

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 that 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 data on how staff time use changed during the stay and the analytic database contained only the averages of the observed portions of the patient's stay. RAND 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 proposed quality and medical needs questions. These 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. 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.

IV. The IRF PPS Patient Assessment Process

A. Background

On August 7, 2001, we published the IRF PPS final rule (66 FR 41316), which described how the IRF would use the IRF Patient Assessment Instrument (PAI) to assess an IRF patient. During the fall of 2001, we conducted training on the IRF-PAI assessment process. The training was held in the cities of Baltimore, Maryland, Chicago, Illinois, San Francisco, California, and Atlanta, Georgia. The training was videotaped. During the training sessions we stated that any IRF could obtain the videotapes free of charge. In addition, we stated on the CMS IRF PPS website that any IRF could obtain copies of the videotapes. The IRS-PAI manual, which contains detailed instructions regarding the completion of the IRS-PAI, is also available on the CMS IRF PPS website.

B. Patient Rights

Section 412.608 specifies that prior to performing the IRS-PAI assessment, the IRF must inform the patient of the rights contained in this section. The rights specified in § 412.608 are as follows:

- (1) The right to be informed of the purpose of the collection of the patient assessment data;
- (2) The right to have the patient assessment information collected be 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 his or her patient assessment.

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). The Privacy Act and 45 CFR 5b.4(a)(3) require that an individual be informed under what authority, and for what purpose, individually identifiable information is being collected by a

Federal agency and maintained in a system of records. In order to ensure compliance with the Privacy Act of 1974, and 45 CFR 5b.4(a)(3), we are proposing that prior to performing the IRS-PAI assessment an IRF clinician must give to each Medicare inpatient two forms. We have published these forms in Appendix B of this proposed rule. In addition, we are proposing that the form entitled "Privacy Act Statement—Health Care Records" is a detailed description of the patient's privacy rights under the Privacy Act of 1974. Also, we are proposing that the form entitled "Data Collection Information Summary for Patients in Inpatient Rehabilitation Facilities" is the simplified plain language description of the Privacy Act Statement—Health Care Records. Additionally, we are proposing that by giving both of these forms to the patient before beginning the IRS-PAI assessment, the IRF would fulfill the requirement that the patient be informed of the five rights specified in § 412.608. Accordingly we are proposing to amend § 412.608 to read as follows:

Patient's rights regarding the collection of patient assessment data.

(a) Before performing an assessment using the inpatient rehabilitation facility patient assessment instrument, a clinician of the inpatient rehabilitation facility must give a Medicare inpatient each of these forms—

- (1) The form entitled "Privacy Act Statement—Health Care Records;" and
- (2) The simplified plain language description of the Privacy Act Statement—Health Care Records which is a form entitled "Data Collection Information Summary for Patients in Inpatient Rehabilitation Facilities."

(b) The inpatient rehabilitation facility must document in the Medicare inpatient's clinical record that the Medicare inpatient has been given the documents specified in paragraph (a) of this section.

(c) The Data Collection Information Summary for Patients in Inpatient Rehabilitation Facilities is the simplified plain language description of the Privacy Act Statement—Health Care Records.

(d) By giving the Medicare inpatient the forms specified in paragraph (a) of this section the inpatient rehabilitation facility will inform the Medicare patient of—

- (1) Their privacy rights under the Privacy Act of 1974 and 45 CFR 5b.4(a)(3); and
- (2) The following rights: