furthermore, a central MDS repository is necessary to support objectives such as policy and regulation development, but would not be as readily available for State functions as State-specific data. Since specific functions (for example, information-based survey process) are performed from this data base at the State level, it would be inefficient to require States to support these functions via access to a central repository.

We disagree that it will be significantly more expensive for States with alternate instruments to collect MDS data. The design of every aspect of the standard MDS system, from the record transmission format to the State data base repository, is intended to support the customizations required by individual States. Thus, although there will be some additional costs during the initial system implementation in States requiring custom formats, the system design makes these costs insignificant. At this time, there is no State variant of the MDS that cannot be accommodated within the context of the standard system architecture.

With respect to transmissions between the State and national repositories, we are requiring that a facility transmit only the core MDS items on the HCFA-designated RAI, the State will only maintain the State-specific elements at the State level.

Comment: A State noted that it currently collects computerized data from only Medicaid-certified nursing facilities because the State can reimburse them. The State asked if computer requirements apply to Medicare-certified facilities, and whether Medicare facilities would submit directly to us.

Response: The requirement to place the MDS in machine readable format applies to all Medicare and Medicaid certified nursing homes. There are no plans to have Medicare-only facilities submit MDS information directly to us. In the impact statement, we address how certified facilities will be reimbursed for information systems equipment and supplies, as well as data encoding and transmission. Long term care facilities certified to participate in Medicare are required under section 1819(b)(3) of the Act to use the State-specified RAI. The State's authority to collect computerized data from Medicare facilities springs from its role as an agent for us in performing Medicare surveys under section 1864 of the Act.

Comment: Commenters discussed auditing procedures that would ensure the accuracy of the data entered into the national data base. Some, including State commenters, believed that the accuracy of the data should be verified through the survey and certification process. A State commenter believed that it would take surveyors approximately 5 minutes to compare a resident's actual records with a computer printout. One commenter pointed out that if the accuracy is checked during the survey, a facility will take the assessment seriously and the assessment would not be viewed as ''paperwork.'' Another supported using surveyors to audit the match between a resident, his or her MDS and a computer editing software system.

Response: We agree that auditing the accuracy of MDS data on an on-going basis is very important in validating the ability of the data to support key operational and policy decisions. Indeed, the establishment of mechanisms to ensure acceptable reliability levels is critical to our ability to move forward with using MDS data for quality assessment and improvement activities, as well as other programmatic purposes. Currently, the survey process includes evaluation of the accuracy of assessments, as required by sections 1819(g)(2)(A)(II) and 1919 (g)(2)(A)(II) of the Act. Surveyors compare information from the most recently completed RAI with the current status of a sample of residents found onsite at the time of survey. We may modify and enhance the methods for accomplishing this task to reflect access to more longitudinal resident status information.

Several States, particularly those with case-mix reimbursement systems, have a separate auditing system in which nurse reviewers conduct an onsite assessment

using the MDS and compare it to that completed by the facility in order to verify the accuracy of the facility's assessment. We have recently completed a study of such methods and will be considering how to most efficiently assure the quality of MDS data. The methods under consideration could involve onsite review by surveyors or others, as designated by us, or offsite data analysis and evaluation, or both. We are also considering whether auditing would be carried out in conjunction with the survey process, as well as the timing and frequency of audits.

Comment: Commenters discussed methods for data verification. A few commenters stated that we should not require auditing and we should accept data as submitted. One State noted that any auditing process will result in cost increases. Another commenter pointed out that the data should be error free before the facility submits it. A commenter suggested that we not require auditing unless the MDS data is used for reimbursement purposes. A few commenters, including a national provider organization, disagreed with the idea of double entering data as a means of ensuring data integrity. They stated that it would be too costly, resulting in an unnecessary expenditure of time, cost, and effort.

Response: We strongly disagree with the comments that verifying accuracy of the data is not necessary. Foremost, it is imperative that the data be accurate and reliable for it to be used in any policy making, planning or resource utilization capacity. Accurate resident status information is necessary not only for reimbursement systems but for the health planning at the State and Federal level. Secondly, accurate assessments are necessary for quality care at the facility level, given that care planning should be based on the resident's assessment.

While data verification may be costly in the short run, we believe that it is cost efficient in the long run, in that accurate data will help prevent unnecessary expenditures or poor policy or reimbursement decisions that might result from erroneous information.

Several States that have computerized MDS data bases have encountered significant inaccuracies in the data originally received from facilities. This problem was rectified by establishing a process for ongoing validation of the accuracy of the data through on-line electronic systems feedback to facilities, or other systems for frequent cross checks and communication.

On-line data editing systems can facilitate timely detection and correction of inaccuracies. Virtually all the States that have computerized MDS data bases have developed built-in edit checks for obvious inaccuracies which would disallow entry of conflicting or invalid data, for example, for a resident coded simultaneously as comatose yet, inconsistently, enjoying playing cards.

We agree that double entering data to ensure validity would be expensive and we are not requiring it. We emphasize, however, the important role that validation plays in the establishment of a data base. To this end, we published standardized range and relational edits in May 1995 that MDS data will have to pass in order to be accepted at the State level.

Comment: Some commenters placed responsibility for the accuracy of the data on the facility. According to a commenter, having the edit checking process occur at the facility is critical, otherwise the State system would quickly become overburdened with rejecting records back to the facility for correction. One recommendation was for a facility to have a system for visually checking MDS information prior to submitting the data. Commenters noted that computer software can validate that the MDS is complete and that responses are within an acceptable range, and can also generate a condensed MDS with the responses, and staff can compare this to the MDS to verify accuracy. A State commenter proposed that we require a facility to maintain an accuracy rate of 95 percent for its data to be accepted by the State. Commenters suggested that a facility only transmit updates and changes to the data base once the original assessment is on file. Another proposal was for us to require a facility to incorporate surveillance and correction procedures as part of its quality assurance program.

Response: We concur that a facility has a responsibility to submit assessment data that is accurate, and there are many ways to accomplish this. A facility is required by section 1919(b)(3) of the Act to conduct a comprehensive, accurate, standardized and reproducible assessment of each resident's functional capacity. We are adding to § 483.20(g) the facility's responsibility to accurately assess residents, as well as § 483.20(f)(3), which notes the facility's responsibility to transmit accurate data to the State. We believe, however, that the State also has a role in verifying the accuracy of the data and systematically monitoring and evaluating the quality and accuracy of the assessment data which will be submitted from facilities.

States will monitor completeness and accuracy of MDS data submissions from the facility. A facility will be in compliance unless an unacceptable percentage of the records completed by the facility during a target period are either not submitted to the State or not accepted by the State because of data errors. We will determine compliance based on a review of missing records for the target period, allowing sufficient time after the close of the specified period for relevant records to be submitted from the facility to the State.

Our initial plan is to have States accept required records submitted by the facility, except when specific data errors occur. Currently, plans are for States to reject records only if:

- A submission file has a missing or misplaced header record or trailer record;
- Any record in the file does not have the correct record length with the last data character being the ''end of record'' delimiter required by the standard data specifications;
- The submission file contains an invalid facility ID code (Fac__Id in the data specifications) in the header record or data record; or
- The total number of records in the submission file does not correspond to the record count given in the trailer record.

We will evaluate this process and make necessary changes based on experience.

A facility is in compliance unless there is an unacceptable error rate for the set of records completed by the facility during a specified period. Determination of compliance is based on a review of records accepted by the State, allowing sufficient time after the close of the specified period for relevant records to be submitted from the facility to the State. The error rate in question is the total number of fields in error, due to either range or consistency errors as identified in the MDS 2.0 data specifications in effect, divided by the total number of required fields across all records for the specified period. The fields that we require for each type of record (for example, admission assessment, quarterly assessment, discharge tracking form, etc.) are detailed in the MDS 2.0 data specifications.

Further, States have a role in training facility personnel in methods of preventing and correcting data errors. The suggestion by a commenter that we require a facility to incorporate surveillance and correction procedures as part of its quality assurance program may be a viable option.

Comment: Other commenters believed that States should bear primary responsibility for the accuracy of the RAI data. One State suggested that the States should provide facilities with report formats that cross check interrelated data. Another commenter proposed that a State keep verification requirements for transmitting data separate from verification of clinical consistency of the data. A commenter pointed out that it was unclear whether we intended that States notify a facility of errant data before transmitting the data to us. One suggestion was for the State to check data for completeness, accuracy and compliance with processing instructions. Another was that the State specify a standardized format for transmitting data that would require compliance with edits. A few commenters thought that the States should be responsible for the quality of the data transmitted to us.

Response: The responsibility for data accuracy must reside with the facility, the source of the data, and a facility should ensure that MDS data pass all standard accuracy edits before transmission to the State. The State does have a responsibility to monitor accuracy of data submitted by a facility and aid the facility in achieving accuracy. The State will perform standard accuracy edits on data files as they are received and report any errors found to the facility. A State will also be able to monitor the error rate for a facility over time and produce an error summary report to share with the facility. The State will also have the ability to monitor the error rates for any MDS software vendor. When systematic problems are found for a vendor, the State will have the opportunity to work with that vendor to correct the problems. We may also develop procedures for onsite data accuracy visits to the facility when error rates are high. We will determine the frequency of such visits during our formal systems design process. MDS data submitted to the State will be transmitted to us at least monthly. We will again edit the data for accuracy. Accuracy edits will be performed at the facility, State, and HCFA levels.

Comment: We received a number of other suggestions to ensure the accuracy of data. One was to allow the registered nurse assessment coordinator to validate the data. A few suggested a computer system that has a basic set of edit checks, like high-low checks, completeness checks, clinical inconsistencies, and incorrect data checks. A consumer advocacy organization pointed out that some States currently have special nurse auditors who validate the match between a resident and his or her MDS. A State suggested that the reliability of MDS data be verified by periodic, random, onsite review of individual records performed by either State program agency staff or by a contracting organization. Another noted that if validity becomes an issue, we could consider a regulatory mechanism for appointing independent assessors.

Response: We agree that the computer systems should have basic edit checks, which ought to be in place both at the facility level and at the State level. The standard data specifications we have developed include valid ranges and required formatting for MDS items and consistency between MDS items. Detailed information concerning these data specifications is available on our MDS World Wide Web site (at http://www.hcfa.gov/Medicare/hsqb/mds20/) and is otherwise available from us and the State survey agency. We anticipate that facilities will be able to select commercially available software packages that use these data specifications. We note that the current regulation grants States the authority to take over the assessment process if a facility knowingly and willfully certifies false assessment statements. Section 483.20(c)(4) allows the State to require that assessments be conducted and certified by individuals who are independent of the facility and who are approved by the State. New York, for example, contracts with their peer review organization to conduct onsite audits of the Patient Review Instrument, used to calculate Medicaid reimbursement. Nurses sample a certain number of resident records. If the records do not pass standards based on resource utilization group, the facility loses its ''delegated status'' to conduct assessments and must hire an independent assessor for 1 year.

Comment: Many of the comments we received regarding privacy and confidentiality issues demonstrated concern regarding privacy issues and indicated that residents' identities need to be protected. Some of the commenters believed that MDS information should be available or reported in the aggregate format. A few commenters wanted identifying data available at the State level but not in any public data sets created. One commenter questioned why we should have access to assessment information of private pay residents. A national provider organization stated that the need for information in planning and quality assurance should not be met at the expense of the resident's and facility's right to confidentiality. Commenters suggested that we develop ways to block resident identifiers or develop an alternate system of identification like numerical coding.

Response: We agree that protecting the privacy of the resident is essential. In establishing this system of records, both we and the State (as HCFA's contractor in performing survey functions) must comply with the Privacy Act (5 U.S.C. 552a), which applies to Federal systems of records containing individually identifiable information. While aggregate summaries of the data can be made public, there are strict Federal guidelines for the release of individually identifiable information by Federal agencies to any individual or organization. A release of personal identifiable information can only be made in limited circumstances described in the Privacy Act. Disclosure may be made under the Privacy Act for ''routine uses,'' which are compatible with the purpose for which the information was collected. These routine uses are described in the Privacy Act System of Records, which is published in the **Federal Register**. Requirements associated with routine uses are also set forth in the System of Records. In most cases, a ''data use agreement'' is required with the recipient being bound, in turn, by the Privacy Act. Some States have additional laws strengthening the protection of privacy of the resident.

We would have difficulty assuring the quality of care in facilities if we only had access to periodic aggregate data. While allowing evaluation of prevalence rates (percent of residents who have a particular condition at a given point in time) over time, such data would largely preclude any quality of care indicators based on incidence rates (percent of residents who acquire a given condition in a facility between two points in time). For example, periodic aggregate data might show the prevalence of decubitus ulcers in the resident population, but we could not review it to determine the incidence of such ulcers while residents are in the care of the facility. A high prevalence of ulcers may indicate that the facility accepts residents with existing ulcers from the hospital, but a high incidence may indicate substandard care. If access were limited to aggregate data, it would also be impossible to evaluate other important outcome measures potentially indicative of quality of care.

Our quality assurance activities in Medicare and Medicaid certified facilities are not limited to selected residents (for example, Medicare or Medicaid residents, or both). Our long term care survey process directs State

survey agencies to review the care provided to all residents of certified facilities, regardless of payor source. For example, quality assurance survey teams review a random sample of residents without respect to payor. We would often have difficulties evaluating the quality of care in Medicare and Medicaid certified facilities if access to data is limited to residents who are Medicare or Medicaid funded. This is especially true in a facility in which Medicare or Medicaid residents, or both, are a minority. This requirement is, therefore, in keeping with the quality protections that are afforded to all residents in certified long term care facilities. We will not give out identifying information unless there is a demonstrated need for it; the routine use permits disclosure only if we determine that the research cannot be reasonably accomplished unless the record is provided in individually identifiable form.

Comment: One commenter was unclear why confidentiality is an issue, since we already have systems in place to guard confidentiality, and these systems could carry over into the MDS system. A professional organization recommended developing a software program that could block identifying information except when needed by designated persons.

Some commenters addressed the question of who should have access to the data base. Several suggestions were submitted, including:

- The State survey and certification agency;
- The reimbursement agency (without resident identifiers);
- The ombudsman (one commenter suggested without resident identifiers while another said consistent with current access rights for resident records);
- The submitting facility (with no access to other facilities); and
- Aggregate data should be available to the public. Commenters proposed that a State have access to facility data in its own State with resident identifiers and to other States and the national data without identifiers.

Response: As aforementioned, under the Privacy Act, when personal information in the possession of the Federal Government on an individual is accessed by name, Social Security number or any other identifying symbol, we must publish a system of records notice. This notifies the public that we are collecting the information and will be accessing it in an individually identifiable way.

The notice lists routine uses for the information, including a list of entities to which we may release information upon request, the uses for which we may release information, and conditions under which we may release individually identifiable information. The Privacy Act requires that the routine uses be consistent with the purpose for which the information is collected. The Privacy Act does not mandate us to release the information. The system of records notice will support research as a routine use, but will require safeguards to ensure the maximum protection of individually identified information. It requires that persons or entities requesting the information sign an agreement to not re-release the data. The system of records notice also permits release to government agencies for purposes of monitoring nursing home care. We already have a routine use disclosure provision in place for handling data requests by those conducting health services or other appropriate research for most of our systems. We evaluate each request on an individual basis, including whether it is appropriate to release any data with identifying information.

Comment: A few commenters recommended that we not release resident-specific information unless the resident has directly consented. One State suggested that we and States issue ''designator'' numbers that would allow resident-specific information to be released. A commenter suggested that we build fines and penalties into the system for breach of confidentiality.

Response: As aforementioned, we will follow all provisions of the Privacy Act, as well as the Freedom of Information Act in managing the information from this proposed data base. Our Freedom of Information Act officer decides whether to release the records if a request is made at the Federal level. Under the Freedom of Information Act, individually identified RAI data generally would be exempt from disclosure as medical (and similar) files, the disclosure of which would constitute a clearly unwarranted invasion of privacy (5 USC 522(b)(6)). Under the Privacy Act, individually identified records may not be disclosed, except for good cause, including routine uses consistent with the purposes for which the information was collected (5 USC 522a(b)). (Aggregate data, not individually identifiable, could be released under either law.)

For records collected under the authority of our RAI requirements, States are bound by the Privacy act as our agent. In addition, most States have their own rules governing protection of privacy for records maintained at the State level. We expect each State to take the appropriate steps to ensure that resident-identifiable information is protected.

We are adding language to § 483.20(f)(5) that prohibits a State from releasing resident-identifiable information to the public, and provides that a facility may release resident-identifiable information to an agent only in accordance with a contract under which the agent agrees not to use or disclose the information except to the extent the facility itself is permitted to do so. We note that the Health Insurance Portability and Accountability Act of 1996 (Public Law 104–191) provides stiff penalties for persons who wrongfully disclose individually identifiable health information. Such penalties can include fines or imprisonment, or both.

RAI data would be part of a resident's clinical record, and as such, would be protected from improper disclosure by facilities under current law. Facilities are required by sections 1819(c)(1)(A)(iv) and 1919(c)(1)(A)(iv) of the Act and § 483.75 (l)(3) and (l)(4), to keep confidential all information contained in the resident's record and to maintain safeguards against the unauthorized use of a resident's clinical record information, regardless of the form or storage method of the records. We recognize that there are circumstances that may necessitate the release of information from the resident's clinical record. However, these instances are limited by regulation to circumstances required by (1) transfer to another health care institution, (2) law, (3) third party payment contract, or (4) the resident (§ 483.75(l)(4)).

The transmission is limited to (1) using a private dial-up network based on a direct telephone connection from the facility or (2) mailing a diskette from the facility. In the case of either telephone communications or the mail, the information transmitted is secure, with interception of information being prohibited by Federal and State law, and strong penalties apply. We and the States both receive large volumes of unencrypted voice phone calls, unencrypted data telecommunications (for example, claims data), and unencrypted mailings, all including resident-specific information.

Section 1902(a)(7) of the Act requires Medicaid agencies to provide safeguards that restrict the use or disclosure of information concerning applicants and recipients to purposes directly connected with the administration of the plan. Moreover, under the agreement between the Secretary and the State survey agency pertaining to

section 1864 of the Act, the State is required to adopt policies and procedures to ensure that information contained in its records from the Secretary or from any provider will be disclosed only as provided in the Act or regulations.

States may allow other agencies within the State to have access to MDS data to the extent that it is related to the operation of the Medicaid programs. All agencies must adhere to the confidentiality requirements of the Medicare and Medicaid programs relative to this information. We are also providing in § 483.315(j) that a State may not release resident-identifiable information to the public. Further, the State may not release resident-identifiable RAI data to a contractor without a written agreement under which the contractor agrees to restrict access to the data.

We believe that adherence to § 483.10(b)(1), Notice of rights and services, adequately addresses the commenter's suggestion that residents be notified. We believe that using designator numbers as a vehicle to permit release of resident-specific information is not feasible. Because such a system would require that all providers use the same number for the same resident, (in other words, to enable tracking of residents across different providers), implementation would be extremely burdensome.

Comment: Commenters addressed other issues pertaining to privacy and confidentiality. We received a recommendation to contact specific individuals who could assist in developing the security of a data base. Another recommendation was to carefully control computer access (in other words who can get to the data via computer at the facility and at the State).

Response: Both at the facility and the State, access to the MDS records for residents, whether those records are hard copy or electronic, must be secured and controlled in compliance with our requirements for safeguarding the confidentiality of clinical records. The facility must take precautions to ensure that only authorized staff have access to confidential information. Electronic MDS data should reside on stand-alone computers in secured physical locations, or access to those data should incorporate standard user ID and password techniques.

Comment: A few commenters thought that only the facility in which a resident resides should be able to make changes in the data entered. One commenter proposed that the data system require the facility to ''close-out'' a resident's information upon discharge or transfer, which would prevent the facility from changing that information. It would also prevent ''a receiving facility'' from entering new data on a transferred resident until the information base is closed by the transferring facility.

Response: We are in agreement that no other facility may make changes in the MDS data. A facility may only change MDS hard copy and electronic data as allowed by our policy. This policy requires that after the facility performs the assessment, it is ''sealed,'' and electronic records are ''locked.'' HCFA policy also require facilities to complete tracking forms indicating resident discharge from and reentry to the facility. The facility must complete and submit these forms and corresponding electronic records to the State within specified time frames. It would not be appropriate to require one facility to ''wait for'' a discharge record from another facility before entering and submitting data for Medicaid payment. This could result in payment delays for the one facility when another facility is delinquent on submitting MDS records.

MDS data bases at the State will be used for a variety of purposes, including quality monitoring, Medicaid and Medicare payment, and policy analysis. It would prove quite cumbersome and, at times unworkable, for all data changes to always be made by the facility of residence and then updated in the State data bases after resubmission from the facility.

Comment: Commenters discussed the schedule for submission of data by facilities, for example on an annual or quarterly basis. A national advocacy organization supported continuous data flow, pointing out that States need up-to-date information due to the survey cycle and their need to be able to respond to complaints when they are received. One commenter said that most facilities in their State routinely transmit on a weekly basis. Other commenters questioned how current would be the data that are to be maintained. The few who responded agreed that the data do need to be up-to-date and agreed with others who said that transmission should coincide with the RAI requirements. Others addressed the need for a transaction log to document transmission.

Some commenters noted that reimbursement agencies may require data on a more frequent basis for the purpose of rate setting. It was also mentioned that requiring transmission on a more frequent basis would be an administrative burden. A few commenters wanted the quarterly reviews to be transmitted also. A national provider group suggested quarterly submission, staggered in order to facilitate managing the large volume of data. For example, at the end of each month, 1/12 of the facilities would submit data for the preceding 3 months.

One commenter recommended that States transmit data to us on an annual basis. There was some support for collecting data on a quarterly basis. A few commenters believed that the States should send us summary information. A few States suggested submitting data on the same schedule as the MDS is completed—that is, upon admission, within 14 days of a significant change, and annually. Others agreed that annual submission would be adequate. A few proposed that data be transmitted twice a year. One commenter believed that all States should submit data on the same date.

Response: In order for MDS information to be timely enough for use in ongoing quality assurance programs, a facility must submit MDS data at least monthly to States. This would entail submitting all full MDS assessments (initial, annual and significant change), and any partial assessments (quarterly, discharge, and reentry) completed since the facility last transmitted data to the States.

States will also submit data to us at least monthly. The regional offices also need timely information in order to perform Federal monitoring surveys. To a certain extent, the role of the regional office mirrors that of State survey agencies. Hence, the regional offices need timely, complete information. Furthermore, this is necessary to enable us to timely evaluate State trends or regional problems. For example, linking resident status information with SNF cost report data could identify potential Medicare utilization problems in relation to certain outcomes or resident status changes.

Analysis regarding the timeliness of MDS data and frequency of transmission requirements has shown that the MDS data base must contain quarterly review information if it is to be used for quality monitoring purposes by State survey agencies. Much of the work being done to develop quality measures relies on quarterly assessment data for each resident. Leading researchers and survey experts agree that the quarterly review data are needed for the timely and reliable identification of resident outcomes for this purpose. There is under development, discussion and testing, a case-mix demonstration payment system using MDS data in calculating appropriate payment rates.

Comment: Commenters made suggestions regarding what edits should

be allowed without requiring the facility to produce a new electronic record or hard copy. One State wanted any change in MDS information to result in a new hard copy. Another State proposed that we allow a typographical error to be corrected at any time. A consumer advocacy organization proposed that if a facility makes changes to a computerized copy, it should be held to the same standard as written records. Another commenter believed that MDS software should create an audit trail of changes made to an assessment that would include the name of the person making the change, the date, the old value, and the new value. The commenter suggested that we permit a facility to keep the most current copy in a hard copy format. A State commenter believed that the computer program should have the ability to update the assessment information without changing the original version. Another State did not want to make changes if the data had been transmitted after the 21st day after admission. Another State proposed using those things that meet the criteria for significant change with regard to edits.

Response: According to current policy, a facility may correct typographical or factual errors within required time frames. To make revisions on paper records, a facility enters the correct response, draws a line through the previous response without obliterating it, and initials and dates the corrected entry. Computer-based systems must have a way to indicate and differentiate between the original and corrected entries on the printout of the corrected form, and to ensure that the correct information is transmitted to the State. Again, we note that the assessment must be accurate. A significant correction of prior assessment is completed at the facility's prerogative, because the previous assessment was inaccurate or completed incorrectly. Version 2.0 of the MDS contains an item response that, when checked, indicates that the assessment is a significant correction of a prior comprehensive assessment. A number of providers have called to our attention that the wording of this item precludes its use when the prior assessment that is being corrected was a Quarterly Review Assessment. We will add code to the MDS version 2.0 that will provide a mechanism for this.

A significant correction of prior assessment differs from a significant change in status assessment, in which there has been an actual change in resident's health status. If there has been a significant change in health status, the facility cannot merely correct the affected items on the MDS. The facility must complete a full new assessment. Any subsequent changes should be noted elsewhere in the resident's record (for example, in the progress notes). As stated previously, however, the procedures and policy governing issues of data storage, retrieval, validation and maintenance in facilities will also be addressed more fully in a forthcoming HCFA publication, such as a State Operations Manual.

Comment: Some commenters requested that the requirements we issue allow electronic signatures. This would avoid duplication by not requiring that the facility keep on file a hard copy with signatures.

Response: In the development of the system, we will consider requirements for electronic signatures.

Comment: Commenters addressed how and to what extent we should standardize electronic formats and how to revise the format to be consistent with technological changes. One State did not think that a standardized electronic format is necessary, and proposed that we request summary reports, findings and group data instead of individualized data, which would obviate the need for a standard format. Several others expressed the belief that we should specify a format. A national provider organization pointed out that a standardized format would facilitate collecting, merging, and analyzing national data. Another commenter noted that it would also decrease software development costs. A State provider organization pointed out that nothing would be more frustrating and costly than software that is not well thought out and requires several revisions. The commenter suggested that we already have experience in formatting because of the case-mix demonstration project.

A State expressed the belief that it would be easier to maintain a single format than have to deal with different software languages and media types. The commenter further said that we or the States should be responsible for making formatting changes and sharing them with those affected. Another recommendation was to use Online Survey, Certification and Reporting System and create a subsystem for MDS data. By accessing an ''enhancement log,'' the system would be under constant review and revision.

Response: We concur that many of these suggestions have merit. In the spring of 1995, we developed and issued a standard record layout and data dictionary. These were made available to facilities and software vendors as well as the States. When these regulations go into effect, the assessment records that facilities transmit to States must conform to the standard layout. Hence, software vendors have been strongly encouraged to use the layout and data dictionary when developing software products for MDS version 2.0. We believe that this will ensure uniformity in format but still allow facility flexibility and choice in terms of the software products they use to encode MDS records.

Comment: A national provider group proposed that we require States to develop and make available a software package that would transmit data in the appropriate format. A few commenters expressed the belief that as long as they meet Federal standards, States and facilities should be able to develop additional standards.

Response: We have developed, and are in the process of testing, a national system for MDS data transmission that will be made available to all States that includes commercially available standard transmission software. We are mandating that the facility transmit MDS data to the State according to minimum data validity specifications and using standard communication and transmission protocols. The State may choose to impose additional data validity specifications, exceeding our mandated minimum specifications.

Comment: We received a few suggestions regarding specific organizations with whom we could consult in developing a standardized format. One suggestion was to form a technical advisory board that would consist of Federal and State personnel, providers, hardware and software vendors, and resident advocacy groups. Another was to contact a specific standards committee to obtain their input on developing a format.

Response: We sought technical assistance from those parties as part of a technical advisory group that we organized as part of the systems design process. We met with several of the groups mentioned above early in the design process to get input on a number of systems development issues. We will continue to seek input throughout the development. We are committed to working closely with interested and affected parties in the design process.

Comment: Commenters suggested that the standardized format should be in either ASCII or EBCDIC, and should include data item description, data item beginning and ending column, data item length, and whether the data is right or left justified. One State noted that some States have already begun to computerize and that the format should be receptive to those programs,

particularly for States utilizing our RAI. A State commenter believed that a data dictionary should be provided for each data submission, which would provide a vehicle for documenting problems with the data submission.

Response: As previously stated, we have been working closely with States that are computerized. Several States were instrumental in developing the data dictionary and record layout. With their expertise, we constructed a standard layout that still allows flexibility for States which have added MDS items. Facilities and States must conform to the standard record layout, which is currently constructed in ASCII.

Comment: Several commenters wondered how facility noncompliance with the requirement to transmit the MDS data would be enforced.

Response: As stated earlier in this preamble, facility noncompliance with the reporting requirement established by this final rule will be subject to the full range of enforcement remedies set forth in part 488, subpart F, ''Enforcement of compliance for long-term care facilities with deficiencies.'' We will treat a facility's failure to comply with MDS reporting requirements as noncompliance under the definition in § 488.301. At a minimum, we will require a plan of correction, and will impose the mandatory denial of payment for new admissions sanction if the facility has not achieved substantial compliance within 3 months from the date of the finding of noncompliance. In such a case, if the facility is still not in compliance with requirements within 6 months from the date of the finding, we will terminate its provider agreement. Also, we may impose one or more other remedies, as determined by us or the State, in accordance with part 488, subpart F.

Facility failure to meet acceptable standards of performance, including failure to transmit the MDS data, or failure to otherwise improve upon its past poor performance, or failure to transmit or to maintain compliance relative to this reporting requirement could be considered by us to be indicative of the facility's inability or unwillingness to perform the resident assessment itself. We believe that this is a reasonable conclusion because if the requirement to conduct a resident assessment has been satisfied and completed, then the administrative reporting requirement would simply and logically follow. Noncompliance that is repeated or which recurs intermittently becomes part of the facility's noncompliance history which is a factor when we or the State selects the appropriate enforcement response. We will sanction, accordingly, a facility that demonstrates little or no commitment to continual, rather than cyclical, compliance. A State will be easily able to ascertain whether a facility is transmitting the required information timely and in the manner that we prescribe, those facilities that fail to meet the standard may be subject to the full range of available remedies, including denial of payment for new admissions and civil money penalties. We do not expect perfection relative to compliance with this reporting requirement; we will incorporate limited tolerance into the compliance assessment process, whereby good faith efforts made by facilities will be considered. An additional level of tolerance will exist during early phases of implementation of the requirement.

Comment: A number of commenters addressed a wide variety of issues relating to the computerization of MDS information. A State commenter stressed that we should emphasize the benefits to facility staff and residents. A consumer advocacy group expressed the belief that we should address how computerization will affect utilization of the RAPs and the individualization of the care planning process.

Response: As mentioned in the previous discussion of data uses, we believe that the automation of this information will be extremely helpful to facilities. We note that computerization of resident assessment information does not relieve facilities of their responsibility to develop, by an interdisciplinary team, a comprehensive, individualized care plan. While software packages exist that will automatically print a plan of care based on responses to MDS items that trigger a RAP, an individual must still exercise professional clinical judgment in customizing the care plan to suit each resident's individual needs.

Comment: Commenters proposed that we develop regulations and manual instructions relating to transmitting data. A State wanted a telecommunications program to be mandated. Another State expressed the belief that we should penalize facilities which do not comply with submission requirements.

Response: Once we develop key specifications for data transmission, we will issue clarifying policy and give instructions to States and providers in a State Operations Manual transmittal. We will require that a facility comply with the policy and regulations covering this data base in order to participate in the Medicare and Medicaid programs. As mentioned above, we are requiring that a facility electronically transmit its data via telecommunications infrastructure to the State. Penalties for not complying with submission requirements are addressed with the comments on proposed § 483.20(b)(6), Automated data processing requirement.

Comment: Some commenters discussed software vendors who have developed RAI packages. Commenters suggested that we develop a program to test vendor software for minimal acceptability.

Response: We are developing several aids to promote the accuracy of RAI software packages developed by commercial vendors. These efforts include the following documents and data files, being published on our World Wide Web site (at http://www.hcfa.gov/Medicare/hsqb/mds20/) and otherwise available from us.

- Detailed specifications for data validity (valid ranges and consistency requirements for MDS items).
- Detailed logic and a test data base for RAP determination.
- Detailed specifications for the file structure, record layout, and field formatting for MDS files submitted by facilities.
- Detailed logic, a test data base, and a test program for Resource Utilization Group calculation.

We are also developing a standard State-level MDS processing system to be distributed to each State. One feature of this system allows RAI software developers to transmit test files of MDS data to the State and receive a detailed log of all data validity errors encountered in the test file.

We will continue to promote processes for assuring the accuracy of software packages developed by vendors even though the approaches to this effort will change over time.

Comment: In the preamble to the proposed rule, we encouraged comment on developing a mechanism for advising us on the need and method to update the MDS and RAPs. Commenters agreed that we do need a method to update the RAI. Several suggested that we establish a clinical advisory panel or commission similar to the project team, clinical panel and advisory committee that developed the RAI. Other ideas included an annual update schedule, including any changes in the MDS as an addendum; sending periodic questionnaires to providers, State agencies and organizations; and a yearly comment period.

Response: We have always recognized that the RAI will need to reflect advances in clinical practice and assessment technology. We will be making periodic revisions to the RAI. In 1994, we awarded a contract to the

Hebrew Rehabilitation Center for Aged, under which we will revise the RAI over a few years. The contractor will convene representatives of States, provider organizations, professional associations, and consumer organizations. These groups will advise us regarding the need to add or refine items or definitions, and regarding areas that are less well understood, and require clarification. As in the past, the revision process will be one in which we seek input from the many interested and affected groups.

Comment: We solicited comment on how to coordinate the assessment process with other assessment protocols such as home health assessments and the uniform needs assessment instrument (comments on coordinating with PASRR are discussed with the comments on proposed § 483.20(b)(5), Coordination). Some who commented merely agreed that it is necessary to coordinate assessments. Others gave suggestions, for example, that we issue a stronger directive that a facility provide a copy of the MDS as part of their post-discharge care, use the RAI in all long-term care settings, and coordinate with the home and community based waiver MDS of OBRA '90.

Response: We recognize the need to coordinate an individual's health care across various health care settings and the importance of assessments in this process. Currently, we have no statutory authority to require this coordination except in the case of coordination of the RAI with preadmission screening programs for individuals who are mentally ill and mentally retarded. However, there is great interest in the development of clinical data sets like the MDS for several provider types, including end-stage renal disease facilities and home health agencies. Work is well underway to develop screening tools in some of these areas.

§ 483.20(b)(1) Resident Assessment Instrument

Comment: Commenters addressed the proposed requirement that the assessment process must include direct observation and communication with the resident, as well as communication with licensed and nonlicensed direct care staff on all shifts. Most supported the requirement. A few commenters were concerned with enforcement of the requirement. Some wanted us to require that the facility communicate with the resident only when clinically feasible, since the resident may not have the cognitive skills to verbally communicate.

Response: The resident is a primary source of information when completing the assessment and may be the only source of information for many items. In the RAI User's Manual and in the State Operations Manual, Transmittal No. 272, we have instructed facility staff to talk with and observe the resident. It is still possible to interact with a resident, even if he or she is unable to communicate verbally. Staff can closely observe the resident and respond to many MDS items based on observation. We acknowledge that evaluating facility compliance may be difficult but we believe that this requirement is too important to delete. However, we do not want to require a specific process for documenting collection of data across shifts. This would burden facilities and limit their flexibility to implement a process that is most appropriate for each facility's specific situation and practices.

Comment: A few commenters believed that only the direct care staff responsible for providing care to the resident on all shifts should be included in the assessment process. Others wanted us to require that the facility talk to other people, such as a resident's family members/guardians, the attending physician, and other licensed personnel.

Response: We did not limit the assessment process to only those staff members responsible for actually providing hands-on care because we believe that facility staff who are not the primary care-givers often have valuable, first-hand information about a resident. For example, housekeeping staff who routinely talk with residents may be aware that a resident prefers extra pillows on her bed because it alleviates her back pain. In the State Operations Manual Transmittal No. 272 and in the RAI User's Manual we suggest that information sources for the assessment should include, but are not limited to, discussion with the resident's attending physician, appropriate licensed health professionals and family members. Family members are a valuable source of information regarding the resident, particularly for cognitively impaired residents, for whom family is often the only source of information regarding the resident. For example; a resident's spouse may be the only person who knows what the resident was like prior to admission to the nursing home, and is able to provide background information that is necessary for staff to complete the Customary Routine section of the MDS.

We require that a physician be a part of the interdisciplinary team that prepares the care plan. We acknowledge that a doctor's schedule may not allow consistent participation in the assessment process. While we encourage facilities to discuss the resident's status with the attending physician to gain and validate information, we are not requiring it. The statute is silent regarding the participation of individuals other than health professionals.

Comment: Some commenters wanted us to clarify that communication with all shifts can be both verbal and written. For example, information could be exchanged at pre-shift meetings, through progress notes or other documentation in the clinical record, or by other means.

Response: We agree that information can be exchanged in a number of ways, and discuss possible mechanisms in the RAI User's Manual. At this time we do not wish to mandate a communication process; rather, each facility should determine how to best exchange information about the resident.

While we did not receive comments regarding the facility assessing the resident using the RAI specified by the State, we are adding to § 483.315(c) that the State must obtain our approval of a State-specified instrument. This is more consistent with sections 1819(e)(5) and 1919(e)(5) of the Act. Furthermore, we are specifying those domains or areas that the facility must assess. We listed these domains in the assessment requirement previously, and inadvertently omitted them at former paragraph (b)(2); a State suggested that removing the domains weakened the requirement. Additionally, surveyors use the regulatory tags for particular domains to cite deficiencies when a facility has problems only in certain assessment areas. The State is responsible for obtaining approval from us for its instrument and to specify its approved instrument to facilities. Facilities must therefore rely upon the State's assertion that the instrument is approved by the Secretary.

Proposed § 483.20(b)(2) When Required

Comment: Several commenters addressed our proposed requirement that a facility complete the comprehensive assessment within 14 days after a resident's admission. Some commenters agreed with the 14-day time period, and wanted us to emphasize that the RAI and quarterly review are a minimum, stressing that all the resident's needs must be identified and care planned as necessary. A commenter requested clarification regarding completion ''within 14 days after admission,'' stating that it could be interpreted differently. For example, the facility could construe the requirement

to mean ''14 days after admission'' or ''the fourteenth day of admission.''

Response: Completion of the RAI specified by the State does not necessarily fulfill a facility's obligation to perform a comprehensive assessment. As previously stated, § 483.25 requires that a facility ensure that each resident attains or maintains his or her highest practicable well-being. A facility is responsible for assessing areas that are relevant for individual residents, regardless of whether they are included in the RAI. For example, in completing the MDS, the assessor simply indicates whether or not a factor is present. If the MDS indicates the presence of a potential resident problem, need, or strength, the assessor should then investigate the resident's condition in more detail. The RAPs may assist in this investigation.

Other problems that are relevant for an individual resident may not be addressed by the RAI at all. For example, the MDS includes a listing of those diagnoses that affect the resident's functioning or needs in the past 7 days. While the MDS may indicate the presence of medical problems such as unstable diabetes or orthostatic hypotension, there should be evidence of additional assessment of these factors if relevant to the development of a care plan for an individual resident. Another example of resident concerns not addressed by the MDS is sexual patterns. Some facilities have responded by creating additional assessment tools which they complete for all residents in addition to the State RAI. This is not a Federal requirement. Additional assessment is necessary only for factors that are relevant for an individual resident. Facility staff have stated that many of the items added to version 2.0 of the MDS may eliminate the need for supplementation of items in facility specific assessments and will hopefully contribute to a more comprehensive assessment for each resident.

A facility is also responsible for assessing and intervening in response to acute or emergent problems such as respiratory distress or fever. While this may seem obvious, surveyors have reported numerous instances in which this has not occurred.

A facility must complete the initial assessment no later than 14 days after a resident's admission. For example, if a resident is admitted on July 1, the assessment must be completed by July 15. Although Federal requirements dictate the completion of RAI assessments according to certain time frames, standards of good clinical practice dictate that the assessment process is more fluid, and should be on-going.

Comment: A few commenters recommended that we require the assessment within the month that the annual is due and not a narrowly defined ''every 365 days.''

Response: The statute requires that a facility conduct an assessment no less often than once every 12 months. The facility should use the completion date of the last assessment (in other words, the date the registered nurse coordinator has certified the completion of the assessment on the RAP Summary form in section V) to calculate when the annual assessment is due. Current policy is that the next assessment is due within 365 days. As we are not aware of any problems regarding this policy, it will remain unchanged.

Comment: Commenters proposed alternatives to the requirement that a facility complete an initial assessment within 14 days of a resident's admission. A commenter suggested that a facility complete the MDS within 14 days of admission, and the RAPs and care plan within 7 days of completing the MDS (instead of completing the MDS and the RAP process in 14 days). This would allow adequate time to complete and document the in-depth assessment. Others believed that 21 days to complete the assessment and 30 days to complete the care plan is necessary.

Response: As mentioned above, the statute currently specifies the time frame for the initial assessment, which does not allow us any latitude. We have defined the RAI to include the MDS, triggers and utilization guidelines, including the RAPs. Since the RAPs are part of the comprehensive assessment, they too must be completed within 14 days after admission or detection of a significant change. Current care planning requirements allow 7 days after completion of the RAI for completion of the plan of care.

Comment: A consumer advocacy group suggested that we require an assessment similar to the quarterly review upon the resident's return from a hospitalization, since some change in the resident's condition had necessitated the hospital visit. Another commenter recommended that we require an assessment when the use of restraints for an individual increased over a prescribed threshold.

Response: We agree that it may be beneficial for the facility to complete another assessment upon return from hospitalization or upon an increase in restraint usage. An increase in restraint use is an example of a situation in which a significant change reassessment is probably necessary. If it becomes necessary to restrain a resident or increase restraint usage, it is likely that the resident's condition has deteriorated and there are behaviors of new onset or increased frequency. In this case, the facility must revise the care plan. If a resident's condition has significantly changed prior to or after hospitalization, the facility must complete a comprehensive, significant change assessment on the resident's return to the facility. Some facilities have instituted a policy requiring a comprehensive RAI assessment each time a resident is readmitted after hospitalization. We prefer, however, to leave our requirement so that it is based on what is clinically warranted (in other words, whether the resident's condition meets the definition of a significant change).

Comment: Several commenters, including some State and national provider organizations, were concerned with the impact that the 14-day requirement would have on facilities whose residents are typically short-stay, such as residents in hospital-based SNFs. A few wanted us to exempt facilities which have an average length of stay less than 30 days from having to complete the assessment. Others wanted all facilities to have 30 days in which to complete the assessment. Some commenters suggested that we develop an alternate instrument that pertains to the specific care needs of short-stay residents. For example, they maintained that the MDS does not contain enough detail on the rehabilitative aspects of care, nor does it capture important information about a post-acute resident's health conditions. Others proposed that we allow a facility to complete only those MDS items that are appropriate for short-stay residents and skip the rest. A few commenters wanted us to convene a clinical advisory panel that would assist in identifying the clinical characteristics of short-stay populations and determining which MDS elements are critical for them.

Response: From the comments received, it is evident that there are a variety of strategies that people believe would be useful in dealing with the assessment of short-stay residents. We cannot, under the law, extend the time frame for completion of the RAI. Nor can we currently exempt any facility certified under the long term care facility requirements, even though it may provide care exclusively or primarily for individuals needing a short period of rehabilitation prior to return to the community. While we are aware that this has long been a concern voiced by some providers, various

clinical experts have long believed that the majority of the RAI gathers useful information for short-stay individuals as well as long-term residents. In 1992 and 1993, we consulted with several panels of expert clinicians and health professional, provider, and consumer groups to identify MDS items that were not pertinent for short-stay individuals. Of the few items that the panels proposed as not being relevant for short-stay individuals, there was no consensus on eliminating items, with all groups in agreement that all individuals in certified facilities would benefit from the RAI assessment process.

We agree that the original MDS did not contain enough relevant information pertinent to short-stay populations. We have added some items to version 2.0 related to special therapies and care needs (previously included in the MDS+, an alternate RAI used by some States) that are very relevant for short-stay populations. A national association representing hospital-based skilled nursing facilities reported finding these MDS+ items useful in identifying nursing and therapy needs for short term stay residents and for determining Medicare coverage and subsequent reimbursement.

We have also added an item to collect information on pain that will assist facilities in providing more focused care for short-stay residents. Furthermore, we will clarify and add material to several of the RAPs specific to short-stay populations as part of our contract with the Hebrew Rehabilitation Center for Aged to refine the RAI, in an effort to facilitate a more effective and efficient assessment for these residents.

Moreover, as this concern has continued to be voiced by providers and as the number of individuals undergoing a short-term, generally rehabilitative stay in certified skilled nursing facilities has continued to increase, we have begun to revisit this issue. We are currently consulting with providers, consumer groups and professional associations for the purpose of informing them about our work on developing a module of assessment items that would be completed as an alternative to many of the core MDS items. In this way, probably through the use of the ''skip pattern'' logic in the MDS, facilities providing care for ''short term stay'' individuals could perform a standardized, reproducible assessment that is more relevant to the resident population, while still adhering to the statutory requirement to perform a comprehensive assessment based on the MDS.

Comment: Several commenters expressed the belief that the MDS is not appropriate or does not collect enough information for special care populations, like pediatrics, individuals with AIDS, individuals with head injuries, individuals who are terminal and are receiving hospice care, and properly placed residents who have mental illness or mental retardation. The concerns were similar to those who addressed short stay residents. A State provider organization asserted that the MDS is designed for a homogeneous, chronic long term care resident and suggested that we develop a variety of assessment parameters. Another State organization stated that 70 percent of the MDS+ elements do not apply to children. The commenter went on to say that about one-fifth of those that do apply are demographic in nature. Commenters noted that facility staff need to know what kinds of behavior usually heralded the onset of a psychiatric crisis for a resident with mental illness, and that the MDS does not sufficiently capture behavioral disorders, mood disturbances, activity potential, and cognitive functioning for individuals with mental illness or mental retardation. To address these concerns, commenters recommended that we:

- Waive special care populations from the RAI requirement;
- Develop additional RAPs to address specific needs;
- Develop additional MDS elements in modules for ''special care'' residents;
- Have skip patterns; or
- Develop a new instrument.

Response: We acknowledge that the MDS may not be completely responsive to the needs of special populations in nursing homes today. We expect to use MDS data to gain a better sense of the clinical characteristics and care needs of the diverse population of long term care facilities, and to refine the RAI as it appears warranted over time. In the meantime, some of the items that were added to the MDS are more responsive to the needs of these residents. For example, items that assess the presence, type, intensity, and treatment of pain were added to version 2.0; this is particularly important for residents in a hospice program. We have expanded significantly the MDS items associated with mood and behavior, and also included the use of programs for treatment of mood and behavior problems. Again, we note that the statute does not allow us to exempt certain populations.

Comment: A State commenter requested that we exempt terminal/hospice residents from RAI requirements since the philosophy of hospice care is vastly different from the rehabilitative approach of the typical nursing facility. Another State commenter noted that SNF/NF residents who are residents of a certified hospice will have two assessments and two care plans because of two sets of requirements; it is possible that the care plans may be conflicting.

Response: When a resident of a Medicare participating SNF/NF elects the Medicare hospice benefit, the hospice and the SNF/NF must coordinate, establish, and agree upon a plan of care for both providers which reflects the hospice philosophy and is based on an assessment of the individual's needs and unique living situation in the SNF/NF. This coordinated plan of care must identify the care and services that the SNF/NF and hospice will provide in order to be responsive to the unique needs of the individual and his or her expressed desire for hospice care. The plan of care must include directives for managing pain and other distressing symptoms and be revised and updated by the SNF/NF and hospice, as necessary, to reflect the individual's current status.

Our policy is that when a resident of a SNF/NF elects to receive Medicare coverage of services under the hospice benefit, both the Medicare hospice conditions of participation and the SNF/NF requirements apply. This means that the facility must assess a resident using RAI. Some confusion arose among the SNF/NF providers concerning the completion of RAPs that were not clinically appropriate. We have issued a clarification memorandum reminding providers that the RAPs are guidelines for assessment. They are not meant as prescriptive courses of actions. Rather, they are intended as frameworks for assessment that are clinically indicated depending on the needs of each individual resident. For example, some of the RAP guidelines may include content suggestive of an aggressive work-up to determine causal factors that may not be appropriate for individuals who are terminally ill (for example, an aggressive work-up to determine the cause of weight loss would generally not be appropriate or expected for a resident receiving hospice care.) Many of the RAPs, however, such as ''Activities'' or maintenance of the resident's ''Activities of Daily Living'' should lead to more aggressive assessment if they are useful in helping facility staff increase the resident's comfort level and ability to attain or maintain his or her highest practicable well-being and create an atmosphere in which the resident will be able to die with dignity.

It is important to remember that RAP documentation and the plan of care may also reflect a resident's right to refuse treatment or services.

In summary, we developed the RAPs to assist facilities in planning appropriate and individualized care for residents. As we revise the RAP guidelines over the next few years, we intend to incorporate material specifically related to terminal care to better address the needs of the hospice residents residing in SNF and NFs.

Comment: Some commenters wanted changes in the proposed definition of ''readmission.'' One asked for clarification of what a ''temporary'' absence meant, asserting that a 5-month absence could be temporary for someone who has lived in the facility for 10 years. A State provider organization thought that ''temporary absence'' should not be defined only as a hospitalization, but should allow for other absences like doctor's visits.

Response: We do not consider it to be a temporary absence when a resident leaves a facility for a doctor's visit; we do not require that a facility conduct a new assessment merely because of such a visit. Readmission is defined as a resident returning to a facility from the hospital or therapeutic leave. We consider an absence to be temporary when the facility fully expects the resident to return. For example, if a resident leaves the facility for a few days during a holiday season, the nursing home would not need to complete a new assessment (unless there has been a significant change). If the resident is absent for an extended period of time, however, it may be difficult for the facility to determine if a significant change has occurred, and the facility may wish to conduct an assessment. Furthermore, if the resident is absent for a year or more, the facility must conduct its annual reassessment upon the resident's return. However, we are not attaching a time frame to temporary absence. This holds regardless of where the resident went and how long he or she was absent from the facility. This policy recognizes that there is variation in bed hold and discharge policies in the States.

Comment: A few commenters expressed concern with the proposed provision in § 483.20(b)(2)(i) that would allow a facility to amend assessment information up to 21 days after admission in some situations. One commenter thought the entire MDS was amendable. A national provider organization recommended that we permit a facility to correct ''technical'' items on the MDS beyond the 21st day because these items would not alter the triggers or RAP process.

Response: In the past, we had not allowed a facility to correct non-factual errors once the assessment was completed. Rather, these non-factual errors were to be noted elsewhere in the resident's clinical record (for example progress notes). A facility corrected non-factual errors on the next assessment (in other words quarterly, annual, significant change). A facility needs to complete a new MDS when the non-factual error would have an impact on the resident's care plan. In this case, a facility should perform another comprehensive assessment (in other words the MDS and RAPs) within 14 days of noting the error. We would note that non-factual errors associated with a resident's assessment and significant change associated with the resident are two different concepts; however, both can result in completing a new comprehensive assessment. As discussed below, we are deleting the 21-day provision.

Comment: A State provider group disagreed with our proposed delineation in § 483.20(b)(2)(i)(B) of categories within the MDS that can be amended, because the commenter did not believe that facilities and surveyors would be able to consistently differentiate which items on the MDS could be changed. The commenter proposed changing the requirement to read ''Further resident observation and interaction indicates a need to alter the initial assessment.''

Response: The provision to amend certain sections within 21 days has been confusing for facilities. We are deleting the 21-day provision. We require that a facility complete the MDS and RAPs within 14 days of a resident's admission, within 14 days of a significant change in a resident's status, and at least annually. By the fourteenth day, the registered nurse must sign and date the RAP Summary form to signify that the assessment is complete, within regulatory time frames. Within 7 days of completing the assessment, the facility must:

- Encode the MDS and RAP summary in a machine readable format;
- Run the encoded MDS through edits specified by us. The facility must correct any information on the encoded MDS that does not pass HCFA-specified edits.

Within 7 days of completing the assessment, the facility must be able to transmit the edited MDS and RAP Summary form to the State according to State or Federal time frames. Therefore, the facility must:

- ''Lock'' the edited MDS record;
- Certify that the MDS meets HCFA-specified edits; and
- Print the edited MDS and RAP Summary form and place them in the resident's record. The hard copy of the assessment must match the assessment that the facility transmits to the State. A facility must, therefore, correct the hard copy to reflect changes associated with the edit correction process.

We believe that this change eliminates the confusion for facilities as to what sections could be changed. It will also decrease the number of corrections the facility will have to make and subsequently transmit to the State due to changed assessment information.

In § 483.20 (b)(2)(ii) and (b)(2)(iii), we proposed that a facility must assess current residents of a nursing facility by October 1, 1991 and residents of a skilled nursing facility by January 1, 1991. We are deleting paragraphs (b)(2)(ii) and (b)(2)(iii) because these requirements are no longer necessary. They were necessary when the proposed regulation was written to make sure that individuals already residing in long term care facilities were comprehensively assessed according to the new requirements.

Comment: There were many comments related to the definition of significant change at proposed § 483.20(b)(2)(iv). Commenters proposed amendments to the definition, deletions to the definition, and additions to the definition. These comments follow.

Several commenters were concerned that the definition leaves too much room for interpretation and were particularly concerned about how this would be evaluated during the survey process. One commenter pointed out that the definition for significant change leaves much to the professional judgment of the surveyor to decide what constitutes a significant change. A few suggested that we delete ''or should have determined'' from the criterion for significant change because it invites surveyor second-guessing of facility multi-disciplinary staff judgment long after the fact.

Other comments related to the notion of permanency in the definition. Commenters asserted that the distinction between acute and chronic changes is often difficult to determine, and that the emphasis on permanency of the change is too exclusive. Some commenters preferred the language in the State Operations Manual at Appendix R or in the original RAI Training Manual. They believed that there is inconsistency between the proposed regulation and the State Operations Manual training manual, for example, the definition of ''permanent.''

