Federal Register

Tuesday,
August 7, 2001

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 412 and 413

Medicare Program; Prospective Payment System for Inpatient Rehabilitation Facilities; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 412 and 413

[CMS–1069–F]

RIN 0938–AJ55

Medicare Program; Prospective Payment System for Inpatient Rehabilitation Facilities

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule establishes a prospective payment system for Medicare payment of inpatient hospital services provided by a rehabilitation hospital or by a rehabilitation unit of a hospital. It implements section 1886(j) of the Social Security Act (the Act), as added by section 4421 of the Balanced Budget Act of 1997 and as amended by section 125 of the Medicare, Medicaid, and SCHIP [State Children's Health Insurance Program] Balanced Budget Refinement Act of 1999 and by section 305 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000. Section 1886(j) of the Act authorizes the implementation of a prospective payment system for inpatient rehabilitation hospitals and rehabilitation units of hospitals. This section also authorizes the Secretary to require rehabilitation hospitals and rehabilitation units to submit data as the Secretary deems necessary to establish and administer the prospective payment system. The prospective payment system described in this final rule replaces the reasonable cost-based payment system under which rehabilitation hospitals and rehabilitation units of hospitals are paid under Medicare.

DATES: *Effective Date:* These regulations are effective on January 1, 2002.

Applicability Date: The provisions of this final rule are effective for cost reporting periods beginning on or after January 1, 2002.

FOR FURTHER INFORMATION CONTACT:

Robert Kuhl, (410) 786–4597 (General information, the case-mix classification system, and transition payments).

Pete Diaz, (410) 786–1235 (Requirements for completing the patient assessment instrument, and other assessment instrument issues).

Nora Hoban, (410) 786–0675 (Payment system, calculation of the payment rates, update factors, relative weights/case-mix index, wage index, transfer policies, and payment adjustments).

SUPPLEMENTARY INFORMATION:

Availability of Copies, and Electronic Access

Copies: To order copies of the **Federal Register** containing this document, send your request to: New Orders, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250–7954. Specify the date of the issue requested and enclose a check or money order payable to the Superintendent of Documents, or enclose your Visa or Master Card number and expiration date. Credit card orders can also be placed by calling the order desk at (202) 512–1800 or by faxing to (202) 512–2250. The cost for each copy is $9. As an alternative, you can view and photocopy the **Federal Register** document at most libraries designated as Federal Depository Libraries and at many other public and academic libraries throughout the country that receive the **Federal Register**. This **Federal Register** document is also available from the **Federal Register** online database through GPO Access, a service of the U.S. Government Printing Office. The website address is: http://www.access.gpo.gov/nara/index.html.

To assist readers in referencing sections contained in this document, we are providing the following table of contents.

Table of Contents

I. Background
- A. General
- B. Summary of the Statutory Provisions Governing the IRF Prospective Payment System
- C. Summary of the November 3, 2000 Proposed Rule
- D. General Overview of the IRF Prospective Payment System
- E. Summary of Public Comments Received on the November 3, 2000 Proposed Rule

II. Requirements and Conditions for Payment Under the Prospective Payment System for IRFs
- A. Classification Criteria for IRFs
- B. Completion of Patient Assessment Instrument
- C. Limitation on Charges to Beneficiaries
- D. Furnishing of Inpatient Hospital Services Directly or Under Arrangements
- E. Reporting and Recordkeeping Requirements

III. Research to Support the Establishment of the IRF Prospective Payment System
- A. Overview of Research for the Proposed Rule
- B. Updated Research for the Final Rule
- C. Research on the Patient Assessment Instrument for the Final Rule
- D. Analyses to Support Future Adjustments to the IRF Prospective Payment System

IV. The IRF Patient Assessment
- A. Implementation of a Patient Assessment Instrument
- B. The Patient Assessment Process
- C. Documentation Requirements for the Patient Assessment
- D. Patient Assessment Schedule and Data Transmission
- E. Quality Monitoring
- F. Training and Technical Support for IRFs
- G. Release of Information Collected Using the Patient Assessment Instrument
- H. Patient Rights
- I. Medical Review Under the IRF Prospective Payment System

V. Case-Mix Group Patient Classification System
- A. Background
- B. Description of Methodology Used to Develop the CMGs Based on the FIM–FRG Methodology for the Final Rule
- C. Description of Methodology Used to Develop the CMGs for Special Cases for the Final Rule
- D. Final Set of CMGs
- E. Methodology to Classify Patients into CMGs
- F. Adjustment to the CMGs

VI. Payment Rates
- A. Development of CMG Relative Weights
- B. Transfer Payment Policy
- C. Special Cases That Are Not Transfers
- D. Adjustments
- E. Calculation of the Budget Neutral Conversion Factor
- F. Development of the Federal Prospective Payments
- G. Examples of Computing the Adjusted Facility Prospective Payments
- H. Computing Total Payments under the IRF Prospective Payment System
- I. Method of Payment
- J. Update to the Adjusted Facility Federal Prospective Payments
- K. Publication of the Federal Prospective Payment Rates
- L. Limitations on Administrative or Judicial Review

VII. Provisions of the Final Regulations

VIII. Regulatory Impact Analysis
- A. Introduction
- B. Anticipated Effects of the Final Rule
- C. Alternatives Considered
- D. Executive Order 12866

IX. Collection of Information Requirements

X. Waiver of Proposed Rulemaking

Regulations Text

Addendum—Tables

Appendix A—Technical Discussion of Cases and Providers Used in RAND Analysis

Appendix B—Inpatient Rehabilitation Facility Patient Assessment Instrument

Appendix C—List of Comorbidities

Appendix D—The IRF Market Basket

Alphabetical List of Acronyms Appearing in the Final Rule

- ADL Activities of Daily Living
- BBA Balanced Budget Act of 1997, Public Law 105–33
- BBRA Medicare, Medicaid, and SCHIP [State Children's Health Insurance Program] Balanced Budget Refinement Act of 1999, Public Law 106–113
- BIPA Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, Public Law 106–554

CMGs Case-mix groups
CMI Case-mix index
CMS Centers for Medicare & Medicaid Services (formerly the Health Care Financing Administration)
COS Clinical Outcomes Systems
DRGs Diagnosis-related groups
FIM Functional independence measure
FRG Function-related group
FY Federal fiscal year
HCFA Health Care Financing Administration (now the Centers for Medicare & Medicaid Services)
HIPAA Health Insurance Portability and Accountability Act of 1996, Public Law 104–191
HHAs Home health agencies
HMO Health maintenance organization
IRFs Inpatient rehabilitation facilities
MDCN Medicare Data Collection Network
MDS–PAC Minimum Data Set for Post-Acute Care
MedPAC Medicare Payment Advisory Commission
MedPAR Medicare Provider Analysis and Review File Tool
OASIS Outcome and Assessment Information Set
ProPAC Prospective Payment Assessment Commission
RAPs Resident assessment protocols
RICs Rehabilitation impairment categories
SNFs Skilled nursing facilities
TEFRA Tax Equity and Fiscal Responsibility Act of 1982, Public Law 97–248
UDSmr Uniform Data Set for medical rehabilitation

I. Background

A. General

On November 3, 2000, we published a proposed rule in the **Federal Register** (65 FR 66304, HCFA–1069–P) to announce, and solicit public comments on, our proposed plans to establish a prospective payment system under Medicare for inpatient hospital services furnished by a rehabilitation hospital or a rehabilitation unit of a hospital. (The proposed rule and all other important information regarding the proposed IRF prospective payment system is contained on our website at www.hcfa.gov/medicare/irfpps.htm.) Section 1886(j) of the Social Security Act (the Act), as added by section 4421 of the Balanced Budget Act of 1997 (BBA)(Public Law 105–33) and as amended by section 125 of the Medicare, Medicaid, and SCHIP [State Children's Health Insurance Program] Balanced Budget Refinement Act of 1999 (BBRA) (Public Law 106–113) and section 305 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Public Law 106–554), authorizes the implementation of such a prospective payment system. Below we provide a history of Medicare payments for inpatient rehabilitation services and a discussion of the legislative changes that have affected these payments.

When the Medicare statute was originally enacted in 1965, Medicare payment for hospital inpatient services was based on the reasonable costs incurred in furnishing services to Medicare beneficiaries. The statute was later amended by section 101(a) of the Tax Equity and Fiscal Responsibility Act of 1982 (Public Law 97–248) to limit payment by placing a limit on allowable costs per discharge. Section 601 of the Social Security Amendments of 1983 (Public Law 98–21) added a new section 1886(d) to the Act that replaced the reasonable cost-based payment system for most hospital inpatient services. Section 1886(d) of the Act provides for a prospective payment system for the operating costs of hospital inpatient stays effective with hospital cost reporting periods beginning on or after October 1, 1983.

Although most hospital inpatient services became subject to a prospective payment system, certain specialty hospitals were excluded from that system. Inpatient rehabilitation hospitals and distinct part rehabilitation units in hospitals were among the excluded facilities. We refer to these inpatient rehabilitation hospitals and units as ''inpatient rehabilitation facilities'' or ''IRFs'' throughout this rule.

Subsequent to the implementation of the hospital inpatient prospective payment system, both the number of excluded IRFs, particularly distinct part units, and Medicare payments to these facilities grew rapidly. In order to control escalating costs, the Congress, through enactment of section 4421 of the BBA, section 125 of the BBRA, and section 305 of the BIPA, provided for the implementation of a prospective payment system for IRFs. Section 4421 of the BBA amended the Act by adding section 1886(j), which authorizes the implementation of a prospective payment system for inpatient rehabilitation services. Section 125 of the BBRA amended section 1886(j) of the Act (as added by the BBA) to require the Secretary to use the discharge as the payment unit for inpatient rehabilitation services under the prospective payment system and to establish classes of patient discharges by functional-related groups. Section 305 of the BIPA further amended section 1886(j) of the Act to allow rehabilitation facilities to elect to be paid the full Federal prospective payment rather than the blended payments otherwise specified in the Act. This final rule implements the Medicare prospective payment system for IRFs, as authorized by section 1886(j) of the Act, as amended.

The statute provides for the prospective payment system for IRFs to be implemented for cost reporting periods beginning on or after October 1, 2000. However, because of the extensive changes required by the statute to change the payment systems for IRFs as well as the demands of simultaneously implementing new prospective payment systems for outpatient hospital and home health services, we determined, in the proposed rule, that it was not feasible to implement the IRF prospective payment system as of October 1, 2000. The creation of each new payment system or modification to an existing payment system requires an extraordinary amount of lead-time to develop and implement the necessary changes to our existing computerized claims processing systems. In addition, it requires additional time after implementation to ensure that these complex changes are properly administered. Therefore, in the November 3, 2000 proposed rule, we indicated our belief that the earliest feasible date to implement the IRF prospective payment system was for cost reporting periods beginning on or after April 1, 2001.

We have evaluated the changes that will be necessary in our various systems for the IRF prospective payment system in order to accommodate suggestions made in the comments (such as developing and administering a revised patient assessment instrument described in section IV. of this preamble) along with changes to other Medicare payment systems required by the BBA, the BBRA, and the BIPA. After an extensive analysis of the changes required to both the providers' and our systems, we have now determined that the earliest feasible date to implement the IRF prospective payment system in this final rule is for cost reporting periods beginning on or after January 1, 2002. We believe that this is the earliest feasible date given the scope and magnitude of the implementation and administrative requirements, including provider training, associated with the IRF prospective payment system and other mandated payment systems.

B. Summary of the Statutory Provisions Governing the IRF Prospective Payment System

Section 4421(a) of the BBA amended the Act by adding a new section 1886(j) to the Act that provides for the implementation of a Medicare prospective payment system for inpatient hospital rehabilitation services furnished in all IRFs. Under the

prospective payment system, IRFs will be paid based on predetermined amounts. These prospective payments will encompass the inpatient operating and capital costs of furnishing covered rehabilitation services (that is, routine, ancillary, and capital costs) but not costs of approved educational activities, bad debts, and other services or items that are outside the scope of the IRF prospective payment system. Covered rehabilitation services include services for which benefits are provided under Part A (the Hospital Insurance Program) of the Medicare program.

Section 1886(j)(1)(A) of the Act provides that, notwithstanding section 1814(b) of the Act and subject to the provisions of section 1813 of the Act regarding beneficiary deductibles and coinsurance responsibility, the amount of payment for inpatient rehabilitation hospital services equals an amount determined under section 1886(j) of the Act. Sections 1886(j)(1)(A)(i) and (j)(1)(A)(ii) of the Act, as in effect prior to the enactment of sections 305(b)(1)(A), (B), and (C) of the BIPA, provide for a transition period covering cost reporting periods that begin during FYs 2001 and 2002 under the prospective payment system. During this transition period, IRFs would receive a payment rate comprising a blend of the ''TEFRA percentage'' of the amount that would have been paid under Part A with respect to those costs if the prospective payment system had not been implemented, and the ''prospective payment percentage'' of payments using the IRF prospective payment system rate. The applicable transition percentages are described in section 1886(j)(1)(C) of the Act. Sections 305(b)(1)(A) and (C) of the BIPA amended section 1886(j)(1)(A) and added a new subparagraph (F) to section 1886(j)(1) of the Act, respectively, to allow an IRF to elect to be paid the full Federal prospective payment rather than a payment determined under the transition period methodology described in detail below. The provisions of section 305(b) of the BIPA take effect as if included in the enactment of the BBA.

Section 1886(j)(1)(B) of the Act, in effect prior to the enactment of section 305 of the BIPA, sets forth a requirement applicable to all IRFs for the payment rates under the fully implemented prospective payment system. Notwithstanding section 1814(b) of the Act and subject to the provisions of section 1813 of the Act regarding beneficiary deductibles and coinsurance responsibility, the amount of the payment for the operating and capital costs of an IRF for a payment unit (as defined in section 1886(j)(1)(D) of the Act) in a cost reporting period beginning on or after October 1, 2002 (FY 2003), will be equal to the per unit payment rate established under the prospective payment system for the fiscal year in which the payment unit of service occurs. Section 305(b)(1)of the BIPA amended section 1886(j)(1)(B) of the Act and added a new subparagraph (F) to section 1886(j)(l) to make the provisions of section 1886(j)(1)(B) of the Act applicable to an IRF that elects, not later than 30 days before its first cost reporting period for which it is subject to the payment methodology of section 1886(j)(1) of the Act, to be paid the full Federal prospective payment rather than a payment determined under the transition period methodology.

Sections 1886(j)(1)(C)(i) and (ii) of the Act set forth the applicable TEFRA and prospective payment rate percentages during the transition period. The two sections specify that, for a cost reporting period beginning on or after October 1, 2000, and before October 1, 2001 (FY 2001), the ''TEFRA percentage'' is 66⅔ percent and the ''prospective payment percentage'' is 33⅓ percent; and on or after October 1, 2001, and before October 1, 2002 (FY 2002), the ''TEFRA percentage'' is 33⅓ percent and the ''prospective payment percentage'' is 66⅔ percent. (As explained earlier in section I.A. of this final rule, we are implementing the IRF prospective payment system for cost reporting periods beginning on or after January 1, 2002. See section VI.H. of this final rule for a discussion of the implementation of the transition period methodology.)

Section 1886(j)(1)(D) of the Act contains the definition of ''payment unit.'' Until the passage of the BBRA, ''payment unit'' was defined by the statute as ''a discharge, day of inpatient hospital services, or other unit of payment defined by the Secretary.'' Section 125(a)(1) of the BBRA amended section 1886(j)(1)(D) of the Act by striking ''day of inpatient hospital services, or other unit of payment defined by the Secretary.'' Accordingly, the payment unit utilized in the IRF prospective payment system will be a discharge.

Section 125(a)(3) of the BBRA amended the Act by adding a new section 1886(j)(1)(E) to the Act that states: ''Nothing in this subsection shall be construed as preventing the Secretary from providing for an adjustment to payments to take into account the early transfer of a patient from a rehabilitation facility to another site of care.'' Our transfer policy is discussed in section VI.B. of this preamble.

Section 305(b)(1)(C) of the BIPA amended the Act by adding section 1886(j)(1)(F) to provide that an IRF may elect, not later than 30 days before its first cost reporting period for which the payment methodology applies to the facility, to have payment made to the facility under the provision of section 1886(j)(1)(B) of the Act (the fully implemented prospective payment system) rather than section 1886(j)(1)(A) of the Act (payment under the transition methodology) for each cost reporting period to which the payment methodology applies.

Section 1886(j)(2)(A) of the Act, as added by section 4421 of the BBA, directed the Secretary to establish case-mix groups (CMGs) based on the factors as the Secretary deems appropriate, which may include impairment, age, related prior hospitalization, comorbidities, and functional capability of the patient. This section also requires the Secretary to establish a method of classifying specific patients in IRFs within these groups. Section 125(a)(2) of the BBRA amended section 1886(j)(2)(A)(i) of the Act to establish classes of patient discharges by functional-related groups. Section 1886(j)(2)(A)(i) of the Act reads: ''classes of patient discharges of rehabilitation facilities by functional-related groups (each * * * referred to as a 'case mix group'), based on impairment, age, comorbidities, and functional capability of the patient and such other factors as the Secretary deems appropriate to improve the explanatory power of functional independence measure-function related groups.''

Section 1886(j)(2)(B) of the Act provides that the Secretary must assign each case-mix group a weighting factor that reflects the relative facility resources used for patients classified within the group as compared to patients classified within other groups.

Section 1886(j)(2)(C)(i) of the Act directs the Secretary to adjust ''from time to time'' the case-mix classifications and weighting factors ''as appropriate to reflect changes in treatment patterns, technology, case-mix, number of payment units for which payment is made * * * and other factors which may affect the relative use of resources.'' Such periodic adjustments must be made in a manner so that changes in aggregate payments are a result of real changes in case-mix, not changes in coding that are unrelated to real changes in case-mix. Section 1886(j)(2)(C)(ii) of the Act provides that, if the Secretary determines that adjustments to the case-mix classifications or weighting factors resulted in (or are likely to result in) a

change in aggregate payments that does not reflect real changes in case-mix, the Secretary must adjust the per payment unit payment rate for subsequent years so as to eliminate the effect of the coding or classification changes.

Section 1886(j)(2)(D) of the Act authorizes the Secretary to require rehabilitation facilities that provide inpatient hospital services to submit such data as the Secretary deems necessary to establish and administer the IRF prospective payment system.

Section 1886(j)(3)(A) of the Act describes how the prospective payment rate will be determined. A prospective payment rate must be determined for each payment unit for which an IRF is entitled to payment under the prospective payment system. The payment rate will be based on the average payment per payment unit for inpatient operating and capital costs of IRFs, using the most recently available data, and adjusted by the following factors:

- Updating the per-payment unit amount to the fiscal year involved by the applicable percentage increase (as defined by section 1886(b)(3)(B)(ii) of the Act) covering the period from the midpoint of the period for such data through the midpoint of FY 2000 and by an increase factor specified by the Secretary for subsequent fiscal years.
- Reducing the rates by a factor that is equal to the proportion of Medicare payments under the prospective payment system as estimated by the Secretary based on prospective payment amounts that are additional payments relating to outlier and related payments.
- Accounting for area wage variations among IRFs.
- Applying the case-mix weighting factors.
- Adjusting for such other factors as the Secretary determines necessary to properly reflect variations in necessary costs of treatment among IRFs.

Until the passage of the BIPA, section 1886(j)(3)(B) of the Act directed the Secretary to establish IRF prospective payment system payment rates during FYs 2001 and 2002 at levels so that, in the Secretary's estimation, total payments under the new system will equal 98 percent of the amount of payments that would have been made for operating and capital costs in those years if the IRF prospective payment system had not been implemented. In establishing these payment amounts, the Secretary must consider the effects of the prospective payment system on the total number of payment units from IRFs and other factors. Section 305(a) of the BIPA amended section 1886(j)(3)(B) of the Act by striking ''98 percent'' and adding ''98 percent for fiscal year 2001 and 100 percent for fiscal year 2002''. The heading for section 305(a) of BIPA is ''Assistance with administrative costs associated with the completion of patient assessment.'' In addition, section 305(b)(2) amended section 1886(j)(3)(B) of the Act to clarify that in establishing the levels of the payment rates under section 1886(j)(3)(B) of the Act, the Secretary is not to account for any payment adjustment for IRFs electing not to be paid under the transition period methodology as allowed under section 1886(j)(1)(F) of the Act as added by section 305(b)(1)(C) of the BIPA. Section VI.E. of this final rule contains a further discussion of the development of payment rates under section 1886(j)(3)(B) of the Act.

Section 1886(j)(3)(C) of the Act provides for an annual increase factor. This factor must be based on an appropriate percentage increase in a market basket of goods and services comprising services for which payment is made under section 1886(j) of the Act (which may be the market basket percentage increase described in section 1886(b)(3)(B)(iii) of the Act).

Under section 1886(j)(4)(A) of the Act, the Secretary is authorized, but not required, to provide for an additional payment to a rehabilitation facility for patients in a case-mix group, based upon the patient being classified as an outlier based on an unusual length of stay, costs, or other factors specified by the Secretary. The amount of the additional payment must approximate the marginal cost of care above what otherwise would be paid and must be budget neutral. The total amount of the additional payments to IRFs under the prospective payment system for a fiscal year may not be projected to exceed 5 percent of the total payments based on prospective payment rates for payment units in that year.

Section 1886(j)(4)(B) of the Act establishes that the Secretary is authorized but not required to provide for adjustments to the payment amounts under the prospective payment system as the Secretary deems appropriate to take into account the unique circumstances of IRFs located in Alaska and Hawaii.

Section 1886(j)(5) of the Act provides for the Secretary to publish in the **Federal Register**, on or before August 1 before each fiscal year, the classifications and weighting factors for the IRF case-mix groups and a description of the methodology and data used in computing the prospective payment rates for that fiscal year.

Section 1886(j)(6) of the Act provides that the Secretary must adjust the proportion (as estimated by the Secretary from time to time) of IRFs' costs that are attributable to wages and wage-related costs, of the prospective payment rates for area differences in wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the IRF compared to the national average wage level for such facilities. Additionally, the Secretary is required to make a budget-neutral update to the area wage adjustment factor no later than October 1, 2001, and at least once every 36 months thereafter. The budget neutral update is based on information available to the Secretary (and updated as appropriate) of the wages and wage-related costs incurred in furnishing rehabilitation services.

Sections 1886(j)(7)(A), (B), (C), and (D) of the Act establish that there shall be no administrative or judicial review, under sections 1869 and 1878 of the Act or otherwise, of the establishment of case-mix groups, the methodology for the classification of patients within these groups, the weighting factors, the prospective payment rates, outlier and special payments and area wage adjustments.

Section 125(b) of the BBRA provides that the Secretary shall conduct a study of the impact on utilization and beneficiary access to services of the implementation of the IRF prospective payment system. A report on the study must be submitted to the Congress not later than 3 years after the date the IRF prospective payment system is first implemented.

C. Summary of the November 3, 2000 Proposed Rule

In the November 3, 2000 proposed rule, we proposed to establish a new subpart P under 42 CFR Part 412 of the Medicare regulations to implement the IRF prospective payment system and to make technical and conforming changes to other appropriate sections under Parts 412 and 413.

In the proposed rule, to support and explain our proposed policies, we presented the following:

- An overview of the reasonable cost-based payment system that would be replaced by the IRF prospective payment system.
- An extensive discussion of past research on IRF patient classification systems and prospective payment systems, including earlier research performed by the RAND Corporation that supported a per discharge based prospective payment system using a patient classification system known as Functional Independence Measures-Functional Related Groups (FIM–FRGs).

• A discussion of the following policy objectives we identified to evaluate the relative merits of the various policy options considered:

—The creation of a beneficiary-centered payment system that promotes quality of care, access to care, and continuity of care and is administratively feasible while controlling costs.

—The provision of incentives to furnish services as efficiently as possible without diminishing the quality of the care or limiting access to care.

—The creation of a payment system that is fair and equitable to facilities, beneficiaries, and the Medicare program.

—The development of an IRF prospective payment system that has the capability to recognize legitimate cost differences among various settings furnishing the same service; and a patient classification system used to group patients and services that is based on clinically coherent categories and, at the same time, reflects similar resource use. This would limit opportunities to ''upcode'' or ''game'' the system.

• A discussion of options considered for the following major components of the proposed IRF prospective payment system: the patient assessment instrument; the patient classification system; the unit of payment; and the data used to construct the payment rates.

• A discussion of the proposed requirement that IRFs complete the Minimum Data Set for Post-Acute Care (MDS–PAC) (a patient assessment instrument) as a part of the data collection deemed necessary by the Secretary to implement and administer the IRF prospective payment system. (As explained in section IV. of this final rule, we are adopting a revised patient assessment instrument.)

• A discussion of the proposed IRF patient classification system using CMGs and the prospective payment system supported by RAND's research using 1996 and 1997 data. The results of this research were released in a report by RAND in July 2000. (This report is contained on our website: www.hcfa.gov/medicare/irfpps.htm.)

• A discussion of the impact of the proposed IRF prospective payment system on the Medicare program and on IRFs.

D. General Overview of the IRF Prospective Payment System

In accordance with the requirements of section 1886(j) of the Act, and following issuance of the November 3, 2000 proposed rule and consideration of public comments, we are implementing a prospective payment system for IRFs that replaces the current reasonable cost-based payment system. The new prospective payment system utilizes information from a patient assessment instrument to classify patients into distinct groups based on clinical characteristics and expected resource needs. Separate payments are calculated for each group with additional case-level and facility-level adjustments applied.

We are requiring IRFs to complete the patient assessment instrument described in section IV. of this preamble, for all Medicare Part A fee-for-service patients admitted or discharged on or after January 1, 2002.

Data from the patient assessment instrument will be used to—

• Determine the appropriate classification of a Medicare patient into a CMG for payment under the prospective payment system (using data from only the initial patient instrument completed after admission, as described in section IV. of this preamble);

• Implement a system to monitor the quality of care furnished to Medicare patients; and

• Ensure that appropriate case-mix and other adjustments can be made to the patient classification system.

Further details of the CMG classification system are discussed in section V. of this preamble.

IRFs are required to input the patient assessment data into a computerized data system. In general, this system consists of a computerized patient grouping software program (GROUPER software) and data transmission software.

Upon the discharge of a Medicare patient, the GROUPER software will determine the appropriate CMG classification number. IRFs must enter the CMG classification number onto the Medicare claim form in accordance with Medicare claims processing procedures. The operational aspects and instructions for completing and submitting Medicare claims under the IRF prospective payment system will be addressed in a Medicare program memorandum issued prior to the effective date of this final rule. We are aware that, beginning October 16, 2002, the submission of electronic claims must be in compliance with the administrative simplification provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104–191, as specified in the Standards for Electronic Transactions final rule published in the **Federal Register** on August 17, 2000 (65 FR 50312). We will be taking the necessary steps in the future to ensure compliance with this provision of the HIPAA.

The payment unit for the IRF prospective payment system for Medicare patients will be a discharge. The payment rates will encompass inpatient operating and capital costs of furnishing covered inpatient rehabilitation hospital services, including routine, ancillary, and capital costs, but not the costs of bad debts or approved educational activities. (A detailed description of the payment policies, including the transition period methodology, appears in section VI. of this final rule.)

E. Summary of Public Comments Received on the November 3, 2000 Proposed Rule

The November 3, 2000 proposed rule provided for a 60-day comment period ending January 2, 2001. We extended this initial comment period an additional 30 days, until February 1, 2001, through the publication of a notice in the **Federal Register** on December 27, 2000 (65 FR 81813).

We received a total of 399 timely items of correspondence containing multiple comments on the November 3, 2000 proposed rule. Major issues addressed by commenters included the use of the MDS–PAC as the patient assessment instrument; various aspects of the CMG classification system, including the recognition of comorbidities; various aspects of the facility and case level payment adjustments; and the requirements to be classified as an IRF.

Summaries of the public comments received and our responses to those comments are set forth below under the appropriate subject heading.

II. Requirements and Conditions for Payment Under the Prospective Payment System for IRFs

In the November 3, 2000 proposed rule, we proposed the conditions that an IRF must meet to be paid under the IRF prospective payment system (proposed § 412.604). In general, if the conditions are not met, we may reduce or withhold Medicare payments or may classify the IRF as a hospital that is paid under the acute care hospital prospective payment system (proposed § 412.604(a)(2)).

A. Classification Criteria for IRFs

1. Provisions of Proposed Rule

In the November 3, 2000 proposed rule, we stated that we were not proposing to change the existing criteria for a hospital or hospital unit to be classified as a rehabilitation hospital or a rehabilitation unit that is excluded

from the acute care hospital prospective payment systems under sections 1886(d) and 1886(g) of the Act, that are codified in regulations in 42 CFR Part 412. In addition, we indicated that we were not proposing to revise the survey and certification procedures applicable to entities seeking this classification.

Under § 412.604(b), we proposed that, to be classified as a rehabilitation hospital or rehabilitation unit, an IRF must meet the criteria set forth in existing §§ 412.23(b), 412.25, and 412.29 for exclusion from the inpatient hospital prospective payment system. Existing § 412.23(b) provides that a rehabilitation hospital must—

- Have a provider agreement under Part 489 to participate as a hospital;
- Except for a newly participating hospital seeking exclusion for its first 12-month cost reporting period, show that during its most recent 12-month cost reporting periods, it served an inpatient population of whom at least 75 percent required intensive rehabilitation services for one or more of 10 conditions specified in the regulations;
- Have in effect a preadmission screening procedure under which each prospective patient's condition and medical history are reviewed to determine whether the patient is likely to benefit significantly from an intensive inpatient hospital program or assessment;
- Ensure that patients receive close medical supervision and furnish rehabilitative nursing, physical therapy, and occupational therapy, plus, as needed, speech therapy, social or psychological services, and orthotic and prosthetic services, through the use of qualified personnel;
- Have a director of rehabilitation who meets the criteria specified in the regulations;
- Have a plan of treatment for each inpatient that is established, reviewed, and revised as needed by a physician in consultation with other professional personnel who provide services to the patient; and
- Use a coordinated multidisciplinary team approach in the rehabilitation of each inpatient in the manner specified in the regulations.

Existing § 412.25 provides that a rehabilitation unit must—

- Be part of an institution that has in effect an agreement under part 489 of this chapter to participate as a hospital; is not excluded in its entirety from the prospective payment systems; and has enough beds that are not excluded from the prospective payment systems to permit the provision of adequate cost information, as required by § 413.24(c);
- Have written admission criteria that are applied uniformly to both Medicare and non-Medicare patients;
- Have admission and discharge records that are separately identified from those of the hospital in which it is located and are readily available;
- Have policies specifying that necessary clinical information is transferred to the unit when a patient of the hospital is transferred to the unit;
- Meet applicable State licensure laws;
- Have utilization review standards applicable for the type of care offered in the unit;
- Have beds physically separate from (that is, not commingled with) the hospital's other beds;
- Be serviced by the same fiscal intermediary as the hospital;
- Be treated as a separate cost center for cost finding and apportionment purposes;
- Use an accounting system that properly allocates costs;
- Maintain adequate statistical data to support the basis of allocation;
- Report its costs in the hospital's cost report covering the same fiscal period and using the same method of apportionment as the hospital;
- As of the first day of the first cost reporting period for which all other exclusion requirements are met, the unit is fully equipped and staffed and is capable of providing hospital inpatient rehabilitation care regardless of whether there are any inpatients in the unit on that date.

In addition, existing § 412.25 contains requirements on changes in hospital size and existing § 412.29 includes specific requirements for new and converted units (as specified in § 412.30), preadmission screening, staffing, plans of treatment, a coordinated multidisciplinary team approach as documented in clinical records, and administration.

2. Public Comments and Departmental Responses

Comment: Many commenters suggested that we update the 10 conditions specified in § 412.23(b)(2) that are used to determine if at least 75 percent of facility's patients require intensive rehabilitative services. One commenter recommended completely eliminating the ''75 percent'' rule to classify a facility or unit as an IRF because we proposed to use the 21 rehabilitation impairment categories (RICs) as defined in the proposed rule.

Response: Currently, hospitals or hospital units that meet the requirements at existing §§ 412.23(b), 412.25, and 412.29 are eligible to be classified as rehabilitation hospitals or rehabilitation units that are excluded from the acute care inpatient hospital prospective payment systems established under sections 1886(d) and 1886(g) of the Act. Section 1886(j) of the Act was added to implement the prospective payment system described in this final rule for excluded hospitals and hospital units that are classified as rehabilitation hospitals and rehabilitation units. As we noted in the proposed rule, we were not proposing changes to the existing requirements for classification under § 412.23(b)(2). We believe that the existing requirements are appropriate in classifying a hospital or unit as an IRF that is paid under section 1886(j) of the Act. Accordingly, for this final rule, we are not revising the existing requirements at §§ 412.23(b), 412.25, and 412.29. However, as more data, including patient data associated with the RICs, become available after we initially implement the IRF prospective payment system, we may reconsider whether it would be appropriate to revisit the requirement regarding the ''75 percent'' rule in the future.

Comment: Several commenters suggested that we amend § 412.30 to clarify that hospitals seeking to convert skilled nursing facility (SNF) beds to excluded inpatient rehabilitation beds must wait for 12 months before being excluded from the acute care hospital prospective payment system (and be paid under the IRF prospective payment system) just as acute care hospitals must do if they convert medical-surgical beds to excluded inpatient rehabilitation beds.

Response: Currently, the 12-month delay for the conversion of beds under § 412.30 to IRF beds does not apply to SNF beds. For this final rule, as stated in the proposed rule, we are not changing the existing criteria for a hospital or hospital unit to be classified as a rehabilitation hospital or a rehabilitation unit that is excluded from the acute care inpatient hospital prospective payment system. We believe that the existing requirements are appropriate in classifying a hospital unit as an IRF that is paid under section 1886(j) of the Act. In accordance with section 125(b) of the BBRA, we indicated that we will be conducting a study of the impact on utilization and beneficiary access to services of the implementation of the IRF prospective payment system. If this study shows the need to change this requirement to include converted SNF beds, we will propose to do so in the future. Accordingly, we are not making any

changes to the existing § 412.30 as the commenters suggested.

3. Provisions of the Final Rule

Under §§ 412.604(a) and (b) of the final regulations, we are specifying that, for cost reporting periods beginning on or after January 1, 2002, hospitals or hospital units that are classified as rehabilitation hospitals or rehabilitation units will be paid under the IRF prospective payment system (except for IRFs that are paid under the special payment provisions at § 412.22(c) of the regulations) as described below.

• Requirements for IRFs. The IRF prospective payment system will apply to inpatient rehabilitation services furnished by Medicare participating entities that are classified as rehabilitation hospitals or rehabilitation units under §§ 412.23(b), 412.25, and 412.29. In addition, we are adopting as final the proposed technical changes to §§ 412.22, 412.23, 412.25, and 412.29 to reflect the application of the classification criteria to IRFs under the IRF prospective payment system.

• Location of IRFs outside the 50 States. IRFs that meet the requirements of §§ 412.22, 412.23, 412.25, 412.29, and 412.30 that are located in Puerto Rico, Guam, the Virgin Islands, American Samoa, the Northern Mariana Islands, and the District of Columbia will be subject to the IRF prospective payment system.

• Hospitals Not Subject to the IRF Prospective Payment System. The following hospitals are paid under special payment provisions described in § 412.22(c) and, therefore, are *not* subject to the IRF prospective payment system rules:

—Veterans Administration hospitals.

—Hospitals that are reimbursed under State cost control systems approved under 42 CFR Part 403.

—Hospitals that are reimbursed in accordance with demonstration projects authorized under section 402(a) of Public Law 90–248 (42 U.S.C. 1395b–1) or section 222(a) of Public Law 92–603 (42 U.S.C. 1395b–1 (note)).

• Other Technical Changes. In addition to the technical changes to §§ 412.22, 412.23, 412.25, and 412.29 cited above, we are adopting as final the proposed technical changes to §§ 412.1, 412.20, 412.116, 412.130, 413.1, 413.40, and 413.64 to reflect payment for inpatient rehabilitation services furnished by IRFs under the IRF prospective payment system, effective January 1, 2002.

B. Completion of Patient Assessment Instrument

Proposed § 412.604(c) provided that, for each Medicare patient admitted or discharged on or after April 1, 2001, the IRF must complete a patient assessment instrument. In the proposed rule under § 412.606(b), we had proposed the use of the MDS–PAC as the patient assessment instrument. However, as discussed in detail in section IV.D. of this preamble, we are replacing the MDS–PAC with our inpatient rehabilitation facility patient assessment instrument. Under § 412.604(c) of this final rule, we are requiring an IRF to complete our inpatient rehabilitation facility patient assessment instrument for each Medicare Part A fee-for-service patient admitted to or discharged from the IRF on or after January 1, 2002.

C. Limitation on Charges to Beneficiaries

Proposed § 412.604(d) specified that an IRF may not charge a beneficiary for any services for which payment is made by Medicare, even if the facility's costs of furnishing services to that beneficiary are greater than the amount the facility is paid under the IRF prospective payment system. Proposed § 412.604(d) further specified that an IRF receiving a prospective payment for a covered hospital stay (that is, a stay that includes at least one covered day) may charge the Medicare beneficiary or other person only for the applicable deductible and coinsurance amounts under §§ 409.82, 409.83, and 409.87 of the regulations.

We did not receive any comments on proposed § 412.604(d) and are adopting it as final with one modification. In the proposed rule, we inadvertently did not specify that, in addition to the applicable deductible and coinsurance amounts, a facility is limited to its charges to beneficiaries and other individuals on their behalf under existing § 489.20(a) of the regulations.

D. Furnishing of Inpatient Hospital Services Directly or Under Arrangement

Proposed § 412.604(e) specified that an IRF must furnish all necessary covered services to the Medicare beneficiary either directly or under arrangements. The IRF prospective payments are payment in full for all inpatient hospital services, as defined in § 409.10. We proposed that we would not pay any provider or supplier other than the IRF for services furnished to a Medicare beneficiary who is an inpatient of the IRF, except for physicians' services reimbursable under § 405.550(b) and services of an anesthetist employed by a physician reimbursable under § 415.102(a) of the regulations.

We did not receive any comments on proposed § 412.604(e) and are adopting it as final with two conforming changes:

We are revising proposed paragraph (e)(1) to conform it to the provisions of existing § 412.50, which lists the types of services that are not included as inpatient hospital services. Section 412.50 was revised on April 7, 2000 (65 FR 18537). However, we inadvertently did not include the revised list in the proposed rule.

Proposed § 412.622(b) (which we are adopting as final) specifies that payments for approved educational activities, bad debts, and per units for blood clotting factor are separate payments made outside the scope of the full prospective payment to IRFs for inpatient rehabilitation services. We are including in § 412.604(e)(l) a citation to § 412.622(b) to clarify that payment for these three types of services are not included in the full prospective payment for all inpatient IRF services.

E. Reporting and Recordkeeping Requirements

Under proposed § 412.604(f), we specified that all IRFs participating in the IRF prospective payment system must meet the recordkeeping and cost reporting requirements of §§ 413.20 and 413.24 of the regulations.

We did not receive any comments on proposed § 412.604(f) and, therefore, are adopting it as final without modification.

