

whose cost report start date occurs later in the calendar year. Therefore, in this final rule, we are not changing the CMG classification system or the facility-level and case-level adjustments, other than the wage adjustment. The adopted changes for the wage adjustment are discussed in detail in section VI. of this final rule.

D. Staff Time Measurement Data

As described in the August 7, 2001 final rule, we contracted with Aspen Systems Corporation (ASPEN) to collect actual resource use or staff time measurement (STM) data in a sample of IRFs. Data were collected using the MDS-PAC patient assessment instrument. FIM data were collected at the same time. We believe that these data, which measure actual nursing and therapy time spent on patient care, may be used to enhance our ability to refine the CMGs.

RAND received ASPEN's analytical database in early spring 2002. After a brief period of working with the data, RAND discovered that their study required details that were not in this summary database. Specifically, about half of the cases within the analytic database had data for only the first part of the patient's stay. RAND needed to have explicit data that tracked how staff time usage changed throughout a patient's stay and the analytic database contained only the averages of the observed portions of the patient's stay. RAND also needed data on patients during the second part of their stay.

In late July 2002, RAND received the backup data, but did not assess it until late August 2002. Further technical questions about the data still exist and must be answered before the modeling of the data can occur.

E. Monitoring

A greater part of the ongoing work to be performed by RAND is an analysis to develop a potential system of indicators to monitor the impact and performance of the IRF PPS. As part of their analysis, RAND will case-mix adjust these measures and distinguish between those that will track the direct impact of PPS on IRFs and IRF patients, and those that will track changes in the pool of potential IRF patients. We anticipate that RAND will develop a set of possible indicators needed to monitor the IRF PPS, develop potential access to care models and measures, and define a possible measure of outcomes.

F. Need To Develop Quality Indicators for IRFs

The IRF PAI is the data collection instrument for IRFs. It contains a blend

of FIM items and quality and medical needs questions. The quality and medical needs questions (which are currently collected on a voluntary basis) may need to be modified to encapsulate those data necessary for calculation of a quality indicator in the future. One of the primary tasks of the RAND contract is to identify quality indicators pertinent to the inpatient rehabilitation setting and determine what information is necessary to calculate those quality indicators. These tasks include reviewing literature and other sources for existing rehabilitation quality indicators. It also involves identifying organizations involved in measuring or monitoring quality of care in the inpatient rehabilitation setting. RAND will convene a technical expert panel to identify a series of quality indicators that can be measured using the IRF-PAI. In addition, quality indicators and data elements must be developed for calculation as well as the independent testing of the developed indicators.

We note that the National Library of Medicine, which is part of the National Institutes of Health within the Department of Health and Human Services, has entered into an agreement with the College of American Pathologists to license the Systematized Nomenclature of Medicine—Clinical Terms (SNOMED CT). SNOMED CT provides a common language that enables a consistent way of capturing, sharing, and aggregating health care data across specialties and sites of care. If in the future, CMS makes changes to the IRF PAI, we will consider whether SNOMED CT includes IRF PAI data terminology and we will consider including SNOMED CT terms. For further information, please visit SNOMED's Web site at <http://www.snomed.org> or the National Library of Medicine Web site at <http://www.nlm.nih.gov>.

IV. The IRF PPS Patient Assessment Process

A. Background

In the August 7, 2001 IRF PPS final rule (66 FR 41316), we described how an IRF would use the IRF Patient Assessment Instrument (PAI) to assess an IRF patient. Training on the IRF-PAI assessment process was conducted in Baltimore, Maryland, Chicago, Illinois, San Francisco, California, and Atlanta, Georgia during the fall of 2001. We also created videotapes of the training that we made available to IRFs free of charge. IRFs were instructed to go to the CMS IRF PPS website to request copies of the videotapes and to access electronic copies of the IRF-PAI

manual, which contained detailed instructions regarding the completion of the IRF-PAI.

B. Patient Rights

Section 412.608 of the existing regulations specifies that prior to performing the IRF-PAI assessment, and in order to receive payment from Medicare, the IRF must inform the patient of the rights contained in this section. These rights are as follows:

(1) The right to be informed of the purpose of the patient assessment data collection;

(2) The right to have the patient assessment information collected kept confidential and secure;

(3) The right to be informed that the patient assessment information will not be disclosed to others, except for legitimate purposes allowed by the Federal Privacy Act and Federal and State regulations;

(4) The right to refuse to answer patient assessment questions; and

(5) The right to see, review, and request changes on the patient assessment instrument.

In addition to the rights specified in § 412.608, a patient has privacy rights under the Privacy Act of 1974 (5 U.S.C. 552a(e)(3)), and 45 CFR 5b.4(a)(3). We have elaborated on these privacy rights in this Preamble statement in order to avoid any confusion. The Privacy Act and 45 CFR 5b.4(a)(3) require that an individual be informed of the following: the authority by which individually identifiable information is being collected by a Federal agency and maintained in a system of records; whether providing the information is voluntary or mandatory; the principal purpose for collecting the information; the routine uses for release of the information; and the effect refusal to provide requested information may have on the individual. The Federal agency should be identified, as well as the location of the system of records. In order to ensure compliance with the Privacy Act of 1974 and 45 CFR 5b.4(a)(3), in the May 16, 2003 proposed rule, we proposed to revise § 412.608 to specify that, prior to performing the IRF-PAI assessment, an IRF clinician must give each Medicare inpatient specific privacy information forms.

We published these proposed privacy forms in Appendix B of the May 16, 2003 proposed rule (and are including them under the Appendix of this final rule). The first proposed form, entitled "Privacy Act Statement—Health Care Records," is a detailed description of the patient's privacy rights under the Privacy Act of 1974. The second proposed form, entitled "Data