Commenters wanted us to clarify what permanent means. Another requested that we delete ''permanent'' and ''apparently permanent'' from the criterion, and that we add ''is significant (major) or likely to be permanent.'' The commenter believes that this will be more consistent with the State Operations Manual Transmittal No. 250, which contains surveyor guidelines and protocols.

A commenter was concerned about whether the examples of significant change in the proposed regulation were intended to be all-inclusive, and believed they should be expanded and clarified. For example, the commenter believed that the regulation should clarify what a ''sudden improvement in resident status'' means.

A few commenters, including a national and a State provider organization, recommended that we change proposed paragraph (b)(2)(iv) to read ''within 14 calendar days after the facility determines * * * that there has been a significant decline or improvement in the resident's physical or mental condition such that in the clinical judgment of the assessor the change in condition appears to be major or permanent.'' They believed that this wording would be more consistent with the original training manual.

A few commenters believed that proposed paragraphs (b)(2)(iv) (A) and (G) are redundant. One commenter was confused as to which elements of the MDS the facility reviews in determining if a significant change has occurred according to the criterion at paragraph (b)(2)(iv)(A). A consumer advocacy organization wanted paragraph (b)(2)(iv)(A) to read ''Apparent permanent deterioration or improvement in two or more activities of daily living or apparent deterioration or improvement in any combination of two or more activities of daily living, communication or cognitive abilities.''

A few provider organizations wanted the criterion revised to read ''Deterioration in behavior or mood to the point where daily problems arise or relationships have become problematic.'' This wording would be more consistent with the original training manual.

A few recommended that we delete ''requires staff intervention'' or else clearly define the phrase. Commenters suggested that we change the wording to ''benefits from staff intervention.'' One believed that the criterion should not be limited to situations requiring staff interventions because there may be instances in which deterioration is not perceived by staff as disruptive or detrimental, and staff would, therefore, not intervene. For example, staff would not intervene, in the commenter's scenario, in a case in which a resident is depressed and whose behavioral presentation is passive.

One suggestion was to reword paragraph (b)(2)(iv)(D) to read ''A marked or sudden deterioration in a resident's health status * * *''. This would clarify that this criterion does not include the expected clinical progression of a given diagnosis or condition.

A few commenters suggested that we delete paragraph (b)(2)(iv)(D) because it is too subjective. One commenter stated that this criterion would have surveyors citing facilities for everything; for example, just the fact that the resident is old means that their life may be in danger of ending.

A commenter suggested deleting ''a factor associated with'' at paragraph (b)(2)(iv)(E) because it does not add anything to the definition. Others offered suggestions for clarifying the criterion at paragraph (b)(2)(iv)(E). A few commenters proposed adding ''* * * that has not responded to treatment in the last 14 days,'' which would give the clinician a time frame in which to evaluate the effectiveness of an intervention. Another commenter proposed adding ''* * * that has not responded to treatment within clinically accepted time period standards.''

A national provider group proposed that we delete the criterion at paragraph (b)(2)(iv)(F) and replace it with ''improved behavior, mood, or functional health status to the extent that the established plan of care no longer matches what is needed by the resident.'' The commenter believed that this would confine the definition of change to a functional measure and focus the criteria on a positive outcome.

A commenter suggested that we add two criteria to paragraph (b)(2)(iv): ''(iv)(H) Potentially reversible deterioration in mental functioning due to suspected delirium. (iv)(I) Deterioration in a resident's family or social circumstances which places the resident's psychosocial well being in danger.'' The commenter believed that the criteria, as published in the proposed rule, do not identify changes that may be temporary, but which could be noteworthy. Furthermore, the commenter does not believe that enough attention has been paid to the psychosocial aspects of change.

One State commented that the definition should not be in the regulation text, but should remain in interpretive guidelines, asserting that it will affect the objectivity of the assessors in determining significant changes since these guidelines will become more concrete.

Response: These substantial comments regarding significant change assessments warranted extensive evaluation of the definition for significant change assessment. Over the past several years, we have been providing clarification regarding the significant change reassessment requirement in surveyor training and other training that we have conducted, as well as through verbal and written communication to States and providers. We believe that it is necessary to include the definition of significant change in the regulation text. However, the definition contained in this final regulation is dramatically altered from that which appeared in our proposed rule, largely in response to the comments we received and the collective experience of providers and States since implementing the RAI process in 1990. This changed definition will remain in the regulation text to reinforce a facility's responsibility to conduct significant change reassessments.

A key to determining whether a significant change has occurred is whether the resident's status has changed to the extent that the plan of care no longer reflects the resident's needs and the facility's plan to address them.

We are revising the definition of significant change, as follows: A significant change means a decline or improvement in a resident's status that will not normally resolve itself without intervention by staff or by implementing standard disease-related clinical interventions, that has an impact on more than one area of the resident's health status, and requires interdisciplinary review or revision of the care plan, or both. An example of a condition that will normally resolve itself without intervention by staff is a resident's 5 pound weight loss, which would trigger a significant change reassessment under the old definition. However, if a resident had the flu and experienced nausea and diarrhea for a week, a 5 pound weight loss may be an expected outcome. If the resident did not become dehydrated and started to regain weight after the symptoms subsided, a comprehensive assessment would not be required. Generally, if the condition has not resolved at the end of approximately 2 weeks, staff should begin a comprehensive assessment.

A significant change reassessment is probably indicated if decline or improvement are consistently noted in two or more areas of decline, or two or more areas of improvement:

Decline

- Any decline in activities of daily living physical functioning in which a resident is newly coded as 3, 4 or 8 (Extensive assistance, Total dependency, Activity did not occur);
- Increase in the number of areas where Behavioral Symptoms are coded as ''not easily altered'' (for example, an increase in the use of code 1 for E4B);
- Resident's decision-making changes from 0 or 1 to 2 or 3;
- Resident's incontinence pattern changes from 0 or 1 to 2, 3 or 4, or placement of an indwelling catheter;
- Emergence of sad or anxious mood as a problem that is not easily altered;
- Emergence of an unplanned weight loss problem (5 percent change in 30 days or 10 percent change in 180 days);
- Begin to use trunk restraint or a chair that prevents rising for resident when it was not used before;
- Emergence of a condition or disease in which a facility judges a resident to be unstable;
- Emergence of a pressure ulcer at Stage II or higher, when no ulcers were previously present at Stage II or higher; or
- Overall deterioration of resident's condition; resident receives more support (for example, in activities of daily living or decision-making).

Improvement

- Any improvement in activities of daily living physical functioning where a resident is newly coded as 0, 1 or 2, when previously scored as a 3, 4 or 8;
- Decrease in the number of areas where Behavioral Symptoms or Sad or Anxious Mood are coded as ''not easily altered;''
- Resident's decision-making changes from 2 or 3 to 0 or 1;
- Resident's incontinence pattern changes from 2, 3 or 4 to 0 or 1; or
- Overall improvement of resident's condition; resident receives fewer supports.

We may revise this list over time, eliminating or adding items as well as other situations that meet the significant change definition. In an end-stage disease status, a full reassessment is optional, depending on a clinical determination of whether the resident would benefit from it.

We believe that this definition is clearer than the proposed definition. It also addresses many of the commenters' concerns, including noting that the change can be for improvement or deterioration, and eliminates the need to interpret whether a change is permanent.

A self-limited condition is a condition that will run its course without intervention. It is of limited duration. Because this implies a decline in status, we are retaining the phrase, ''a sudden or marked improvement.''

Comment: Commenters requested that we specify that the time limits for reassessments begin once the assessor makes a clinical determination that the change in resident status is permanent, major, or both (in other words, within 14 days). This would prevent an inconsistent outcome.

Response: In paragraph (b)(2)(iv), we proposed that the facility must conduct the reassessment within 14 days after the facility determines that a significant change has occurred. We are retaining this provision (in § 483.20(b)(2)(ii)).

Comment: Some commenters addressed the overall goal of reassessments due to significant change. One commenter stated that the clinical goal should be to identify functional changes and evaluate their source. Early identification of illness, injury, etc., may allow intervention to reverse and prevent permanent loss of function. The commenter cautioned that the evaluations can be expensive and counter-productive. Others maintained that some changes are the natural result of the aging process or of disease processes like Alzheimer's disease. Some believed that these changes can be anticipated and care planned without conducting a new assessment. A commenter wanted us to add a new criterion to the definition for potentially reversible deterioration in mental functioning due to suspected delirium.

Response: We believe the commenter's suggestion for a new criterion is included under the new definition. The primary role of the RAPs, which a facility also must complete for a significant change reassessment, is to help the facility to identify causal or risk factors that can be eliminated or minimized. Completing the RAP process helps the facility determine what services the resident needs. It would be more costly if the facility does not detect a significant change and the resident is allowed to decline. The resident could develop complications from the onset of a health problem or require hospitalization. Furthermore, significant change reassessments will help the staff to determine if a change is the expected result of a disease process or could be reversed. Such would be the case in a drug-induced delirium.

Comment: A few commenters thought that the final regulation should allow for consultation with a physician (the medical director, for example) to determine the significance or permanence of a resident's change. Therefore, they maintained, the facility staff would not have the responsibility to make the determination and would not be cited for it.

Response: We encourage consultation with physicians, but it is not our intent to absolve facilities from their responsibility to monitor resident status. The statute requires that a registered nurse conduct or coordinate the assessment. The registered nurse, by virtue of licensure requirements and State practice acts, has responsibility for assessing and monitoring an individual's status, and notifying a physician, as is warranted by changes in the individual's status.

Proposed § 483.20(b)(3), Quarterly Review (Redesignated as § 483.20(c))

Comment: Several commenters discussed the proposed quarterly review requirements. Most agreed that a facility should assess a resident at least quarterly. A few, including a State, wanted us to mandate the use of a standard form. They believe that this would provide consistency.

Response: OBRA '87 required that a long term care facility examine each resident no less frequently than once every 3 months and, as appropriate, revise the resident's care plan. We are accepting the recommendation to mandate a standard instrument. Not only will this provide consistency across the nation, but it will facilitate computerization of the quarterly review assessment items. In keeping with the Federal requirement for a uniform resident assessment instrument, the Quarterly Review form is considered part of the RAI. States may modify this form or use an alternate instrument by submitting a request to us. However, each State's Quarterly Review form must include at least those items on the HCFA Quarterly Review form.

Comment: One commenter said that the requirement for a quarterly assessment should be taken in the spirit of four times a year and not a rigid every 90 days. This would allow the facility to be flexible so that a resident's health status or the facility schedule could be taken into account.

Response: If a resident is experiencing a transient condition or is out of the facility when his or her quarterly review is due, the facility can wait until the resident's condition stabilizes or the resident returns to the facility. The facility should document the circumstances associated with the delay in conducting the quarterly review. Regarding timing of the quarterly review, we draw from the statutory language, which states that the facility must examine each resident no less

frequently than once every 3 months. This is also consistent with the regulations in effect prior to the publication of the proposed regulation. We would also point out that the calculation of when the quarterly review is due based on when the last assessment or quarterly review completed by the facility. For example, if a facility completed a quarterly review March 1, and completed a significant change reassessment April 15, the facility must complete the next quarterly assessment no later than July 15. If there had not been a significant change, the next quarterly assessment would have been due no later than June 1.

Comment: A few commenters wanted us to provide that the quarterly review determines if a comprehensive reassessment is necessary. Furthermore, they stated that the care plan may need to be revised as a result of the quarterly assessment. One commenter proposed that quarterly reviews must also review any section of the MDS relevant to problems triggering or found in the assessment.

Response: The purpose of the quarterly review is to ensure that the resident assessment data is accurate, and that the facility continues to have an accurate picture of the resident, in order to monitor and plan care. If the quarterly review indicates that a significant change has occurred, the facility needs to conduct a comprehensive reassessment. This also applies to the comment proposing a requirement to review other areas in the MDS if the quarterly review finds a problem. The facility is not limited to only reviewing the required portions of the MDS that comprise the quarterly review. While we encourage facilities to review any section that might be relevant to an individual resident, we are not requiring at this time that a facility review particular sections. We are providing in § 483.20(d) that the facility must revise the plan of care when indicated by the assessment.

Comment: Several commenters wanted additional MDS items or sections required as part of the quarterly review. One commenter thought that the quarterly review should include the entire MDS, providing additional longitudinal information for an outcome-based quality assessment system. Some commenters wanted all or a portion of Section N, Skin Condition, from the MDS+, added. One commenter noted that skin condition is a vital part of nursing care and the resident's psychosocial well-being. Others wanted at least one item added from former Sections B, Cognitive Patterns, C, Communication/Hearing Patterns, E, Physical Functioning and Structural Problems, F, Continence in Last 14 Days, H, Mood and Behavior Patterns, K, Health Conditions, L, Oral/Nutritional Status, and P, Special Treatments and Procedures.

Response: We are not requiring that a facility complete the entire MDS on a quarterly basis, as we thought the additional burden this would impose was not warranted clinically. Based heavily upon suggestions submitted by commenters, we have added several items to the quarterly review, including an item on skin condition. The primary use of the quarterly assessments is to regularly ensure that the care plan is responsive to the needs of the resident. A secondary use of the information collected through quarterly assessments is that of quality monitoring at the resident and facility level. Some of the items on the quarterly review form have been identified as quality measures. An example of a quality indicator is urinary incontinence. The MDS item H.1 is one of the items that we use to monitor quality of care associated with urinary incontinence. A mandated quarterly review assessment will provide for the consistent collection and use of such data.

We are also requiring that a facility transmit its quarterly review assessment records to the State. There are several reasons for this. Analysis of resident-level data over time is necessary to generate quality measures (in other words, a quality indicator system requires quarterly assessment data for each resident). As noted in the discussion on establishment of the national data base, a facility can identify opportunities to improve its own outcome and care practices through the quality measures. Quarterly data will also help a facility in its quality assurance program. Furthermore, if MDS data is to be used for quality monitoring purposes by surveyors, it must be timely. This means that we must require facilities to transmit their quarterly review records, in addition to admission, annual and significant change assessments, in order to use MDS data in the long term care survey process. Leading researchers and survey experts in this area believe that quarterly data is absolutely necessary for the timely and reliable identification of resident outcomes, both at the facility level and the resident level.

Proposed § 483.20(b)(4) Use (Redesignated as § 483.20(d))

Comment: A few commenters requested a definition of maintaining ''all resident assessments.'' They were confused as to whether this meant just the MDS, or also the Identification Face Sheet, documentation of the quarterly reviews, the RAP Summary sheet, and information pertaining to the decision to proceed to care planning.

Response: ''All resident assessments'' includes all the documents mentioned by the commenters—all MDS forms (Sections AA through R, and V—the RAP Summary Form), the Quarterly Review forms, and Discharge and Reentry forms. The RAP Summary form indicates which RAPs were triggered, whether care planning was done for each of the RAP conditions, and where data from the RAP assessment process is documented.

We also require that a facility complete a subset of items when a resident is discharged, which includes identifying information about the resident, the type of discharge and the destination upon discharge. As mentioned in the discussion on the national data base, we are also requiring that the facility transmit this information to the State and to us. This will allow for the closure of a resident's current stay at the facility. Furthermore, we are requiring that a facility complete a subset of MDS items upon a resident's reentry to the facility (§ 483.20(f)). This will allow the facility to ''reopen'' the resident's record in the facility system as well as at the State and national levels.

Comment: We requested that the public advise us on what the requirements should be for facilities to keep a hard copy of the MDS on a resident's file if the assessment is computerized. A few commenters urged us to allow flexibility. One pointed out that society is making large strides toward paperless environments, and a Federal regulation should not inhibit such progress. Other commenters thought that a hard copy should remain in the resident's record even if the assessment is computerized. Commenters recommended that hard copies stay in the record for 2 years, as the proposed regulation discussed. Another commenter suggested 1 year. A consumer advocacy group noted that hard copies should always be accurate because it is the copy most likely to be used by direct care staff. A State said that a hard copy on the record is essential because appropriate staff may not always be available to retrieve data from the computer. A few commenters did not want us to require that a facility keep a hard copy of the MDS in a resident's active record. Commenters believed that paper records are expensive to maintain, and it should be acceptable if a hard copy were readily

accessible to staff, residents, and surveyors. A State commenter thought that a coding system would need to be created to handle old assessments and reassessments. Commenters submitted other ideas. One suggestion was to keep the original MDS on the chart and not require a computerized copy. Another was to allow either the original or a computerized version. A State suggested printing a hard copy at the time of survey, and that all electronic assessment records should be created according to the intervals called for under the MDS. The commenter believed that the computerized system should be able to save or change information as needed. Another State said that we should require no further storage of a hard copy version once the facility produces and transmits a computer version.

Response: In order to be used as intended, by clinical staff at all levels, we believe that it is necessary for the facility to keep a hard copy in the resident's record of all assessments for the past 15 months. This issue is also discussed in responses to comments on § 483.20(b)(5). We agree that direct care staff would be most likely to use a hard copy of the assessment, and believe that it would be problematic for clinical staff to be expected to retrieve assessments from the computer, both in terms of their ability and willingness to do so and also having the necessary equipment available on all clinical units. Unless all charting is computerized, we believe that a facility should maintain RAI assessments as a part of the resident's clinical record. However, if a facility has a ''paperless'' system in which each resident's clinical record is entirely electronic, the facility does not need to maintain a hard copy of the MDS. To qualify for this exception, the facility's MDS system must meet the following minimum criteria:

- The system must maintain 15 months' worth of assessment data (as required in § 483.20(d)) and must be able to print all assessments for that period upon request;
- The facility must have a back-up system to prevent data loss or damage;
- The information must always be readily available and accessible to staff and surveyors; and
- The system must comply with requirements for safeguarding the confidentiality of clinical records.

Furthermore, the facility must maintain evidence that identifies the Registered Nurse Assessment Coordinator and other staff members that completed a portion of the assessment.