III. Research To Support the Establishment of the IRF Prospective Payment System

A. Overview of Research for the Proposed Rule

In 1995, the Rand Corporation (RAND) began extensive research, sponsored by us, on the development of a per discharge based prospective payment system using a patient classification system known as Functional Independence Measures-Functional Related Groups (FIM-FRGs) using 1994 data. The results of RAND's earliest research were released in September 1997 and are contained in two reports available through the National Technical Information Service (NTIS). The reports are—

• Classification System for Inpatient Rehabilitation Patients—A Review and Proposed Revisions to the Function Independence Measure-Function Related Groups, NTIS order number PB98–105992INZ; and

• Prospective Payment System for Inpatient Rehabilitation, NTIS order number PB98–106024INZ.

These reports can be ordered toll-free by calling the NTIS sales desk at 800–553–6847 or by e-mail at www.orders@ntis.fedworld.gov.

In summarizing these reports, RAND found in the research based on 1994 data that, with limitations, the FIM–FRGs were effective predictors of resource use based on the proxy measurement: length of stay. FRGs based upon FIM motor scores, cognitive scores, and age remained stable over time (prediction remained consistent between 1990 and 1994 data). Researchers at RAND developed, examined, and evaluated a model payment system based upon FIM–FRG classifications that explains approximately 50 percent of patient costs and approximately 60 to 65 percent of costs at the facility level. Based on this earlier analysis, RAND concluded that an IRF prospective payment system using this model is feasible.

In July 1999, we contracted with RAND to update their earlier research. The update included an analysis of FIM data, the FRGs, and the model rehabilitation prospective payment system using more recent data from a greater number of IRFs. The purpose of updating the earlier research was to develop the underlying data necessary to support the Medicare IRF prospective payment system based on case-mix groups for the proposed rule. RAND expanded the scope of their earlier research to include the examination of several payment elements, such as comorbidities, facility-level adjustments, and implementation issues, including evaluation and monitoring.

Specifically, as described in the proposed rule (65 FR 66313), RAND performed the following tasks:

• Constructed a data file, using 1996 and 1997 FIM data from the Uniform Data Set for medical rehabilitation (UDSmr) and the Clinical Outcomes System (COS). Our files and other sources were used to obtain data on Medicare beneficiaries and IRFs for 1996 and 1997.

• Determined that the FIM data from UDSmr and COS data are representative of the Medicare population.

• Identified factors or variables that were used to design the proposed prospective payment system.

• Developed data on the elements of the proposed prospective payment system regarding RICs, the CMGs, relative weights and payment rates for each CMG, facility-level adjustments, and patient-level adjustments.

• Developed data to examine the joint performance of all of the payment system elements by simulating facility payments for our analysis of the impact of implementing the payment system.

• Developed data to assist in identifying specific issues in connection with implementing the payment system.

• Presented options regarding the design and development of a system to monitor the effects of the payment system and other changes in the health care market on IRFs and on other post-acute care providers, including home health agencies and skilled nursing facilities, by measuring factors such as access, utilization, quality, and cost of care.

RAND issued a report on the findings on its analysis of the 1996 and 1997 data in July 2000. We have made the report available on our web site at www.hcfa.gov/medicare/irfpps.htm.

B. Updated Research for the Final Rule

In the November 3, 2000 proposed rule, we indicated we would refine some of the patient CMGs and corresponding weights and rates if further analysis of the data file and consideration of the comments that we received in response to the proposed rule warranted such refinements.

RAND has updated their research, as discussed below, to include patient assessment data and Medicare beneficiary data from more recent years than the data used to develop the provisions of the proposed rule. RAND's analysis of the later data assisted us in developing responses to comments on the proposed rule and identifying aspects of the patient classification and payment systems where refinements were justified or where further research was necessary. We discuss the details of refinements that we believe are necessary in section V. (Case-Mix Group Patient Classification System) and in section VI. (Payment Rates) of this final rule.

1. Sources and Description of More Recent Data

We used 1996 and 1997 Medicare program data and patient assessment data to develop the provisions of the proposed rule. For this final rule, we used 1998 and 1999 Medicare program data and patient assessment data as follows:

• Medicare Program Data—Calendar year 1998 and 1999 Medicare Provider Analysis and Review (MedPAR) files were used in RAND's updated research. The MedPAR file contains the records for all Medicare hospital inpatient discharges (including discharges for rehabilitation facilities). The data in the MedPAR file include patient demographics (age, gender, race, residence zip code), clinical characteristics (diagnoses and procedures), and hospitalization characteristics (admission date, discharge date, days in intensive care wards, charges by department, and payment information).

The Medicare cost report data are contained in the Health Care Provider Cost Report Information System (HCRIS). The cost report files contain information on facility characteristics, utilization data, and cost and charge data by cost center. For RAND's updated research, we obtained the HCRIS data from the most current available cost data for cost reports (FYs 1998, 1997, and/or 1996). Supplementary information to this file includes: (1) The wage data for the area in which an IRF is located; (2) data on teaching hospitals, including the number of residents assigned to rehabilitation units and the distribution of resident time across inpatient and outpatient settings; (3) data on the number of Medicare cases at each IRF that represent Supplemental Security Income (SSI) beneficiaries; and (4) information about payments under the existing reasonable cost payment system.

• Patient Assessment Data—We entered into an agreement with the University at Buffalo Foundation Activities, Inc. to obtain 1998 and 1999 UDSmr patient assessment data. For the proposed rule, we entered into an agreement with Caredata.com, Inc. to retrieve COS patient assessment data. However, as mentioned in the proposed rule, the COS has been discontinued as of July 2000. COS patient assessment data for 1998 and 1999 were available though, for a majority of COS providers that operate under the HealthSouth Corporation. Accordingly, we entered into an agreement with the HealthSouth Corporation to retrieve patient assessment data for 1998 and 1999. Collectively, we will refer to the patient assessment data from the UDSmr (1996 through 1999), the COS (1996 and 1997), and the HealthSouth Corporation (1998 and 1999) as FIM data throughout this final rule.

The FIM data include demographic descriptions of the patient (birth date, gender, zip code, ethnicity, marital status, living setting), clinical descriptions of the patient (condition requiring rehabilitation, ICD–9–CM diagnoses, functional independence measures at admission and discharge) and the hospitalization data (encrypted hospital identifier, admission date,

discharge date, charges, payment source, and an indicator of whether this is the first rehabilitation hospitalization for this condition, a readmission, or a short stay for evaluation).

2. Description of the Methodology Used To Construct the Data File

In the proposed rule (65 FR 66314), we described the methodology that RAND used to construct the data file that formed the basis of the proposed CMG patient classification system and the resulting payment weights, rates, and payment adjustments using 1996 and 1997 data. RAND updated and expanded the data file to include the 1998 and 1999 data as follows:

RAND linked the 1998 and 1999 FIM patient records with patient records on the respective MedPAR files that describe the same discharge. RAND determined the Medicare provider number(s) that correspond to each facility code in the FIM data. Next, RAND matched the FIM patients and MedPAR patients within the paired facilities.

Because of the proprietary and sensitive nature of the FIM patient records, certain data fields that specifically identify the patient and the servicing IRF were encrypted. Therefore, as in RAND's previous research, it was necessary to subject the FIM and MedPAR records to a sophisticated and complex matching probability technique. The result produces the most statistically valid match of patient/facility records and a data file that contains the characteristics of each Medicare beneficiary and his or her servicing IRF.

Because of the complex scope and nature of the matching technique used, we have included in Appendix A of this final rule a technical discussion of each step taken to create the updated data file. The tables contained in Appendix A show the actual effects of applying the matching technique on both the patient and facility records for 1996 through 1999.

3. Representativeness of the Updated Data File

It is extremely important to examine the quality of the resulting match, including the extent to which the linked MedPAR and FIM records are representative of the MedPAR universe. We believe that the updated data file described in Appendix A, contains the best available and most representative data to construct a prospective payment system for all IRFs within the parameters of the statutory requirements. Our analysis of the updated data file allows us to develop the CMG patient classification and payment system, described in sections V. and VI. of this final rule.

C. Research on the Patient Assessment Instrument for the Final Rule

In the proposed rule (65 FR 66315), we set forth the proposed requirements regarding the completion of the MDS–PAC rather than the FIM patient assessment instrument. We stated that we would test further whether the MDS–PAC results in patient classifications that are equivalent to the classifications that occurred with the FIM (that is, the assessment instruments that were used to design the prospective payment system).

We expanded RAND's scope of work under the 1999 contract to include a study of the MDS–PAC and FIM instruments to answer the following questions:

- How accurate is the MDS–PAC for use in classifying cases into CMGs for the proposed IRF prospective payment system?
- How do the validity, reliability, and consistency of the FIM and the MDS–PAC elements compare?
- What are the costs associated with the data collection on the FIM and MDS–PAC instruments?
- Are comorbidities being coded accurately on the FIM and the MDS–PAC instruments?
- Does the additional data in the MDS–PAC provide an opportunity for better groupings in the future?

Work on this project was performed by the Harvard Medical School under the RAND contract. The design and results of this study are discussed in detail in section IV. of this final rule.

D. Analyses to Support Future Adjustments to the IRF Prospective Payment System

The principal goal of the analysis described in section III.B. of this final rule is to determine the extent to which measurable patient characteristics, as reported on a patient assessment instrument, permit classification of patients into identifiable groups that accurately reflect the use of resources in IRFs. The research to date indicates that CMGs are effective predictors of resource use as measured by proxies such as length of stay and cost. The use of these proxies is necessary because data that measure actual nursing and therapy time spent on patient care, and other resource use data, are not available. The collection of data on patient characteristics and patient-specific resource use may enhance our ability to refine the CMGs in a manner that supports our policy objectives for future refinement of the IRF prospective payment system. Accordingly, we have contracted with Aspen Systems Corporation to collect actual resource use data in a sample of IRFs. The data collected by Aspen will be submitted to RAND for analysis to determine if the data can be used to support future refinements to the CMGs.

IV. The IRF Patient Assessment

A. Implementation of a Patient Assessment Instrument

1. Statutory Authority and Proposed Rule

Under section 1886(j)(2)(D) of the Act, ''The Secretary is authorized to require rehabilitation facilities that provide inpatient hospital services to submit such data as the Secretary deems necessary to establish and administer the prospective payment system under this subsection.'' The collection of patient data is indispensable for the successful development and implementation of the IRF prospective payment system. A comprehensive, reliable system for collecting standardized patient assessment data is necessary for: (a) The objective assignment of Medicare beneficiaries to appropriate IRF CMGs; (b) the development of a system to monitor the effects of an IRF prospective payment system on patient care and outcomes; (c) the determination of whether future adjustments to the IRF CMGs are warranted; and (d) the development of an integrated system for post-acute care in the future.