Comment: Commenters expressed concern with the proposed requirement to maintain assessments from the previous 2 years on the resident's clinical record. One stated that the intent of this requirement is unclear, as it does not appear to serve any purpose for facility staff in care planning, in that facility staff will be using the most recent assessment information they have to aid them in the development of the care plans. According to commenters, maintaining 2 years' worth of assessment data in the resident's active record would be too bulky and cumbersome. It could even add to facility costs associated with purchasing large chart binders and chart racks. One commenter stated that the full 2-year cycle of a resident would have approximately 42 pages of assessment documentation in the chart. If the resident had two episodes of ''significant change'' in that time period, this would add an additional 18 pages. Commenters maintained that a thick record would be prohibitive and intimidating, adding that quantity does not always translate into quality.

Several commenters maintained that surveyors look at only the previous year's assessment information. Also, the MDS does not require that the assessor look back over more than 180 days, so 1 year's worth of data would be sufficient. They stated that earlier assessment information would be easily retrievable from the record if needed. Commenters asserted that medical information that is more than 12 months old is likely irrelevant and outdated. A commenter believed that the regulation's intent could be met if historic materials were retrievable and available to the assessor during the reassessment and course of care. A commenter suggested that we require that the facility maintain all full comprehensive resident assessments completed within a 12-month period in a resident record. One commenter wanted the 2-year requirement to be effective on the date of the final rule.

Response: The original intent of the proposed requirement was to enable a facility to better monitor a resident's decline and progress over time. We are not able to determine if requiring that a facility maintain assessment information for a 2-year period has facilitated the analysis of this longitudinal data. We believe that the information is necessary to evaluate the resident's plan of care, but have decreased the required time period to 15 months of assessment records, since the survey cycle allows for up to 15 months between surveys. Additionally, computerizing MDS records will allow a facility to access prior assessments in a timely and more efficient manner.

Comment: A professional organization did not believe that 2 years of assessment data was enough to capture a decline in the resident's status and thought that we should require a facility to maintain 3 years of assessment data. Another suggestion was that we require a facility to maintain at least two comprehensive assessments in the record with the appropriate quarterly review and RAP summary forms.

Response: Requiring that a facility maintain assessment data on a resident's record for 3 years would be too cumbersome for most facilities; however, a facility can maintain as many years of assessment information as it likes. It is possible that having this amount of longitudinal data would be helpful for a facility in tracking resident progress. However, we are only requiring that a facility keep 15 months of the documentation associated with the RAI in the resident's active record.

Comment: Commenters requested that we permit a facility to keep prior assessment data in a ''thinned'' chart or another appropriate location as opposed to on the active chart. A few commenters did not feel that we should mandate where the facility keeps documentation. Commenters suggested that we revise the requirement to provide that the facility must maintain in active status all resident assessments completed within the previous 2 years and use the results of the assessments to develop, review and revise the resident's comprehensive plan of care.

Response: As stated above, we are revising the regulation to require that a facility maintain 15 months of assessment records. We would note, however, that a facility need not store assessment data in one binder to meet this requirement. A facility may choose to maintain the data in a separate binder or kardex system, as long as the information is kept in a centralized location and is accessible to all professional staff members (including consultants) who need to review the information to provide care to the residents. It is not acceptable for the assessment data to be stored where staff cannot easily use it.

Comment: Another suggestion was we require the facility make available the 2 years of data within 1 hour of request.

Response: We emphasize that the primary purpose of maintaining the assessment data is so that a facility can monitor resident progress over time. The information should be readily available at all times.

Proposed § 483.20(b)(5) Coordination (Redesignated as § 483.20(e))

Comment: Commenters addressed the proposed requirement that the facility coordinate the assessment with any State-required preadmission screening program. Most who addressed this issue agreed that coordination was needed to prevent duplicative efforts, particularly as part of the Level II PASRR. Some, including States and provider organizations, stated that the responsibility for coordination should be a State function and not the facility's responsibility, noting that a facility has little or no control over the screenings. One commenter noted that the facility should not be penalized during a survey because the State mental health authorities are unable to do appropriate plans of care. A commenter requested that we not mandate this coordination because, in most States, coordination will be extremely difficult to accomplish. A commenter suggested that we provide, instead, that the facility coordinate assessments to the maximum extent possible.

Response: We agree that coordinating the MDS with Federal PASRR requirements, to the extent practicable, will prevent duplicative efforts and the unnecessary expenditure of resources. The proposed regulation required that the facility coordinate ''to the maximum extent practicable'' with the PASRR program and we are retaining this language as is.

With respect to the responsibilities under the PASRR program, the State is responsible for conducting the screens, preparing the PASRR report, and providing or arranging the specialized services that are needed as a result of conducting the screens. The State is required to provide a copy of the PASRR report to the facility. This report must list the specialized services that the individual requires and that are the responsibility of the State to provide. All other needed services are the responsibility of the facility to provide. The PASRR report also lists some nursing facility services the State PASRR evaluator recommends for the facility to consider including in the plan of care. We note that the survey agency should not cite a facility when the State fails to fulfill its responsibility. However, if a facility fails to fulfill its responsibilities to, for example, prepare fully developed care plans, then the survey agency may cite it.

We would also like to point out that the requirements relating to the preadmission screening and annual resident review program were amended on October 19, 1996 by Public Law 104–315. In summary, the legislation amended section 1919(e)(7) of the Act by removing the Federal requirement for the annual resident review. Section 1919(b)(3)(E) of the Act was also amended by the addition of a requirement that a nursing facility notify the State mental health authority, mental retardation, or developmental disability authority, as applicable, promptly after there is a significant change in the physical or mental condition of a resident who is mentally ill or mentally retarded. Finally, the legislation amended section 1919(e)(7)(B) of the Act to require that the State mental health or mental retardation authorities conduct a review and determination after the nursing facility has informed them that there has been a significant change in the resident's physical or mental condition. In developing regulations to implement the new provisions of the law, we will try to ensure that States and facilities are not be subjected to duplicative requirements or the unnecessary expenditure of resources.

Comment: Commenters were concerned that the condition of a resident may necessitate a new comprehensive assessment done earlier than annually, which would be administratively problematic for State mental health authorities trying to coordinate their reviews.

Response: From the beginning of the PASRR program, a significant change in the condition of a resident with mental illness or mental retardation has required a judgement call to be made concerning whether an annual resident review was necessary. While this requirement may initially have caused some difficulty in scheduling, these procedures should already be in place.

Comment: A few commenters submitted suggestions as to specific ways that the RAI and PASRR could be coordinated. One suggested that we expand items 11 and 12 in the former Section I, Identification Information, which pertain to mental health history and conditions related to mental illness or mental retardation. Another suggested that we grant psychologists the same status under these regulations to practice to the full extent of their licensure as has been recognized under the PASRR regulations. One commenter believed that Level II screening could serve as part of the cognitive, psychosocial, mood, and behavior RAPs. A State commenter recommended that the mental health authority use the MDS for nursing decisions to refer someone into the community mental health system for further review. Another commenter proposed that the facility forward a copy of the MDS to the State mental health authority, and that relevant information from hospital admissions be incorporated into the MDS.

Response: There are several elements of the MDS that could assist in determining if the resident has mental illness or mental retardation and whether nursing home level of care or specialized services, or both, are necessary. We have changed the language in the Section AB, Demographic Information of the MDS to be consistent with PASRR language and definition regarding mental illness and developmental disabilities. We will further consider the coordination of the RAI and PASRR in the development of the regulations to implement the new legislation.

Comment: A commenter suggested that we add paragraph (b)(5)(i), which would provide that State mental health and mental retardation authorities may determine for those residents whose mental status and/or intellectual functioning has remained stable over a 2-year period, based on annual resident review criteria, as defined under subpart C, § 483.100 *et seq.*, and on-site evaluation and record review, whether the data contained in the annual RAI/MDS is sufficient to make a determination of continued need for NF services and/or specialized services, or whether further evaluation is required. The commenter believed that much of the information needed for Level II screening can be obtained from the RAI, especially for long-standing nursing home residents with mental illness or mental retardation. The State mental health authority would still be making the determination of level of services as required under the PASRR requirements.

Response: We agree, as noted above, that the RAI data may serve as the basis for State mental health and mental retardation authorities to evaluate and make determinations about the need for NF care and for specialized services. However, section 1919(e)(7) of the Act prohibits a State mental retardation authority and a State from delegating their responsibilities to a nursing facility or to an entity that has a direct or indirect affiliation or relationship with a facility. However, those responsible for conducting the evaluations should use applicable up-to-date data from the MDS.

Comment: A State commenter suggested including results of the PASRR reviews on the MDS, for example the dates of the reviews, special needs, dates of recent

hospitalizations, and whether the resident needs specialized services.

Response: We encourage facilities to keep the results of a resident's PASRR with his or her MDS. We are not mandating that a facility record PASRR information on the MDS. The decision about how much information to share with a facility is up to the State's discretion, as is the choice of assessment instrument and the coordination of the various assessments. We believe that a State should have the flexibility to determine what a facility must retain.

Comment: A State commenter submitted several MDS elements that help them identify residents who have mental illness or mental retardation (including a list of ICD–9 codes recorded in the former Section J that would indicate a developmental disability). The commenter noted that RAI software exists that enables them to make this determination. Other MDS items are useful in deciding if someone is exempt from PASRR because of terminal illness, dementia, or a severe medical condition.

Response: We concur that several MDS items would be helpful in identifying residents with mental illness or mental retardation. We encourage States to develop or refine PASRR programs, or individuals performing surveys of the facilities, as well as those conducting preadmission screening under Public Law 104–315, to use the information to the maximum extent possible. We disagree with the commenter who suggested that an individual with a terminal illness, dementia or a severe medical condition is exempt from the screening requirements. We believe the commenter misconstrued the current requirement at § 483.130, which permits a State to make advance group determinations when included in an approved State plan. Categorical determinations are categories for which the State mental health or mental retardation authorities may make an advance determination that nursing home services or specialized services are needed for an individual with mental illness or mental retardation. These categories may include cases in which the resident has received convalescent care after an acute physical illness that required hospitalization and do not meet the criteria for an exempt hospital discharge. Dementia is not considered a serious mental illness for the purposes of PASRR. Therefore, a person with a primary diagnosis of dementia would not be considered to have mental illness and would not be subject to PASRR screening (unless he or she is also mentally retarded).

Proposed § 483.20(b)(6) Automated Data Processing Requirement (Redesignated as § 483.20(f))

Comment: Several commenters believed that the proposed October 1, 1994 date for capability of computerization was unrealistic. A national provider organization stated that, based on the regulation process and time frames, it was possible that we would require that the systems be in place before the final rule was published, and this would be unfair. Commenters offered alternative dates, which included an implementation date of October 1, 1995; at least 2 years from the effective date of the final rule; and postponing implementation until a reimbursement mechanism is in place. Another suggestion was that we publish a rule specifically on computerization.

Response: We agree that an implementation date for facility computerization of October 1, 1994 should be deferred until June 22, 1998.

To redesignated § 483.20(f), we are adding the requirement that a facility transmit at least monthly to the State all assessments completed in the previous month. This includes admission assessments, significant change reassessments, annual reassessments, quarterly reviews, and information captured upon reentry to the facility, transfer, discharge and death. We are requiring the latter information for a number of reasons. States that are already computerized have noted that this information is required to close out the resident's record at the State level for the facility from which the resident was discharged. We are aware that there are some States which, for Medicaid payment purposes, must know where Medicaid recipients are every 24 hours. Information upon reentry, transfer, discharge and death will allow State and Federal agencies to analyze long term trends in resource utilization, particularly in regards to movement across various types of care providers. Additionally, discharge information will permit facilities to close out residents' records on their system. In the State Operations Manual, we will provide facilities with instructions on which MDS items must be completed to document this information. Furthermore, as discussed elsewhere, we believe that the information will provide facilities with invaluable data they can use in a variety of ways.

Comment: A State commenter asserted that we should develop penalties for non-compliance regarding the computerization requirement. The commenter questioned whether the penalties would fall on individual facilities, States, or both. The State suggested that, as an alternate to penalties, we could provide monetary incentives for timely and accurate submission.

Response: The requirements to encode the assessments in a machine readable format and transmit the information to the State are like all other requirements that a facility must meet to participate in the Medicare and Medicaid programs. We believe that computer-aided data analysis facilitates a more efficient, comprehensive and sophisticated review of health data. Manual record reviews, on the other hand, are labor intensive and more time consuming, and may, therefore, tend to be more occasional or anecdotal. Additionally, utilization of the quality measures and other types of quality monitoring, such as observation of trends and patterns, is enhanced through computer aided data analysis.

Facility noncompliance with requirements established by this final rule will be subject to the full range of enforcement remedies set forth in part 488, subpart F, Enforcement of Compliance for Long-Term Care Facilities with Deficiencies. However, at a minimum, we will require that a facility complete a plan of correction and we will impose the mandatory denial of payment for new admissions sanction if the facility has not achieved substantial compliance within 3 months from the date of the finding of noncompliance. Further, if the facility is still not in compliance within 6 months from the date of the finding, we will terminate its provider agreement. We may impose one or more other remedies, as determined by us or the State in accordance with part 488. Additionally, noncompliance that is repeated or that recurs intermittently becomes part of the facility's noncompliance history, which is a factor when we or the State selects the appropriate enforcement response. A facility that demonstrates little or no commitment to continual, rather than cyclical, compliance will be sanctioned by us accordingly. We are not offering incentives for timely and accurate submission at this time, but may consider such a concept as we revise the survey process.

Proposed § 483.20(c) Accuracy of Assessments (Redesignated as § 483.20(g))

Proposed paragraph (c) described the requirements regarding who conducts and coordinates the assessment, certifying its completion and accuracy,

and penalties for knowingly and willfully falsifying the assessment. In this final rule, we are redesignating content of proposed paragraph (c) related to accuracy of assessments as paragraph (g), coordination, as paragraph (h), certification, as paragraph (i), and penalties for falsification, as paragraph (j).

Proposed § 483.20(c)(1) Coordination (Redesignated as § 483.20(h))

Comment: Commenters requested clarification on the definition of ''health professionals.'' Some, including a State commenter, wanted to know if nurse aides who are on the State's nurse aide registry could complete and document portions of the assessment.

Response: A licensed health professional, as defined at § 483.75(e), includes a physician, physician assistant, nurse practitioner, physical, speech or occupational therapist, physical or occupational therapy assistant, registered professional nurse, licensed practical nurse, or licensed or certified social worker. Furthermore, the definition of nurse aide, at § 483.75(e), specifically excludes licensed health professionals.

A facility may assign responsibility for completing the RAI to a number of qualified staff members. It is the facility's responsibility to ensure that all participants in the assessment process have the requisite knowledge to complete an accurate and comprehensive assessment. In most cases, participants in the assessment process are licensed health professionals. Some State licensure and practice acts specifically prohibit nursing assistants, and in some cases licensed practical nurses, from conducting assessments. While nurse aides certainly can and should contribute their knowledge of the resident to the assessment process, nurse aides typically are not trained in specific assessment skills, some of which require a significant amount of knowledge.

Comment: A commenter stated that staff that are mandated to complete certain sections of the assessment, like gait and movement, behavior, and aspects of incontinence, do not have the appropriate skills, clinical experience, or training to understand and assess the issues involved. The commenter stated that surveyors lack this expertise and training also.

Response: We are not requiring that specialized professionals complete any sections of the MDS. As stated in the previous response, a facility must ensure that staff conducting the assessment have the requisite knowledge to accurately complete the assessment. We disagree with the generalization that facility staff and surveyors do not have the skills and training necessary to accurately assess residents. We conduct a significant amount of training for surveyors on how to gauge the accuracy of assessments. Provider groups and facilities also conduct training in these areas.

Comment: A commenter expressed concern that requiring the participation of professionals other than registered nurses could place a burden on a facility that does not employ staff in certain disciplines. The commenter recommended that the we combine the requirements for coordination and certification to provide that each assessment must be conducted or coordinated by a health professional, in cooperation with other health professionals, as desired, and that a registered nurse must review, sign and certify the completion of the assessment.

Response: See previous responses. We do not require the participation of specialized professionals other than registered nurses. The personnel participating in an assessment are determined by the needs of the individual resident. For someone who has significant rehabilitation potential, for example, it would be reasonable for a physical therapist to conduct part of the assessment. It is acceptable, though, for a registered nurse to conduct the entire assessment as long as it is accurate.

Comment: A consumer advocacy organization suggested that we prohibit the use of assessment nurses hired solely for the purpose of completing the MDS and who have no relationship to care provided. This suggestion was based on a reference in the preamble to the proposed rule (p. 61633) to staff who have clinical knowledge about the resident, such as staff nurses.

Response: The requirements for care planning state that a registered nurse with responsibility for the resident be a part of the interdisciplinary team that prepares the care plan. This implies that the registered nurse is directly involved in the resident's care and is fully knowledgeable about the resident. We believe that the assessment is conducted most accurately and efficiently in conjunction with the registered nurse who has primary responsibility for the resident's care. We believe that this is in line with the intent of Congress. However, it would be beyond our purview to prohibit ''assessment nurses.'' A facility is required by the statute to complete an accurate assessment.

An evaluation of the RAI process, conducted by the Research Triangle Institute in 1993, under contract with us, indicates that it is rare for a facility to designate a sole staff member to conduct the entire assessment. Registered nurses, who are often the primary assessors get substantial contribution from others in at least some MDS domains, even in facilities which designate an ''assessment specialist nurse.'' We cannot necessarily state that a nurse hired solely to conduct assessments does not have the necessary clinical knowledge. Additionally, the survey process would detect inaccuracies in the assessment if an assessor did not have the necessary clinical knowledge to accurately complete resident assessments.

Proposed § 483.20(c)(2) Certification (Redesignated as § 483.20(i))

Comment: Commenters suggested that we require that an individual who completes portions of the assessment date his or her signature. This would also apply to the assessment coordinator when he or she signs and certifies the completion of the assessment.

Response: We agree with this suggestion and have changed the form to reflect this.

Proposed § 483.20(c)(3) Penalty for Falsification (Redesignated as § 483.20(j))

Comment: Commenters, including a national provider organization, supported the distinction between clinical disagreement and false statements. A commenter requested a definition of clinical disagreement. One commenter expressed concern regarding guidelines for surveyors and protections to ensure hard copy validity. For example, if there is oversight in completing a section of the MDS, but the registered nurse signs to certify completion, we could cite the facility for falsification. A commenter also suggested that clinical disagreement on the RAP Summary form does not constitute a material or false statement.