2. Proposed Rule—Patient Assessment Instrument

In the November 3, 2000 proposed rule (65 FR 66315), we proposed to use the MDS–PAC as the standardized patient assessment instrument under the IRF prospective payment system (§§ 412.604(c) and 412.606). We acknowledged that the nature of the patient data we would collect may evolve over time. We stated our belief that the present structure of independent Medicare post-acute benefits, which includes payment systems, coverage requirements, and quality assessment instruments based primarily on site of care, may provide incentives that result in reduced access and choice for beneficiaries and may contribute to inappropriate care. We are continuing to reevaluate the methods we use to pay for the delivery of post-acute services, with the objective of developing an integrated approach. The use of post-acute care patient assessment instruments is one way to operationally advance an integrated

approach. We believe that MedPAC recognized the integrating function that post-acute care patient assessment instruments can play when, in its 1999 Report to Congress, MedPAC recommended that the Secretary collect a core set of patient assessment information across all post-acute care settings (Recommendation 5A).

As we strive to develop an integrated approach to the delivery of post-acute services, we are trying to implement MedPAC's March 2001 Report to Congress recommendation that the Secretary: (1) minimize reporting burden and needless complexity; and (2) assure that only the data necessary for payment and quality monitoring are collected (Recommendation 6B). We believe that the revised IRF patient assessment instrument contained in this final rule meets this MedPAC recommendation.

In the November 3, 2000 proposed rule, we proposed that only the IRF clinicians that we specified assess Medicare patients in IRFs using the MDS–PAC as the patient assessment instrument. We proposed that an IRF clinician assess a Medicare IRF patient on Day 4, Day 11, Day 30, and Day 60 of the patient's IRF stay, and also when the patient was discharged. We proposed that the patient assessment data for each of these assessments would be transmitted to us. In addition, we proposed to impose penalties on the IRF based on late completion of the MDS–PAC and late transmission of the MDS–PAC data.

As discussed in detail in section IV.B. of this preamble, based on the public comments received, we have decided to use a patient assessment instrument that is different from the MDS–PAC and is more similar to the UDSmr patient assessment instrument.

3. Public Comments Received on Proposed Use of MDS–PAC as the Patient Assessment Instrument

In the November 3, 2000 proposed rule, we sought public comment on the use of MDS–PAC as the assessment instrument for the IRF prospective payment system, including: comments and supporting data regarding the additional burden and cost, if any, associated with this instrument; the suitability of the instrument for the rehabilitation setting and as a model for other post-acute care settings; views on whether the instrument has been properly tested and validated for industry-wide use; and the utility and reliability of the quality data items contained in the instrument.

- We received numerous comments regarding our proposal to use the MDS–PAC as the patient assessment instrument. In general, the commenters stated that—
- We should use the UDSmr patient assessment instrument, commonly referred to as the ''FIM,'' instead of the MDS–PAC as the patient assessment instrument for the IRF prospective payment system;
- The MDS–PAC consisted of too many items;
- The reliability and validity of the items associated with monitoring quality of care had not been appropriately demonstrated;
- The FIM is as appropriate as the MDS–PAC to both classify patients into CMGs and monitor quality of care;
- The number of proposed patient assessments was excessive;
- The MDS–PAC item scoring scales for the FIM-like motor and cognitive items would contribute to errors scoring these items;
- The inconsistency of the item assessment time periods would detract from the accuracy of the assessment;
- An IRF's accreditation by JCAHO and CARF would be jeopardized or made unnecessarily burdensome and complicated if an IRF had to use the MDS–PAC;
- Clinicians other than those listed in the proposed rule should be allowed to certify that the assessment instrument had been properly completed;
- The list of the types of clinicians who could complete portions of the assessment should be expanded;
- The penalties associated with late completion or transmission of the MDS–PAC were too harsh;
- The policies for the IRF prospective payment system should only apply to patients admitted to an IRF after the system's implementation date; and
- More specifics regarding the assessment instrument test transmission should be given.

Below we give an overview of the patient assessment policies specified in the proposed rule, followed by a discussion of the public comments received and our response to those comments.

We have by no means abandoned our goal of ultimately establishing a common system to assess patient characteristics and care needs for all post-acute care services and pursing more integrated approaches to their payment and delivery. As we stated earlier, that goal was endorsed by MedPAC in its March 1999 Report to the Congress, in which MedPAC recommended that the Secretary collect a core set of patient assessment information across all post-acute care settings (Recommendation 5A).

In its March 2001 Report to Congress, MedPAC recommends that ''The Secretary should develop for potential implementation a patient classification system that predicts costs within and across post-acute settings'' (Recommendation 6C). We continue to share MedPAC's view of the utility of implementing a common patient assessment data system and a common patient classification system across post-acute settings. The implementation of these common systems would facilitate across post-acute settings consistency of payments, consistency of patient assessment burden, and consistency of quality of care monitoring. We believe that the assessment instrument set forth in this final rule will help achieve these goals.

The patient assessment instrument adopted in this final rule supports both our payment and quality objectives. In addition, we note that section 545 of BIPA requires the Secretary to report to Congress by January 1, 2005, on the development of standard instruments for the assessment of the health and functional status of patients, for items and services offered in all settings and to include in the report a recommendation on the use of such standard instruments for payment purposes. We believe that as a result of the study necessary to develop the report, we will make refinements in the design and application of our IRF patient assessment instrument. The refinements will provide us with even more essential information on which to base policy decisions related to post-acute care and its characteristics, including the quality of care furnished and our payment methods. We note that only Medicare Part A fee-for-service (original Medicare) IRF patients must be assessed by an IRF clinician using the patient assessment instrument.

In the proposed rule, we discussed our premise that the implementation of the per-case prospective payment system based on the ''functional-related group'' methodology requires the use of a standardized data collection instrument that contains the elements required to classify a patient into a distinct CMG. To classify a patient into a distinct CMG, the data collection instrument must first assign the patient into one of the various high level categories that are based principally on ICD–9–CM diagnoses plus some additional patient information. These high level categories are called Rehabilitation Impairment Categories (RICs). After that initial classification step, the level of the patient's impairment, as determined by the patient's motor and cognitive function

scores, and the age of the patient are used to classify a patient into a distinct CMG within the higher level RIC. How a patient's comorbidities may affect a patient's CMG is discussed in section VI. of this preamble. Additional data elements are required to identify the patient and for monitoring the quality of care furnished to patients in IRFs.

In the proposed rule, we indicated that we had explored several available approaches to the collection of the required data elements: These included: (a) The development of a new data collection instrument, the MDS–PAC (as discussed in the proposed rule); (b) the adoption of an instrument closely modeled on the UDSmr and the COS instrument; and (c) the incorporation verbatim into a new instrument (MDS–PAC) of the UDSmr/COS data elements that are relevant to payment. We indicated in the proposed rule that we proposed to use the first option, the MDS–PAC. We are referring readers to the November 3, 2000 proposed rule for a detailed description of the MDS–PAC instrument (65 FR 66304).

Comment: We received many comments stating that the proposed MDS–PAC assessment instrument was too long and too complex. The commenters stated that the length and complexity of the patient assessment instrument create an unreasonable time burden in terms of performing the patient assessment. The unreasonable time burden in turn translated into excessive IRF patient assessment costs. The commenters urged us to use the FIM as the patient assessment instrument.

Response: Our goal was to collect comprehensive patient assessment data, with that data being used to classify patients into payment groups and for quality of care purposes. However, after analysis of the public comments, we have decided to reconsider the number and complexity of patient assessment items and, therefore, are adopting in this final rule the use of a modified version of the UDSmr patient assessment instrument (FIM) as our patient assessment instrument (§§ 412.604(c) and 412.606(b)) rather than the MDS–PAC. We have decreased the number of assessment items and changed some of the FIM items in an effort to make them easier to understand and complete.

We recognized that many rehabilitation hospitals already use the FIM. Another organization known as Caredata.com used to market a patient assessment instrument that is very similar to the UDSmr patient assessment instrument. (We have been notified that, as of July 2000, Caredata.com discontinued the part of its business operations related to patient data analysis and reporting that was similar to the function UDSmr continues to perform for IRFs.) The FIM assessment system has been under development since the mid-1980s. The FIM was developed by researchers who were funded by a consortium of rehabilitation professional associations and the Department of Education at the State University of New York (SUNY) at Buffalo in the 1980s. The FIM is marketed by the UDSmr, maintained by SUNY/Buffalo, and is proprietary. There has been extensive training in and experience with the data elements, particularly the functional components, that enter into the construction of the CMGs. We believe that with a few modifications it can be the basis for a valid and reliable instrument to measure impairments in IRFs. The reliability and validity of using the FIM to assess IRF patients have been documented by a substantial list of publications produced both in the United States and overseas (for example, Sweden and Japan), by the developers of the system and by independent investigators. We also conducted a study of the FIM. We discuss the results of that study concerning the reliability and validity of the patient assessment instrument in section IV.E. of this preamble.

Many rehabilitation providers are clients of UDSmr. Our 1997 data show that approximately 68 percent of Medicare patients had a UDSmr or COS data file, indicating that these patients were assessed with the FIM. (We received comments indicating that currently approximately 85 percent of IRFs use the FIM. UDSmr also indicated that approximately 85 percent of IRFs currently use the FIM.)

The developers of the FIM offer a certification course to train assessors in the use of the instrument. This results in high rates of intrarater and interrater reliability, with Cronbach alpha coefficients of more than 0.9 for both the motor and cognitive subscores. The Cronbach alpha coefficient is a statistical measure of interrater reliability with perfect reliability equal to 1.0. Therefore, a score of 0.9 indicates a very high level of interrater reliability.