Response: It is the responsibility of the nurse coordinating the assessment to make sure that the MDS is complete before he or she certifies completion. Failure to do so could result in a deficiency, based upon information gathered by the surveyor.

For purposes of this regulation, clinical disagreement pertains to coding an item based on observation of the resident over time and on clinical judgment. If, based on observation, one nurse codes a resident as needing supervision for locomotion while another nurse codes the same resident as needing limited assistance based on her observation, we would consider that

to be clinical disagreement and not falsification. However, if an assessor were to complete the assessment without observing the resident and gathering data, we would consider that to be a material and false statement. Clinical disagreement applies to the entire RAI, including the RAP Summary form, and care planning decision making process. The survey process is not intended to usurp clinical decisions from the facility.

§ 483.315 Specification of Resident Assessment Instrument

This section describes requirements for the States in specifying a resident assessment instrument. It also lists the components an instrument must contain if a State wishes to specify an instrument other than the Federally designated RAI.

Our December 28, 1992 proposed rule placed the entire MDS and instructions for its use in the regulation text. The proposed rule also required that a facility encode the MDS in a machine-readable format, in accordance with HCFA-specified formats. We are removing the MDS from the regulation text. Because the law requires a standard assessment, the regulation mandates that a State instrument contain, in its exact form, the contents of our designated instrument, as set forth in the State Operations Manual. This instrument is comprised of the MDS and common definitions, the triggers and utilization guidelines (including resident assessment protocols (RAPs)). We will ordinarily not approve an instrument that does not contain the HCFA-designated resident assessment instrument (RAI). The States may add items to the Federal instrument, but may not change the MDS items, definitions or triggers, delete any items, or alter the utilization guidelines pertaining to the RAPs. This is necessary for the standardization and consistency required by law. We believe that removing the MDS from the regulations text is advantageous. It will allow us to easily modify the MDS so that it requires collection of information that is clinically relevant and meets evaluative needs as clinical practice evolves. By directly discussing and negotiating with affected parties, it will be possible to maintain a resident assessment process that reflects current standards of clinical practice while obtaining public comment.

It has always been our intent that we would revise the RAI on an ongoing basis to reflect changes in clinical practice and advances in assessment technology. The first revision of the MDS and RAPs, known as version 2.0, was published in Transmittal No. 272 of the State Operations Manual in April, 1995, and is contained in the preamble of this rule. For the purpose of this rule, State and provider requirements related to the RAI pertain to the most current version of the RAI that has been published by us (that is, presently dated 10/18/94H, but subject to future revision). We expect to publish revisions to the RAI, such as new or revised RAPs, in the State Operations Manual no more frequently than annually, in order to minimize the burden on providers of transitioning to a revised RAI.

We believe that the regulatory provisions that we are including in the final rule adequately describe the fundamental MDS requirements and that the form and details of the MDS are best set forth in interpretive issuances. This will permit us to easily modify details such as the measurement scales for a particular condition, or the symptoms that may be relevant to that condition, and to respond to advances in clinical standards.

We relied heavily on public comments received on the proposed rule in modifying the MDS and RAPs contained in version 2.0 of the RAI. We also drew on the expertise of a small work group comprised of representatives of three States that had extensive experience in working with the industry to successfully implement the RAI requirements. In this way, we were able to address ''real world'' concerns as well as misinterpretations regarding individual MDS items. We also received comments on a draft of the revised RAI during a public meeting with national associations representing nursing home providers, professional disciplines and consumers on December 10, 1993. Under HCFA contract, Dr. John Morris of the Hebrew Rehabilitation Center for Aged led the RAI revision effort from 1993 to 1994 and oversaw field testing.

Proposed § 483.315(a) State Responsibilities (Redesignated as § 483.315(c))

Comment: A State commenter noted that 30 days to specify an instrument after we designate or change its instrument is not enough time. The commenter stated that the survey agency would need to coordinate with the State Medicaid agency. Furthermore, any change to the HCFA-designated RAI would require the State to study the benefits and costs of modifying the State-specified RAI vs. the revised HCFA-designated RAI, notifying and training facilities, modifying computer systems, etc. The commenter suggested 180 days. For the aforementioned reasons, a commenter recommended that providers have advance notice of changes to the RAI. Another commenter asked if we would extend the time without specifying the number of days.

Response: We agree that 30 days may not be enough time for a State to decide whether to adopt our changes or seek approval for an alternate instrument. However, we believe that the commenter's recommendation of 180 days is too long. Therefore, we are changing the requirement to give States 90 days to decide whether they accept our changes or wish to specify an alternate.

Comment: Commenters questioned whether the State would be required to seek approval from us to re-adopt our forms every time we make a revision to the forms. One commenter asked if a State that has already specified the HCFA-designated RAI will now have to respecify it. Commenters suggested that a State that has specified our instrument should be expected to automatically adopt any revisions without additional paper work.

Response: Our State Operations Manual Transmittal No. 272 contains information on a State's responsibilities related to respecification of its RAI. We require that a State notify us of its intent to use our revised RAI or alternate instrument and specify the effective date for its use. A State will continue to respecify its instrument whenever we change the Federally-designated RAI. This enables us to monitor when a State decides that it no longer wishes to use our instrument. As the quarterly review form is now part of the Federally-designated RAI, we require a State to specify the form to their facilities or to include an alternative form in the package that it submits to us.

Comment: Commenters suggested revisions to paragraph (a)(2). A commenter wanted to change ''* * * State must assure implementation'' to read ''must assist with implementation of RAI through training and technical assistance.'' The commenter stated that training and technical assistance does not ensure implementation, and proposed that we add paragraph (a)(2)(I), which would provide that States must assure implementation of RAI through the survey process. Another suggested that we require that the State ensure facility implementation by providing the necessary technical direction and education and training to facilities at least annually. This would accommodate changes in facility and surveyor staff, facilitate proficiency and maintenance of assessment skills.

Response: We accept an amended version of the first two suggestions. We are providing in § 483.315(c)(3) that, after specifying an instrument, the State must also provide periodic educational programs for facility staff to assist with implementation of the RAI. This parallels sections 1819(g)(1)(B) and 1919(g)(1)(B) of the Act. We acknowledge that training does not necessarily mean implementation. We do not wish to specify intervals at which training must be conducted. Training should be based on provider needs and should be targeted to focus on identified facility weaknesses. We do not wish to take away State discretion in this area. We are also providing in § 483.315(c)(4) that a State must audit implementation of the RAI through the survey process. Furthermore, we are reordering the text to be more sequential in regard to the action the State must take.

Comment: A commenter stated that the proposed requirement at § 483.315(a)(3) could have a negative impact on facility assessment and care planning schedules. The commenter suggested that we permit a facility to use its current RAI until we approve an alternative. Another commenter requested that we allow States 180 days to secure approval for an alternative instead of the proposed 4 months.

Response: It appears that the commenter misunderstood when we would require a facility to implement a newly specified RAI. A facility does not have to use a newly specified RAI or State alternate RAI until the date that the State requires it, which would be well after the State receives approval from us. Once the State receives our approval for an alternate instrument, the State must specify the instrument for use in all Medicare and Medicaid certified long term care facilities. The State would need a realistic implementation time frame which would not unreasonably have an impact on facilities. This time frame should accommodate training and the absorption of change.

With respect to the proposed requirement that States have 4 months to obtain our approval, we are eliminating the time frame entirely. The time frame was necessary initially when States were specifying instruments for the October, 1990 implementation of OBRA '87. Furthermore, our experience working with States that are developing alternate instruments is that a State may require more than 4 months.

In § 483.315(a)(4), we proposed that, within 30 days of receiving our approval of an alternate RAI, the State must specify the RAI for use by all Medicare and Medicaid facilities. We are changing the requirement to allow States 60 days to specify the instrument to their long term care facilities (redesignated § 483.315(c)(2)). This will give the State time to contact each of their certified facilities as well as reproduce the form for distribution to them. Additionally, we are deleting the provision that says that HCFA approval of an alternate RAI continues for 2 years. Our experience shows that many States make changes to their instrument on a more frequent basis.

Comment: A few commenters questioned whether a State would need to notify us if it redesigns the RAP Summary sheet.

Response: Since the RAP Summary sheet is part of the State-specified and HCFA-approved RAI, the State would need to obtain our approval to alter the sheet. Since we are removing the MDS from the regulations text, we are making substantial changes to § 483.315, which addresses the contents of the HCFA-designated RAI. We are adding to the regulations text the major domains contained on the revised MDS. This reemphasizes the statutory mandate that alternate instruments contain at least all the MDS elements. For the same reason, we are also listing the assessment domains addressed in our RAPs.

Proposed § 483.315(c) Secretarial Approval (Redesignated as § 483.315(g))

Comment: Commenters suggested that we delete this paragraph. According to commenters, if States are allowed to reorder sections of the MDS, use other RAPs, etc. it would be difficult to have consistency in data collection and submission to us. The commenter suggested that we require a State that wants an alternate instrument to include a HCFA section that would incorporate our system.

Response: We agree with the commenters' suggestion to delete most of the content of proposed paragraph (c). We are replacing it with a provision that requires the State's alternate instrument to comply with the standard format, vocabulary and organization requirements set forth in the State Operations Manual (redesignated paragraph (g)). There are a number of factors that warrant consistent ordering of data and assessment items across all States. First, nursing home chains that operate facilities in a number of States would benefit from some consistency in the ordering of the MDS items, if not simply to facilitate effective use of their training and education resources. Second, software vendors would also welcome standardization of the ordering of the MDS items in all States, as many of them market their software to facilities throughout the country and to nursing home chains that operate in a number of States. It also would minimize the effort in revising their software. Third, we could also achieve consistency in training State surveyors on use of the RAI. Fourth, educational materials, resources, and education programs for nursing homes and schools that prepare health care professionals could be developed more cost-effectively and distributed more widely with some consistency in how the MDS is ordered. Finally, data submission to us and States will require standardization in the ordering of the MDS items. Therefore, to facilitate standardization across States, we are requiring consistent ordering of MDS sections. We will require that States desiring to add additional data and assessment items, add those items in section S of the MDS, which has been designated as the section for State-specific items.

Comment: A few commenters thought that we should convene a clinical advisory panel to evaluate any alternate RAPs that States submit. They were concerned that the proposed supporting documentation could merely be the consensus of the same experts who designed the alternates. This would not protect the scientific integrity of the assessment system.

Response: We will convene a clinical panel periodically to evaluate the need to modify the RAI, and to review and evaluate newly developed RAPs, including those developed both by us and States. The process by which State-developed RAPs are submitted for our approval is also described in the State Operations Manual. We intend to have an open, inclusive revision process.

Comment: Commenters suggested that we require that any alternate instrument be cross-validated with the MDS on a large sample of residents. States should submit the data from the cross-validation to us for comparison of outcomes between States who use the HCFA-designated RAI and those that do not.

Response: Alternate instruments must contain all MDS items. This negates the need to cross-validate with the MDS. We have reviewed the revised items and new items added to the MDS for face validity, and we tested the individual items in early 1994. We encourage States to field test and validate the new items, as well as allow review by other qualified individuals prior to including the additional items on their instrument and submitting it for approval.

State Requirement to Establish a Data Base of Resident Assessment Information

Consistent with the purpose of the proposed rule and, after considering the comments submitted, we are adding a new paragraph (h) to § 483.315, which delineates State requirements in establishing a data base of resident assessment information. In the proposed rule, we posed questions about the State's role in collecting and maintaining the RAI data base, and we concluded that specific requirements are necessary to ensure uniformity. Furthermore, we believe these requirements are necessary to successfully design and implement a national data base of resident assessment information. Paragraph (h) includes provisions for specifying a transmission method for a facility to send information to the State, specifying edits that the data must pass, and provisions to transmit the data to us. A State will also be responsible for resolving incorrect data submitted by a facility. While the facility will edit the data before transmission to the State, the State, which has already computerized assessment information, may note that the data transmitted is not entirely complete or accurate, and must send it back to the facility for correction. Additional edits at the State level will help identify incorrect assessment information.

A State must edit the data it receives from a facility according to formats we specify, but may add State-specific edits that do not cancel or interfere with HCFA-specified edits. This will help ensure that the data we receive is uniform, complete and accurate. Furthermore, we are requiring that a State generate reports and analyze data, as specified by us. For example, we could require States to run a profile of each facility, which would allow the facility to analyze the prevalence of a certain medical diagnosis amongst its residents.

For a number of reasons, as discussed below, we are requiring each State to use a complete system that is developed or approved by us. We will develop a single, open system by which States will manage and analyze data. We believe that there are a number of advantages to standardizing both the data analysis and the data management functions which outweigh potential disadvantages.

Cost

Initial system costs will be substantially reduced by producing a single system versus funding the development of 50 different systems.

Ongoing maintenance costs will be substantially higher if States implement their own proprietary MDS systems. The costs associated with modifying individual State systems to incorporate changes in the MDS or HCFA specifications, formats or edits would be 50 times those associated with modification of a standardized system and distribution of new software or other specifications to each State.

Additional cost savings for data analysis activities will be realized by us. Given that we envision standardizing the State data analysis function, system standardization at the data management level will ensure that the necessary infrastructure to support data analysis is already in place. If States develop proprietary data management systems, we would probably have to fund additional system/structural costs when our proposed data analysis requirement becomes effective.

Data Reliability

It would be difficult to maintain quality controls and ensure adequate data reliability across 50 State systems. For example, each time we issue a change in transmission specifications or data fields, each of 50 States would have to modify their proprietary systems to accommodate the requirement. Past experience with MDS software vendors, as well as other Federal systems, demonstrates that there is a great degree of variation in the ability of vendors or agencies to consistently implement system changes. This would pose a serious threat to the long term integrity of the national MDS data repository. Standardization would ensure that changes are implemented completely, reliably, timely and in a coordinated manner across all States.

Programmatic Needs

Our desire to implement an MDS data-driven long term care survey process based on quality measures cannot be efficiently realized without standardization at the initial ''data management'' level. Assuming that we are redesigning our provider survey model as an automated, data-driven system, each survey agency will have to be able to integrate directly with the State MDS repository. If each State has a unique design for this repository, this integration will not be possible in a cost-effective manner. Each State would have to use HCFA-developed MDS data format specifications to extract MDS data into the standardized survey system. Allowing the development of 50 State proprietary systems would also result in long term inefficiencies in that each State would be required to rewrite their data extraction procedures each time we want to make a change to the survey process, quality measures or in the MDS itself. Even if we had unlimited resources for State customization, this would have a serious impact on our ability to introduce changes in a timely and consistent manner.

HCFA Initiatives to Implement Standardized Clinical Data Sets

These changes are an integral part of the Administration's efforts to achieve broad-based improvements in the quality of care furnished through Federal programs and in the measurement of that care, while at the same time, reducing procedural burdens on providers. Quality assessment and performance improvement rests on the assumption that a provider's own quality management system is the key to improved performance. Our objective is to achieve a balanced approach combining our responsibility to ensure that essential health and quality standards are achieved and maintained with a provider's responsibility to monitor and improve its own performance. To achieve this objective, we are now developing revised requirements for several major health care provider types. All of these proposals are directed at (1) improving outcomes of care and satisfaction for patients, (2) reducing burden on providers while increasing flexibility and expectations for continuous improvement, and (3) increasing the amount of, and quality of, information available to everyone on which to base health care choices and efforts to improve quality. We note that our revised approach to quality assurance responsibilities is closely linked both to the Administration's commitment to reinventing health care regulations and to our own strategic plan. These initiatives have three common themes. First, they promote a partnership between us and the rest of the health care community, including the provider industry, practitioners, health care consumers, and the States. Second, they are based on the belief that we should retain only those regulations that represent the most cost-effective, least intrusive, and most flexible means of meeting our quality of care responsibilities. Finally, they rely on the principle that making powerful data available to consumers and providers can produce a strong nonregulatory force to improve quality of care.

The MDS is the first of several clinical data sets we envision creating and implementing in various care settings. Standardized information on clinical

status and health care outcomes is necessary for more objective and focused quality monitoring. Consequently, interest in standardized clinical data sets has skyrocketed, with much activity occurring in this arena in both the public and private sectors. We view our efforts with the MDS as a prototype for the next several years, during which we propose to build and implement clinical data sets across several provider types. These data sets will feed into quality indicator systems, which will supplement our traditional survey processes. At this point, we are beginning work on designing a comprehensive standardized assessment tool for home health agencies as well as field testing the uniform needs assessment instrument, which we are evaluating for use by all providers and view as forming the ''core'' of all care-setting specific data sets. Additionally, we propose development of standardized patient process and outcome measures for the End Stage Renal Disease program and a standardized instrument for the Intermediate Care Facility for the Mentally Retarded program in fiscal years 1996–97. In view of these initiatives, it would be much more economical and efficient to put in place now, within each State, standardized system designs and structures to support increased clinical data management and analysis. Otherwise, we will be responsible for funding and coordinating State efforts to implement data systems for each provider type as we implement new requirements.

In the system design process we explored several options, particularly regarding State systems and gathered a significant amount of information about current status of State systems. For example, we sent two questionnaires to the States to determine whether they had developed an MDS system, what the configuration might be, and what sort of direction and assistance non-computerized States would want from us. We convened several meetings across the country which were attended by more than 45 States. At these meetings we presented the concept of standardization. Reaction was quite supportive. We are aware that States which already have systems will have to make significant adjustments and will provide assistance in the process.

III. Provisions of the Final Rule

In summary, in this final rule, we are adopting, without change, the provisions of the proposed rule with the exception of the following.