The principal objective of the FIM is to assess person-level disability in the inpatient medical rehabilitation setting. FIM data are collected at admission and discharge, and, when possible, 6 months after discharge. The strength of the FIM assessment instrument is that it is a well-evolved and extensively tested approach to the assessment of the critical components of care provided by IRFs and the measurement of patient improvement in functional capacity. The variations among facilities in the difference between the observed and expected improvement in function are used as indicators of the quality and the effectiveness of the facilities. UDSmr analyzes FIM data for providers and generates benchmark data that allow IRFs to compare the outcome of their performance on the functional independence measures relative to other providers participating in the system.

In sections VIII. and IX. of this final rule, we discuss in detail the burden of the use of a modified version of the FIM patient assessment instrument that we will use under the IRF prospective payment system.

Comment: Many commenters stated that the item scoring scales for the FIM-like motor and cognitive items would cause errors in scoring these items, because the scoring scales were different from the FIM motor and cognitive items.

Response: We have incorporated the actual FIM motor and cognitive items into our revised patient assessment instrument. Therefore, the scoring of these items will be exactly as currently done for these FIM items. In addition, in consultation with UDSmr staff, we made the coding of some other items on our patient assessment instrument as similar as possible to how the FIM motor and cognitive items are coded.

Comment: One commenter requested a patient assessment item that would be used to collect speech-language data that are more descriptive of speech-language problems the patient may have.

Response: Our patient assessment instrument is now a slightly modified version of the UDSmr patient assessment instrument. Consequently, we will be using the UDSmr assessment items to assess a patient's communication ability. As we state repeatedly in this preamble, we want to limit the burden on IRFs. Therefore, we are being parsimonious in what items are added to the UDSmr instrument, and are only adding items that clearly increase the capability of our instrument to classify a patient into a CMG or items that clearly collect needed and proven quality of care data. At this time, we do not have data that clearly indicate the value of changing the UDSmr communication assessment category of items.

Comment: Several commenters stated that the inconsistency of assessment time periods for different patient assessment instrument items would detract from the accuracy of the patient assessment. The different item assessment time periods would create confusion about how to perform the

assessment and create an additional assessment burden.

Response: In the proposed rule, we specified that the item we proposed to use to assess ''Indicators of Delirium-Periodic Disordered Thinking/Awareness'' requires an assessment time period that is 7 calendar days in length. We also specified that the items we proposed to use to assess ''Bladder Continence'' and ''Bowel Continence'' each requires an assessment time period that is 7 to 14 calendar days in length. We stated that we would conduct additional testing of the MDS–PAC to determine if the assessment time period for these items should be changed. In addition, we stated that, if the additional testing indicated that the assessment time periods for these items should not be changed, we would make appropriate changes to the patient assessment schedule.

We conducted testing of both the MDS–PAC and the UDSmr patient assessment instrument. Our additional testing confirmed that the assessment time periods for the bowel and bladder items should, in some cases, remain as long as 14 calendar days in length. In addition, we consulted with UDSmr staff regarding the assessment time period for the bladder and bowel items in the FIM, because the algorithms for these items indicate an assessment time period as long as 14 days. UDSmr staff recommended that the assessment time period for the bladder and bowel items remain as long as 14 days.

Our patient assessment instrument is a slightly modified version of the UDSmr patient assessment instrument, and contains all 18 of the UDSmr patient assessment instrument functional independence measures that are used to measure both motor and cognitive functioning. Therefore, in accordance with the public comments that recommended we make the assessment time periods for our patient assessment instrument items consistent, and in recognition of the assessment time periods used for the items in the UDSmr patient assessment instrument, in this final rule we are requiring that the assessment time period for all of our patient assessment instrument items is 3 calendar days, except for some items as discussed below. We are not including in our assessment instrument the MDS–PAC item ''Indicators of Delirium-Periodic Disordered Thinking/Awareness.'' Our additional testing did not confirm that this MDS–PAC item was as valid or reliable as our earlier testing indicated.

In general, the proposed rule specified an admission assessment time period that covers calendar days 1 through 3 of the patient's current IRF hospitalization, and an assessment reference date that is the third day of the admission assessment time period. These 3 calendar days are the days during which the patient's clinical condition would be assessed so that the clinical, as opposed to demographic, data that are required on the patient assessment instrument can be collected. In addition, these 3 calendar days must be days during which the patient was furnished Medicare Part A fee-for-service inpatient rehabilitation services. In this final rule, for the admission assessment, we are retaining the general guideline that the assessment reference date is the third calendar day of the admission assessment time period. However, we believe that it may be necessary to allow additional time to assess certain items in order to most appropriately capture patient information to facilitate the payment and quality of care monitoring objectives of our IRF patient assessment instrument. Our item-by-item guide will provide specific guidelines on the observation period for individual items. We note that the UDSmr coding manual allows for an admission assessment time period for some items that is longer than 3 calendar days.

Specifically, clinical experience may indicate the optimal clinical assessment of the activity covered by an item would be more accurately obtained by using a longer assessment time period. Consequently, for a given patient assessment item, the item-by-item guide may specify an assessment time period that is longer than the general guideline of the first 3 calendar days of the patient's current hospitalization. In that situation, the IRF may use information from a variety of sources to assess the patient's clinical condition for the time period that is prior to the patient's current IRF hospitalization. The other sources could be one or more of the following: (1) The patient's physician; (2) the patient's clinical record if the patient is coming directly from an acute care hospital or a SNF; (3) the medical record maintained by an HHA if the patient was being furnished services by an HHA immediately prior to the IRF hospitalization; (4) information obtained from the patient's family or someone who has personal knowledge of the patient's clinical condition; or (5) information obtained from the patient. For example, in order to perform the optimal clinical assessment for item ''X'', the admission assessment time period may need to be 7 calendar days. Therefore, in this example, the IRF would assess that item using data collected during the first 3 calendar days of the patient's current IRF hospitalization, and for the other 4 calendar days preceding the admission use data gathered from one or more of the specified other sources.

We believe that only one set calendar day should be the assessment reference date. In the example situation above, in order to have only one assessment reference date, the assessment reference date would remain being the third calendar day of the patient's current IRF hospitalization, but the span of calendar days for the admission assessment time period would be 7 calendar days with respect to that item.

The discharge assessment may also have items that require an assessment time period longer than 3 calendar days. If the patient has not been an IRF patient during the time period covered by this longer assessment time period, the IRF may obtain the data for these items using one of more of the sources specified above.

In this final rule, we are adopting the proposed provision that, for the discharge assessment, the assessment reference date is the day that the first of either of the two following events occurs: (1) The patient is discharged from the IRF; or (2) the patient stops being furnished Medicare Part A inpatient rehabilitation services, which includes the situation when a patient dies. In general, we are adopting the proposed rule provision that the assessment time period will be the 3 calendar days immediately prior to the assessment reference date. However, similar to the admission assessment, the assessment time period for some items for the discharge assessment will be different than the 3 calendar days prior to the assessment reference date. In addition, for the discharge assessment, in no case will the discharge assessment time period include a calendar day(s) prior to the admission assessment reference calendar date or the admission assessment reference calendar date itself. For example, a patient admitted on July 1, 2002, will have an admission assessment reference date of July 3, 2002. If that patient is either discharged from the IRF or stops being furnished Medicare Part A inpatient rehabilitation services on July 12, 2002, the discharge assessment reference date is July 12, 2002. In this case, the discharge assessment time period for any of the items will not be the time period prior to or include July 3, 2002. Otherwise, we would be capturing data already recorded on the admission assessment. The goal of the discharge assessment is to obtain motor and cognitive data for the time period between the admission

assessment and the discharge assessment.

In the final rule, for admission assessments, we are adopting the proposed assessment completion date of 1 calendar day after the assessment reference date. For discharge assessments, the completion date is the 5th calendar day in the period beginning with the assessment reference date. Charts 1, 2, and 3 and the accompanying discussion of the charts in section IV.D. of this preamble further illustrate the application of the assessment reference date and other associated patient assessment schedule dates.

Comment: Several commenters stated that they used the FIM to comply with the accreditation process administered by either the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) or the Commission on Accreditation of Rehabilitation Facilities (CARF). These commenters believed that substituting the MDS–PAC for the FIM as the patient assessment instrument would jeopardize their accreditation that was based on use of the FIM. The commenters stated it would be burdensome if they had to use the MDS–PAC and the FIM to satisfy both our requirements and the requirements of JCAHO and CARF.

Response: The patient assessment instrument that we are adopting in this final rule incorporates the majority of the UDSmr patient assessment instrument items. Therefore, we believe that use of our assessment instrument contains the same motor and cognitive items that IRFs need to maintain their JCAHO or CARF accreditation.

Comment: Several commenters stated that our proposed list of clinicians who would be authorized to sign the patient assessment instrument attesting to the completion and accuracy of the data recorded in the assessment instrument was too restrictive. They believed that additional types of clinicians should be authorized. However, the commenters believed that no clinician should have to attest to the accuracy of the data recorded for each item, because it would normally be difficult or impossible for a clinician to verify the accuracy of the data recorded by one or more other clinicians during the time period we proposed to allow for completion of the assessment instrument.

Several commenters stated that the type of clinician who was authorized to complete a portion of our assessment instrument should be expanded to include several other types of clinicians.

Response: In this final rule, we are using a patient assessment instrument that is a modified version of the UDSmr patient assessment instrument. The UDSmr patient assessment instrument does not have an attestation section. Therefore, we are not including the attestation section in our patient assessment instrument in order to increase the similarity between the two assessment instruments. We are revising proposed § 412.606 in these final regulations to remove the attestation provisions.

In addition, because we are using a slightly modified version of the UDSmr patient assessment instrument, we will follow UDSmr's item coding format. The data for the UDSmr patient assessment instrument items can be collected and recorded on the instrument by any clinician trained in how to collect and record the data. Therefore, we have decided to allow any clinician who is employed by the IRF or is a contract clinician of the IRF, and who has been trained in how to perform a patient assessment using our assessment instrument, to perform a patient assessment and record data for any item on the patient assessment instrument. Similar to UDSmr, we believe that any clinician who has been properly trained in collecting the patient assessment data is capable of satisfactorily collecting the data. The IRF will be responsible for ensuring that the data recorded by any clinician of the IRF on the patient assessment instrument are accurate and complete and in accordance with the policies contained in these final regulations (§ 412.606(c)(1) and (2)).