- We are adding greater specificity to the proposed requirement that each facility establish a data base of resident assessment information and transmit MDS data to the State at least monthly (§ 483.20(f)).
- We are adding a new requirement that each State establish a data base of resident assessment information received from facilities, using a system to manage and analyze data that is developed or approved by us, and transmit that information to us at least monthly (§ 483.315(h)).
- We are adding a definition of ''significant change'' in a resident's physical or mental condition to clarify when a facility must conduct a comprehensive assessment of a resident (§ 483.20(b)(2)).
- Instead of including the entire content of the MDS, the utilization guidelines for resident assessment instruments, common definitions, resident assessment protocols and instructions in the regulations text or in an appendix to the text, we are providing descriptions of the RAI, the MDS, and RAPs. We are providing a description of the assessment areas included in the MDS (§ 483.315(e)), and a description of the domains addressed in the RAPs (§ 483.315(f)), both of which must be included in the RAI specified by a State (§ 483.20(b)(1)).
- To address concerns about confidentiality of resident data, we are providing that a facility and a State may not release resident-identifiable information to the public, and may not release the information to an agent or contractor without certain safeguards (§§ 483.120(f)(5) and 483.315(j)).
- In this final rule, we are not adopting the proposed technical revisions to part 456 concerning inspection of care reviews of SNFs and ICFs. We will include these revisions in another document.

IV. Regulatory Impact Statement

A. General

Consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612), we prepare a regulatory flexibility analysis unless we certify that a rule will not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, all nursing homes are considered to be small entities. Individuals and States are not included in the definition of a small entity.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. Such an analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 50 beds.

B. Affected Entities

We require that all certified nursing homes assess residents using a standardized data set known as the MDS. Nursing homes have been collecting this information manually since October 1990. Most States implemented a second generation assessment instrument, known as MDS 2.0, on January 1, 1996. The use of the MDS as the core of the comprehensive assessment requirement has improved the quality of nursing home services by ensuring that the assessment is consistently based on all information that is necessary to evaluate a resident's needs. Accurate and comprehensive resident assessments have improved the accuracy of the care planning process and, ultimately, the care provided by the nursing home. The myriad benefits associated with the MDS have been well documented in a study we commissioned to evaluate the outcomes of using the MDS. One of the more striking changes documented by the study was an association of the use of the MDS with a significant reduction in hospitalization among more cognitively impaired nursing home residents, without a concomitant increase in mortality. The study also identified major reductions in rates of decline (especially among various types of residents) in important areas such as nutritional status, vision, and urinary incontinence. However, in order to realize the full benefits of the MDS, the information needs to be computerized, and configurable as an analytical tool. Publication of this rule will allow this goal to be realized.

The automation and transmission of MDS data by nursing homes and States to us will improve the delivery of quality care in the nation's nursing homes in several ways. An automated MDS data base will provide information that will benefit both the policy and operational components of State and Federal governments, as well as furnish valuable information to long term care providers. The MDS system will also establish a means of providing consumers with quality-related information to make health care decisions.

More specifically, the MDS data base will enable us and the States to provide nursing homes with aggregated State and national resident status information and trends. This will allow nursing

homes to compare themselves to similar homes and is consistent with a quality improvement model. Furthermore, by establishing their own in-house quality assurance analyses from these computerized data, nursing homes will be able to evaluate the effectiveness of treatment modalities given a certain outcome. This type of information will assist nursing homes in making better use of their staff and other resources, and also eliminate the allocation of resources that do not achieve desired outcomes. In short, the MDS data base will provide nursing homes with the information to identify and correct their own problems.

States will have access to timely MDS data that will improve their ability to focus on-site inspection activities associated with the long term care survey process. Since we require MDS data for all residents regardless of payor source in nursing homes, these data elements can be configured into quality measures. The quality measures flag individual residents and facilities when there may be a problem with the quality of care provided. For example, the indicators may identify those residents who were admitted to a nursing home without pressure sores, but who developed sores in the nursing home. Similarly, a nursing home that has a relatively high percentage of residents with pressure sores may indicate a problem when compared to other facilities. This resource will significantly improve States' ability to identify areas of potential quality concerns in an effective and efficient manner, and facilitate the partnership of States and industry in identifying opportunities to improve care. At both the Federal and State level, information from the MDS data base will provide a valid and reliable tool for evaluating and improving the efficacy and effectiveness of survey and certification activities.

States have also identified a myriad of other intended uses for MDS data that include Medicaid payment, utilization review, preadmission screening and resident review, Medicaid coverage authorization, and State policy analysis and trending. It is our intention that a standardized MDS data system will support States' unique needs and should not necessitate the creation of distinct and duplicative data bases at the State level.

C. Costs Associated With Automating the MDS

We anticipate that both nursing homes and States will incur some incremental costs from computerizing and transmitting the MDS. We estimate total start-up costs of $20.3 million, which represents costs incurred by nursing homes (we will be supplying the MDS systems directly to the States). We also estimate total ongoing annual costs of about $34.7 million, which includes $27 million in costs for nursing homes and $7.7 million in costs for States. Total costs include Medicare benefit costs of $9.5 million. Total costs also include an annual administrative cost of $3.5 million that will be absorbed within HCFA's program management appropriation. However, the benefits associated with computerizing the MDS far outweigh the additional costs of automating the data. The following represents our estimates of the individual costs associated with this effort.

Nursing Homes

Upon publication of this rule, all nursing homes must computerize the MDS. Most costs associated with computerizing the MDS will be related to hardware and software. At the current time, we estimate that approximately 70 percent of the nation's 17,000 Medicare, Medicaid or dually certified nursing homes have already computerized the MDS or have the capability to do so. Another 16 percent of nursing homes already have some kind of computer system that will require upgrading to meet the requirements for MDS, and only 14 percent have no computer system at all. Additionally, some facilities with currently operating MDS systems may require hardware and software upgrades to support aspects of the national MDS system (for example, a faster modem or installation of the Windows operating system).

Under the Balanced Budget Act of 1997, nursing homes will be reimbursed for Medicare under a prospective payment system for cost reporting periods beginning on or after July 1, 1998. Prior to July 1, 1998, costs incurred by nursing homes associated with computerizing the MDS will be paid on a reasonable cost basis. Generally, these costs are considered capital costs and are subject to the applicable Medicare rules. Additionally, it is likely that nursing homes will also incur certain routine services costs which will also be paid on a reasonable cost basis. These costs are subject to cost limits. In the past, the routine cost limits have included an add-on to account for the costs associated with the Omnibus Budget Reconciliation Act of 1987 (OBRA 1987), including the cost of conducting resident assessment. When a provider incurs cost related to OBRA 1987 that exceed its limit (including the add-on), we have allowed the fiscal intermediary to make an adjustment to the costs limits. This policy is described in a notice published in the **Federal Register** on October 7, 1992 (57 FR 46177).

The Balanced Budget Act of 1997 also prescribes a public process for the determination of rates for payment under Medicaid State Plans for nursing home services in which the proposed rates, the methodologies underlying the establishment of such rates, and the justifications for the proposed rates are published, thereby giving providers, beneficiaries and their representatives, and other concerned State residents an opportunity for review and comment. States have flexibility in designing the details of their payment systems for NF care, and to the extent that NFs incur costs in computerizing the MDS (such as the acquisition of hardware or software, staff training, or additional staffing), the State may take these costs into account in setting its rates.

- *Hardware:* We estimate total hardware costs associated with automating the MDS to be approximately $2,500 for a typical nursing home, which includes the computer and communications components capable of running MDS software and transmitting MDS assessments, and a laser printer. This estimate is based on the most recent cost data available for a system that includes an Intel Pentium processor. As noted earlier in this rule, we expect that only 14 percent of all nursing homes will need to buy an entirely new system. Seventy percent of all nursing homes are already using an automated MDS collection tool (although some may require upgrading in order to transmit the MDS data), and the remaining 16 percent already have some sort of computer system that simply requires upgrading.

The aforementioned cost estimate is based on the type of system that we anticipate many nursing homes will choose to purchase. At a minimum, a nursing home should have at least a 486 personal computer, either connected to a network or as a stand-alone, with 8 megabytes of RAM, at least 100 megabytes of available hard disk space, a 14 inch color monitor, keyboard, mouse, a 3.5 floppy drive and a laser printer. To operate the transmission software, this machine must run the Windows operating system, version 3.1 or higher. All nursing homes will also need a 28.8 Kbps modem for telecommunication of data, as well as a common data communications software package to transmit MDS assessments to the State. This communications package must meet our specifications related to

transmission of MDS data and represents current technology.

Ongoing hardware maintenance costs for nursing homes are expected to average about $100 annually.

- *Software:* Nursing homes desiring to meet only the requirement for data submission can use a less costly software package to accomplish the basic encoding and formatting functions. A nursing home must submit MDS records to the State that conform to a specific ASCII layout and incorporate them into files with header and trailer records that conform to required formatting standards. However, we anticipate that most nursing homes, seeking to gain efficiency in general operations, will choose more capable programs, some of which could be used to meet (1) other clinical or operational needs (for example, care planning, order entry, quality assurance, billing) or, (2) other regulatory requirements for reporting resident information. The standardized record formatting specifications and additional policies on MDS automation that we developed should be used by individual nursing homes, multi-facility chains, and software vendors to develop products for encoding and transmission of MDS 2.0 data. This information has been available to the public for about two years through the Internet, and is located on the HCFA Web site.

There are currently over 100 vendors marketing MDS software products. While we are not requiring record specifications and automation policies until this rule is published, we developed them earlier to provide guidance to the industry and to minimize the need for a facility to modify and replace systems once this regulation is published. At this time, we estimate that such software packages will be available on the market for approximately $1,250 for those nursing homes that have not yet become MDS automated. We expect that a nursing home's private sector software vendor will provide primary support to the facility in terms of MDS encoding and transmission to the State. State personnel, however, will work with facilities and software vendors in educating them about this process.

- *Supplies:* Supplies necessary for collection and transmission of data including diskettes, computer paper, and toner, will vary according to the size of the nursing home in terms of residents served and assessments required. Dividing the nursing homes into groups, supply costs are estimated at the following three levels: small facilities (with less than 145 residents), $175/year; medium facilities (with 145 to 345 residents), $225/year; and large facilities (with greater than 345 residents), $275/year.
- *Maintenance:* There are costs associated with normal maintenance of computer equipment, such as the replacement of disk drives or memory chips. Typically, such maintenance is provided via extended warranty agreements with the original equipment manufacturer, system reseller, or a general computer support firm. These maintenance costs are estimated to average no more than $100 per year.
- *Training:* Nursing home staff will need training on automating the MDS. Since many nursing homes will choose to have their staff input MDS data at the time of the resident assessment, we estimate that a typical nursing home will train two nurses for about 3 hours each. We expect that this training will be supplied by the vendor supplying the MDS encoding software, and estimates that the training will cost an average nursing home about $144 based on an average hourly rate for nurses of $24.

Other nursing home staff will need training in transmitting the data to the State and interpreting messages of record errors. We expect that this training will require about 3 hours of staff time, and will cost an average nursing home about $66, based on an average hourly rate of $12 for technical staff. This cost also includes travel expenses and travel time, since facility staff may need to travel to a centralized training site within the State (we anticipate that training will be provided in multiple sites in the State once the system is implemented). We expect that the State survey agencies will supply this training.

- *Data entry:* Nursing homes will have flexibility in the method used to enter data, but the method must comply with our requirements for safeguarding the confidentiality of clinical records. Data can be entered directly by a clinical staff member (that is, the nurse responsible for coordinating or completing the assessment), from a hard copy of a completed MDS by a clerical staff member, or by a data entry operator with whom the nursing home may contract to key in the data. We estimate that data entry staff could require approximately 15 minutes to enter each MDS. Nursing homes must collect and transmit MDS data, which for the admission assessment, annual updates, as well as significant changes in the resident's status, significant correction assessments, quarterly review assessments, which include a subset of the MDS items, discharge records, and reentry records. Additionally, nursing homes must allow time for data validation and preparation of data for transmission, as well as for correction of returned records that failed checks at the State data-editing level. We estimate that a 100 bed facility will incur an annual data entry cost of $1,250, (or $12.50 per resident per year), based on an estimate of five MDSs per bed (annual plus ''significant changes'') and an hourly rate of $10.
- *Data Transmission:* The State agencies will fund the costs of transmitting data from the nursing homes to their respective States. However, nursing home staff time must manage the data transmission function, correct communications problems, and manage reports logs transmitted from the State agency. We estimate that it will take an additional hour of staff time to perform data transmission related tasks each month. This staff time will cost an average size nursing home about $144 per year.

States

We expect that overall responsibility for fulfilling requirements to operate the State MDS system will rest with the survey agency. However, the State may enter into an agreement with the State Medicaid agency, another State component, or a private contractor to perform day-to-day operations of the system. If the State MDS system is operated by an entity other than the survey agency, the State must ensure that the survey agency has suitable access to this system to fully support all MDS-driven functions that the State will require of the survey agency (for example, quality indicator reporting, survey targeting). The State is also responsible for reporting MDS data to a central repository to be established by us.

States will primarily use the MDS data to focus the long term care survey process and to provide nursing homes and consumers with MDS-derived information. A State's MDS system includes the following components: computing hardware that includes data base, communication, supporting file, and print servers for client workstations; local and wide-area data networks; and application software for performing all aspects of MDS-related functions and tasks. As such, the MDS system will be designed and developed within a broad class of systems known as Client/Server architecture.

We plan to provide each State with a standardized hardware environment scaled to meet each State's anticipated processing volumes. Additionally, a standardized suite of software applications will be provided to each State to perform all MDS-related

functions, including receipt and validation of MDS records, posting of records to the master repository, and analytical applications to be used to inform and support the long term care survey process. A HCFA contractor will work closely with each State to customize the ''turn-key'' MDS system to integrate it into a State's current computer and network structure. The contractor will visit each State to install and test equipment, and ensure that the MDS system is fully operational. We currently plan to phase in State deployment of the system, roughly from August through December 1997.

We will place this system in each State and it will be operated by personnel within the designated State agency. We are requiring that the State systems do the following: receive MDS records from nursing homes; authenticate and validate the records received from nursing homes; provide feedback to the nursing homes by indicating acknowledgment of the transmission of the data and specifying the status of record validation; store the MDS records in a permanent data base within the State; create system management reports and logs; generate provider performance reports including quality indicator reports designed to support a future data-driven survey process and provider survey targeting functions; perform other analytical functions, as defined by us; create ad-hoc reports; and retransmit validated MDS records from each State agency to a national MDS data repository developed and maintained by us.

Just as in nursing homes, some States are already using some sort of an automated MDS collection tool. At least 12 States have already developed MDS data bases. In nearly all cases, the State Medicaid agency has been the driving force in getting MDS data to the State level. System designs and approaches have varied considerably (that is, while two States have recently moved to modem transmission, other States still perform data entry at the State level from hard copies forwarded by nursing homes).

We are providing the MDS system to States primarily for use in the Survey and Certification program. As such, most Federally reimbursable costs incurred by the States for automating the MDS will be funded through that program. However, we anticipate that many States will also choose to use MDS data in administering their Medicaid programs. When that is the case, Federal reimbursement is applicable to the extent a State uses the MDS for administering its Medicaid program. As a result, it may be appropriate for a State to allocate some MDS costs to its Medicaid administrative cost claims.

When a State does use MDS in administering its Medicaid programs, it should apportion Federal costs associated with automating the MDS and operating the data system between the Medicare and Medicaid Survey and Certification program, and the Medicaid program (as administrative costs, when applicable). The State should apportion MDS costs to these programs based on the State's determination of each program's utilization of the MDS system. Costs charged to the Medicare and Medicaid Survey and Certification program will be prorated in terms of the proportion of SNFs and NFs in the State that participate in the Medicare and Medicaid programs. Costs for SNFs and NFs are split equally between the two programs. The Federal financial participation rate for the Medicaid Survey and Certification Program is 75 percent. The Federal financial participation rate for costs apportioned as Medicaid administrative costs is 50 percent. When the State licensure program benefits from the automation of the MDS, the State should also share in the MDS automation costs.

Several States asked if we could reimburse Medicaid administrative costs associated with the development of MDS at Federal financial participation rates greater than 50 percent, the rate used in computing Medicaid reimbursement for general administration of the program. Specifically, they asked if we will reimburse these costs at the same rates used to reimburse the costs of designing, developing, implementing and operating a Medicaid Management Information Systems (MMIS).

Section 1903(a)(3) of the Act and implementing regulations at § 433.111 describe the MMIS as a mechanized claims processing and information retrieval system. Federal financial participation is available at 90 percent in expenditures for design, development, installation or enhancement of the system, while 75 percent is available for costs relating to its operations (namely, processing claims and producing related management information). The MDS is not a Medicaid claims processing and information retrieval system. We reimburse other systems not directly related to performing MMIS functions, such as the MDS, at the 50 percent level of Federal financial participation.

Commenters asked whether automated systems to collect and analyze data for rate setting purposes meet the MMIS definition. Because rate setting is outside the claims payment and information retrieval processes required by section 1903(a)(3) of the Act, those costs are not eligible for enhanced Medicaid reimbursement under the MMIS definition. However, in those instances when specific data elements from a separate system like MDS must be transferred to the MMIS in order to calculate individual provider payments, the cost of modifying and operating the MMIS to accept and use the data from the outside source qualifies for enhanced Federal financial participation if the State follows the regulations and guidance found in §§ 433.110 through 433.112, 433.116 and in Part 11 of the State Medicaid Manual.

For example, a major function of the MMIS is to produce both beneficiary and provider profiles for program management and utilization review purposes. NF resident and provider profiles are required by § 433.116(g). However, both NF resident and NF provider profiles historically have been very limited because the data elements on a nursing facility claim provide few details of services provided. A State may wish to improve the MMIS profiling capability by importing MDS data to prepare augmented profiles of nursing facility and nursing facility residents. If the State does that, the enhanced Federal financial participation will be available for the costs of modifying and operating the MMIS to accept and use the data from MDS if the State acts in accordance with the regulations in §§ 433.110 through 433.112, 433.116 and the guidance in Part 11 of the State Medicaid Manual. Please note that we currently encourage States to modify their MMIS to accept encounter documents from Medicaid managed care organizations to extend the MMIS profiling capability to cover both managed care and fee-for-service providers and patients. Therefore, it seems appropriate that we would reimburse the cost of modifying MMIS to accommodate MDS usage also at the enhanced MMIS rates, if the State meets the conditions in the aforementioned regulations and State Medicaid Manual.

The following is our estimate of State costs for automating the MDS:

- *Hardware:* We will hire a contractor to purchase, deliver, and install the MDS equipment in each State. Since we will be providing the equipment to the States, the States will not incur any cost for hardware. This equipment will include both a communications server and a data base server. The number of nursing homes within each State will be the driving factor in determining each State's computer needs. We will scale

system requirements to meet the data storage and transmission needs of the individual State.

- *Software:* Since we are developing the software for each State's MDS system, we will pay the costs associated with this system and supply the system directly to the States. Software that we will supply to the States will include communications software and data base software, as well as customized analytical software to generate reports. When a State develops its own customized MDS applications, the costs of developing and maintaining these additional software applications (and any related hardware components) will not be Federally funded.
- *Operational Staff Time:* States may plan to reassign existing staff or hire additional full-time equivalents to manage the automation project and perform day-to-day operation of the standardized MDS system. The staff members assigned to MDS automation tasks will need to have skills in a variety of areas: technical computer, network, and telecommunication skills; data processing operations; and, user support and training (including support for both State and facility users). In hiring or reassigning staff, we encourage States to recruit generalists who can perform a wide range of the above tasks.

Each State's actual staffing requirements will vary depending on the State's size (that is, as measured by the number of nursing homes regulated). To assist in determining staffing requirements within particular States, we assigned States to one of three categories based on the number of certified nursing homes in their jurisdiction: less than 144, 144 to 356, and those greater than 356 facilities. We estimate that 1.5 full-time equivalents will be required to manage all MDS-related operations for each of the three categories; for instance, States in the smallest group should budget for 1.5 full-time equivalents, 3 full-time equivalents in the second group, and 4.5 full-time equivalents in the largest group. This includes an MDS Automation Project Coordinator.

Specifically, an average sized State regulating about 300 nursing homes will require about three full-time equivalents to fulfill the following MDS-related tasks: MDS project coordination (oversight of daily operations); technical operations (systems management, configuration and troubleshooting); training and support operations (facility and MDS software vendor startup training); and operations (functions associated with transmission logging and error tracking and resolution). We estimate that MDS-related staffing costs for an average size State will be about $133,000 per year.

- *Supplies and Maintenance of Equipment:* States can expect about $600 per year in additional costs for products that are consumed, such as printer toner and paper. The MDS data management and analysis equipment to be installed within each State is comprised of standard ''off-the-shelf'' hardware and software components that are generally covered under typical service agreements that the States may already have in place. We will ask States to extend these agreements to cover hardware components delivered as part of the MDS project. These costs will again vary according to the size of the State requirements, but on average, the typical State will incur about $750 per year in additional cost for systems maintenance. We will maintain and upgrade centrally the standardized MDS software components that we develop and distribute to States.
- *Training:* We plan to centralize training of State personnel who will be responsible for administrative and technical aspects of system operations. Additionally, we will provide separate training on the technical aspects of the system including its communications, networking, data base and software application functions, daily operations and on-going systems management.

In order to promote national consistency in MDS system operations and troubleshooting, we request that each State designate one individual as the MDS Automation Project Coordinator. This person will be our key contact within each State for managing MDS system issues. We are planning to convene at least one national meeting of the MDS Automation Project Coordinators each year. We will use this forum to present new information, gather suggestions for system improvements, exchange ideas on MDS system operations, administration and troubleshooting issues, and to discuss objectives for future system development and refinement.

With our technical support and guidance, States will work closely with the provider community in providing information on specific requirements related to the submission of MDS assessments to a repository maintained by the State. The standardization of the State MDS system extends back to the provider communications function, in that nursing homes will use a common data communications software package to transmit MDS assessments to the State. State personnel will work with the nursing homes and software vendors in educating them about this process. We expect that the commitment of staff resources to this task will be most intensive during the first 6 months of this process. However, States should also expect some ongoing allocation of full-time equivalents to support this process on an ongoing basis.

We anticipate annual travel costs associated with training for an average size State to be about $2,700 per year.

- *Data Transmission:* States will incur data communication costs for transmission of MDS assessments from nursing homes. These costs have two basic elements:

(1) Fixed monthly line fees of approximately $32.50 per line per month. The number of lines required varies from 4 to 16 according to the number of nursing homes supported by a State. On average, a State's fixed line cost will be $3,806 per year.

(2) Line connect and long distance charges of approximately $.27 per minute. We estimate that the typical nursing home will require, on average, 5 minutes ($1.35) of connection time per month for MDS submissions. This translates into an average connection cost of $5,376 per year per State.

We will fund the cost of the States transmitting their MDS data to our central repository. Therefore, we do not expect that States will incur data transmission costs to us.

D. Conclusion

While we acknowledge that nursing homes and States will bear some incremental costs associated with this proposal, these costs are well justified when considered within the context of the anticipated increased quality of care for nursing home residents, as well as the potential uses of the automated data by the facilities, States, and us. The foregoing estimates may actually overstate anticipated costs because they do not take into account cost-savings achieved by improving nursing homes' management information systems, as well as potential improvements in resident's overall health status. Nor do they represent the savings inherent in a more focused, uniform approach by both the States and us in assessing quality of care in the nation's nursing homes.

For these reasons, we are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined, and we certify, that this rule will not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals.

In accordance with the provisions of Executive Order 12866, this regulation

was reviewed by the Office of Management and Budget.

V. Information Collection Requirements

Sections 4204(b) and 4214(d) of OBRA '87 provide a waiver of Office of Management and Budget review of information collection requirements for the purpose of implementing the nursing home reform amendments. Therefore, the information collection requirements referenced in this rule are exempt from the Paperwork Reduction Act of 1995.

List of Subjects in 42 CFR Part 483

Grant programs—health, Health facilities, Health professions, Health records, Medicaid, Medicare, Nursing homes, Nutrition, Reporting and recordkeeping requirements, Safety.

42 CFR chapter IV is amended as follows:

PART 483—REQUIREMENTS FOR STATES AND LONG TERM CARE FACILITIES

1. The authority citation for part 483 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

2. In § 483.20, paragraphs (d) through (f) are redesignated as (k) through (m), respectively, paragraphs (b) and (c) are revised and new paragraphs (d) through (j) are added to read as follows:

§ 483.20 Resident assessment.

* * * * *

(b) *Comprehensive assessments.*

(1) *Resident assessment instrument.* A facility must make a comprehensive assessment of a resident's needs, using the resident assessment instrument (RAI) specified by the State. The assessment must include at least the following:

(i) Identification and demographic information.

(ii) Customary routine.

(iii) Cognitive patterns.

(iv) Communication.

(v) Vision.

(vi) Mood and behavior patterns.

(vii) Psychosocial well-being.

(viii) Physical functioning and structural problems.

(ix) Continence.

(x) Disease diagnoses and health conditions.

(xi) Dental and nutritional status.

(xii) Skin condition.

(xiii) Activity pursuit.

(xiv) Medications.

(xv) Special treatments and procedures.

(xvi) Discharge potential.

(xvii) Documentation of summary information regarding the additional assessment performed through the resident assessment protocols.

(xviii) Documentation of participation in assessment.

The assessment process must include direct observation and communication with the resident, as well as communication with licensed and nonlicensed direct care staff members on all shifts.

(2) *When required.* A facility must conduct a comprehensive assessment of a resident as follows:

(i) Within 14 calendar days after admission, excluding readmissions in which there is no significant change in the resident's physical or mental condition. (For purposes of this section, ''readmission'' means a return to the facility following a temporary absence for hospitalization or for therapeutic leave.)

(ii) Within 14 calendar days after the facility determines, or should have determined, that there has been a significant change in the resident's physical or mental condition. (For purposes of this section, a ''significant change'' means a major decline or improvement in the resident's status that will not normally resolve itself without further intervention by staff or by implementing standard disease-related clinical interventions, that has an impact on more than one area of the resident's health status, and requires interdisciplinary review or revision of the care plan, or both.)

(iii) Not less often than once every 12 months.

(c) *Quarterly review assessment.* A facility must assess a resident using the quarterly review instrument specified by the State and approved by HCFA not less frequently than once every 3 months.

(d) *Use.* A facility must maintain all resident assessments completed within the previous 15 months in the resident's active record and use the results of the assessments to develop, review, and revise the resident's comprehensive plan of care.

(e) *Coordination.* A facility must coordinate assessments with the preadmission screening and resident review program under Medicaid in part 483, subpart C to the maximum extent practicable to avoid duplicative testing and effort.

(f) *Automated data processing requirement.* (1) *Encoding data.* Within 7 days after a facility completes a resident's assessment, a facility must encode the following information for each resident in the facility:

(i) Admission assessment.

(ii) Annual assessment updates.

(iii) Significant change in status assessments.

(iv) Quarterly review assessments.

(v) A subset of items upon a resident's transfer, reentry, discharge, and death.

(vi) Background (face-sheet) information, if there is no admission assessment.

(2) *Transmitting data.* Within 7 days after a facility completes a resident's assessment, a facility must be capable of transmitting to the State information for each resident contained in the MDS in a format that conforms to standard record layouts and data dictionaries, and that passes standardized edits defined by HCFA and the State.

(3) *Monthly transmittal requirements.* A facility must electronically transmit, at least monthly, encoded, accurate, complete MDS data to the State for all assessments conducted during the previous month, including the following:

(i) Admission assessment.

(ii) Annual assessment.

(iii) Significant change in status assessment.

(iv) Significant correction of prior full assessment.

(v) Significant correction of prior quarterly assessment.

(vi) Quarterly review.

(vii) A subset of items upon a resident's transfer, reentry, discharge, and death.

(viii) Background (face-sheet) information, for an initial transmission of MDS data on a resident that does not have an admission assessment.

(4) *Data format.* The facility must transmit data in the format specified by HCFA or, for a State which has an alternate RAI approved by HCFA, in the format specified by the State and approved by HCFA.

(5) *Resident-identifiable information.* (i) A facility may not release information that is resident-identifiable to the public.

(ii) The facility may release information that is resident-identifiable to an agent only in accordance with a contract under which the agent agrees not to use or disclose the information except to the extent the facility itself is permitted to do so.

(g) *Accuracy of assessments.* The assessment must accurately reflect the resident's status.

(h) *Coordination.* A registered nurse must conduct or coordinate each assessment with the appropriate participation of health professionals.

(i) *Certification.* (1) A registered nurse must sign and certify that the assessment is completed.

(2) Each individual who completes a portion of the assessment must sign and

certify the accuracy of that portion of the assessment.

(j) *Penalty for falsification.* (1) Under Medicare and Medicaid, an individual who willfully and knowingly—

(i) Certifies a material and false statement in a resident assessment is subject to a civil money penalty of not more than $1,000 for each assessment; or

(ii) Causes another individual to certify a material and false statement in a resident assessment is subject to a civil money penalty of not more than $5,000 for each assessment.

(2) Clinical disagreement does not constitute a material and false statement.

* * * * *

3. Subpart F consisting of § 483.315 is added to read as follows:

Subpart F—Requirements That Must be Met by States and State Agencies, Resident Assessment

§ 483.315 Specification of resident assessment instrument.

(a) *Statutory basis.* Sections 1819(e)(5) and 1919(e)(5) of the Act require that a State specify the resident assessment instrument (RAI) to be used by long term care facilities in the State when conducting initial and periodic assessments of each resident's functional capacity, in accordance with § 483.20.

(b) *State options in specifying an RAI.* The RAI that the State specifies must be one of the following:

(1) The instrument designated by HCFA.

(2) An alternate instrument specified by the State and approved by HCFA, using the criteria specified in the State Operations Manual issued by HCFA (HCFA Pub. 7) which is available for purchase through the National Technical Information Service, 5285 Port Royal Rd., Springfield, VA 22151.

(c) *State requirements in specifying an RAI.*

(1) Within 30 days after HCFA notifies the State of the HCFA-designated RAI or changes to it, the State must do one of the following:

(i) Specify the HCFA-designated RAI.

(ii) Notify HCFA of its intent to specify an alternate instrument.

(2) Within 60 days after receiving HCFA approval of an alternate RAI, the State must specify the RAI for use by all long term care facilities participating in the Medicare and Medicaid programs.

(3) After specifying an instrument, the State must provide periodic educational programs for facility staff to assist with implementation of the RAI.

(4) A State must audit implementation of the RAI through the survey process.

(5) A State must obtain approval from HCFA before making any modifications to its RAI.

(6) A State must adopt revisions to the RAI that are specified by HCFA.

(d) *HCFA-designated RAI.* The HCFA-designated RAI is published in the State Operations Manual issued by HCFA (HCFA Pub. 7), as updated periodically, and consists of the following:

(1) The minimum data set (MDS) and common definitions.

(2) The resident assessment protocols (RAPs) and triggers that are necessary to accurately assess residents, established by HCFA.

(3) The quarterly review, based on a subset of the MDS specified by HCFA.

(4) The requirements for use of the RAI that appear at § 483.20.

(e) *Minimum data set (MDS).* The MDS includes assessment in the following areas:

(1) Identification and demographic information, which includes information to identify the resident and facility, the resident's residential history, education, the reason for the assessment, guardianship status and information regarding advance directives, and information regarding mental health history.

(2) Customary routine, which includes the resident's lifestyle prior to admission to the facility.

(3) Cognitive patterns, which include memory, decision making, consciousness, behavioral measures of delirium, and stability of condition.

(4) Communication, which includes scales for measuring hearing and communication skills, information on how the resident expresses himself or herself, and stability of communicative ability.

(5) Vision pattern, which includes a scale for measuring vision and vision problems.

(6) Mood and behavior patterns, which include scales for measuring behavioral indicators and symptoms, and stability of condition.

(7) Psychosocial well-being, which includes the resident's interpersonal relationships and adjustment factors.

(8) Physical functioning and structural problems, which contains scales for measuring activities of daily living, mobility, potential for improvement, and stability of functioning.

(9) Continence, which includes assessment scales for bowel and bladder incontinence, continence patterns, interventions, and stability of continence status.

(10) Disease diagnoses and health conditions, which includes active medical diagnoses, physical problems, pain assessment, and stability of condition.

(11) Dental and nutritional status, which includes information on height and weight, nutritional problems and accommodations, oral care and problems, and measure of nutritional intake.

(12) Skin condition, which includes current and historical assessment of skin problems, treatments, and information regarding foot care.

(13) Activity pursuit, which gathers information on the resident's activity preferences and the amount of time spent participating in activities.

(14) Medications, which contains information on the types and numbers of medications the resident receives.

(15) Special treatments and procedures, which includes measurements of therapies, assessment of rehabilitation/restorative care, special programs and interventions, and information on hospital visits and physician involvement.

(16) Discharge potential, which assesses the possibility of discharging the resident and discharge status.

(17) Documentation of summary information regarding the additional assessment performed through the resident assessment protocols.

(18) Documentation of participation in assessment.

(f) *Resident assessment protocols (RAPs).* At a minimum, the RAPs address the following domains:

(1) Delirium.
(2) Cognitive loss.
(3) Visual function.
(4) Communication.
(5) ADL functional/rehabilitation potential.
(6) Urinary incontinence and indwelling catheter.
(7) Psychosocial well-being.
(8) Mood state.
(9) Behavioral symptoms.
(10) Activities.
(11) Falls.
(12) Nutritional status.
(13) Feeding tubes.
(14) Dehydration/fluid maintenance.
(15) Dental care.
(16) Pressure ulcers.
(17) Psychotropic drug use.
(18) Physical restraints.

(g) *Criteria for HCFA approval of alternate instrument.* To receive HCFA approval, a State's alternate instrument must use the standardized format, organization, item labels and definitions, and instructions specified by HCFA in the latest issuance of the State Operations Manual issued by HCFA (HCFA Pub. 7).

(h) *State MDS collection and data base requirements.* (1) As part of facility

survey responsibilities, the State must establish and maintain an MDS Database, and must do the following:

(i) Use a system to collect, store, and analyze data that is developed or approved by HCFA.

(ii) Obtain HCFA approval before modifying any parts of the HCFA standard system other than those listed in paragraph (h)(2) of this section (which may not be modified).

(iii) Specify to a facility the method of transmission of data to the State, and instruct the facility on this method.

(iv) Upon receipt of data from a facility, edit the data, as specified by HCFA, and ensure that a facility resolves errors.

(v) At least monthly, transmit to HCFA all edited MDS records received during that period, according to formats specified by HCFA, and correct and retransmit rejected data as needed.

(vi) Analyze data and generate reports, as specified by HCFA.

(2) The State may not modify any aspect of the standard system that pertains to the following:

(i) Standard approvable RAI criteria specified in the State Operations Manual issued by HCFA (HCFA Pub. 7) (MDS item labels and definitions, RAPs and utilization guidelines).

(ii) Standardized record formats and validation edits specified in the State Operations Manual issued by HCFA (HCFA Pub. 7).

(iii) Standard facility encoding and transmission methods specified in the State Operations Manual issued by HCFA (HCFA Pub. 7).

(i) *State identification of agency that collects RAI data.* The State must identify the component agency that collects RAI data, and ensure that this agency restricts access to the data except for the following:

(1) Reports that contain no resident-identifiable data.

(2) Transmission of data and reports to HCFA.

(3) Transmission of data and reports to the State agency that conducts surveys to ensure compliance with Medicare and Medicaid participation requirements, for purposes related to this function.

(4) Transmission of data and reports to the State Medicaid agency for purposes directly related to the administration of the State Medicaid plan.

(5) Transmission of data and reports to other entities only when authorized as a routine use by HCFA.

(j) *Resident-identifiable data.* (1) The State may not release information that is resident-identifiable to the public.

(2) The State may not release RAI data that is resident-identifiable except in accordance with a written agreement under which the recipient agrees to be bound by the restrictions described in paragraph (i) of this section.

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program; and No. 93.773, Medicare—Hospital Insurance)

Dated: December 3, 1997.

Nancy-Ann Min DeParle,

Administrator, Health Care Financing Administration.

Dated: December 9, 1997.

Donna E. Shalala,

Secretary.

[FR Doc. 97–32828 Filed 12–22–97; 8:45 am]

BILLING CODE 4120–01–P