B. The Patient Assessment Process

As discussed in section IV.A. of this preamble, we are requiring that IRFs use our IRF patient assessment instrument to collect data on Medicare patients being furnished care in IRFs. In the proposed rule, we did not state specifically that Medicare Part A fee-for-service patients are the only Medicare patients that must be assessed using the CMS patient assessment instrument. Therefore, in this final rule, for clarity we are stating that Medicare Part A fee-for-service patients are the only Medicare patients that must be assessed using our IRF patient assessment instrument. Our IRF patient assessment instrument consists of nine sections, each to collect different categories of patient information. These categories include identification and demographic information about the patient, medical information, and information related to quality of care and basic patient safety. Appendix B of this final rule contains the CMS IRF patient assessment instrument. However, our IRF patient assessment instrument must be approved by the Office of Management and Budget (OMB) prior to its use. Therefore, we may be required to make changes to the patient assessment instrument while the instrument is undergoing the OMB approval process. After the patient assessment instrument is approved by OMB, we will make it available on the IRF prospective payment system website (www.hcfa.gov/medicare/irfpps.htm). (In the proposed rule, we included an item-by-item guide for the proposed MDS–PAC patient assessment instrument. Because we are changing the patient assessment instrument from the proposed MDS–PAC to a modified version of the UDSmr patient assessment instrument, we will need to develop additional instructions to supplement the UDSmr guide.)

The additional instructions supplementing the UDSmr guide will, in effect, be our draft item-by-itself guide to the IRF patient assessment instrument. Once the IRF patient assessment instrument is approved by OMB, we will submit the draft item-by-item guide to OMB for public review and comment, in compliance with the Paperwork Reduction Act of 1995 (PRA). When we submit the draft item-by-item guide to OMB for public review and comment, we will place it on the IRF prospective payment system website specified above. We anticipate that this draft item-by-item guide will be available for review and comment beginning September 2001. We will be providing appropriate training on the IRF patient assessment instrument and the item-by-item guide, after both the issuance of this final rule and OMB approval of the patient assessment instrument and the item-by-item guide.

IRFs must computerize and electronically report the patient assessment data (§ 412.614). Each year tens of thousands of Medicare patients are treated in IRFs. As discussed in more detail later in section IV.D. of this preamble, each Medicare Part A fee-for-service patients will be assessed two times by an IRF clinician using our inpatient rehabilitation facility patient assessment instrument. Therefore, there will be a large quantity of data collected and submitted to us each year. As a result, it would be unrealistic for us to perform a meaningful analysis of this large amount of data for payment, medical review, and quality monitoring purposes in the absence of the capability to use automated data collection. An analysis of IRF patient assessment data would allow us to use the data in a manner similar to how we use SNF patient assessment data. (See 42 CFR 413.343 and 483.20 and the July

30, 1999 SNF prospective payment system final rule (64 FR 41644).)

One use of SNF patient assessment data is to support quality of care monitoring. The SNF patient assessment data is reliable and effective in supporting early identification of potential quality of care problems. Early identification, in turn, helps to focus the survey process on these identified problem areas.

Using SNF patient assessment data, we have developed indicators of the quality of care in SNFs. These quality of care indicators are used for internal quality improvement and public reporting to help beneficiaries make more informed decisions. The quality of care indicators are also used to support analytical evaluations of the quality of services that SNFs furnish. For example, we use MDS data to provide us with objective and detailed measures of the clinical status and care outcomes of residents in a SNF. In addition, quality of care indicators can be used to analyze the relationship between Medicare policy changes and quality of care.

Computerization of the IRF patient assessment data makes it easier and more practical for an IRF to use the patient assessment data to classify a patient into a CMG. Electronic transmission of the patient assessment data by the IRF makes the creation of an IRF patient assessment database feasible. That database, in turn, permits the data to be accessed easily in various formats for different analytical purposes, which can be used to support the Medicare program's fraud and abuse efforts, for medical review purposes, and for uses similar to how the SNF MDS data are used.

Beginning on January 1, 2002, for Medicare Part A fee-for-service patients, IRFs must collect patient assessment data using the CMS IRF patient assessment instrument as part of the IRF's inpatient assessment process. This data collection requirement applies to Medicare beneficiaries who are already inpatients as of January 1, 2002, as well as beneficiaries admitted as inpatients on or after January 1, 2002 (§ 412.606(b)). In addition, IRFs must use our patient assessment instrument to assess inpatients in accordance with the assessment schedule discussed in section IV.D. of this preamble and specified in § 412.610(c).

The IRFs must encode the patient assessment data by entering the data into a computer software program that we will provide at no charge to IRFs (§ 412.614(a)). The patient assessment data records will be considered ''locked'' when they have passed all of our specified edits and are accepted by the IRF patient assessment database to which the IRF transmitted its records.

IRFs also must maintain all completed Medicare patient assessments that were performed using the CMS IRF patient assessment instrument for the previous 5 years, either in a paper format in the patient's clinical record or in an electronic computer file format that can be easily obtained (§ 412.610(f)). We are imposing this requirement because the assessments may be needed as part of a retrospective review conducted at the IRF for various purposes (for example, as part of the documentation that the IRF used to determine the medical necessity of the Medicare-covered services the IRF furnished). Also, completed patient assessments that are available at the IRF could be beneficial to other entities that appropriately have access to these records (for example, a State or Federal agency conducting an investigation due to a complaint of patient abuse or a suspicion of fraud). In addition, retention of the patient assessment instrument by the IRF will provide a backup to the electronic database.

We will use data from the initial patient assessment to classify patients into a CMG (§ 412.620(a)(3)). The CMG determines the base payment rate that the IRF receives for the Medicare-covered Part A services furnished by the IRF during the Medicare beneficiary's episode of care.

IRFs must complete a successful transmission of test patient assessment data to us by a date that we will specify in program instructions. A successful transmission by the IRFs of test data to us is necessary to determine connectivity with the system and to identify any transmission problems. Our system will transmit a test data feedback report to each IRF indicating that the test data transmission was either completely successful or experienced problems. Problems will be specified in the test data transmission report.

We will provide training and technical support to the IRFs on administering and completing our IRF patient assessment instrument, as well as transmitting the data.

C. Documentation Requirements for the Patient Assessment

The admission patient assessment will be used to classify each Medicare Part A fee-for-service patient into a CMG, and the CMG will be used to determine the IRF payment. While the admission assessment is used to place a patient in a CMG, the discharge assessment is used to determine the relevant weighting factors, if applicable, associated with comorbidities. Section VI. of this preamble discusses comorbidities. One principle governing appropriate Medicare payment and utilization of Medicare inpatient services is that there must be documentation establishing that the inpatient services furnished to a patient meet the requirements set forth in section 1862(a) of the Act (for example, are reasonable and necessary for the diagnosis or treatment of illness or injury) (§ 412.606(a) and (c)).

When the data recorded on the patient assessment instrument accurately reflect the patient's clinical status, they form the basis for documenting that services furnished to the IRF Medicare inpatient are reasonable and necessary. There may be cases in which we raise questions about the accuracy of the recorded patient assessment items and, by extension, the associated medical necessity of the services that the IRF furnished. In these cases, other provider documentation may be examined to verify the information recorded on the patient assessment instrument. Other documentation that will support the accuracy of the recorded data (and the medical necessity for the services furnished to the inpatient) must be recorded in the patient's medical record and could include, but is not limited to: (1) Physician's orders; (2) physician's notes; (3) nursing notes; (4) notes from therapists; (5) diagnostic tests and their results; and (6) other associated information, such as social worker or case manager notes.

A patient's clinical status for a given time period, as indicated by the completed patient assessment instrument, must be verifiable and consistent with the clinical information independently or separately recorded in the patient's clinical record. Otherwise, inaccurately completed patient assessments might be used to classify patients into CMGs that would, in turn, form the basis for Medicare payment for medically inappropriate or unnecessary services.

Facilities must transmit each Medicare inpatient's patient assessments to us, and submit claims for Medicare payment to the fiscal intermediary, in accordance with the Medicare Part A claims processing procedures. Payment to the IRF will be made according to the CMG recorded on the claim sent to the fiscal intermediary.

D. Patient Assessment Schedule and Data Transmission

In the November 3, 2000 proposed rule, we discussed our proposal to implement the patient assessment instrument as part of the IRF prospective payment system. We

included a discussion of the patient assessment schedule; what assessment items would be collected on each assessment; the penalties for late completion of assessments; the computerization of the patient assessment data; the transmission of the patient assessment data, including the late transmission penalty; and the patient assessment instrument computer software that would be required to be used.

1. Assessment Schedule

In the proposed rule, we stated that we were proposing to require that a Medicare patient be assessed at Day 4, Day 11, Day 30, and Day 60 of his or her IRF stay, and also when the patient either is discharged from the IRF or stops receiving Medicare Part A inpatient rehabilitation services (65 FR 66325 and 66326 and proposed § 412.610(c)). Given that the mean length of stay in an IRF is 15.81 days (median length of stay is 14 days), we solicited comments in the November 3, 2000 proposed rule on the benefits of mid-stay assessments, that is, the Day 11, Day 30, and Day 60 assessments. We noted that the IRF stay of a small percentage of patients is over 30 days, and an even smaller percentage of patients stay over 60 days.

In proposed § 412.602, we proposed that an interrupted stay is one in which an IRF patient is discharged from the IRF and returns to the same IRF within 3 consecutive calendar days. In counting the 3 calendar day time period to determine the length of the interruption of the stay, the first day of the start of the interruption of the stay is counted as ''day 1,'' with midnight of that day serving as the end of that calendar day. The 2 calendar days that immediately follow would be days 2 and 3. If the patient returns to the IRF by midnight of the third calendar day, the patient would be determined to have had an interrupted stay of 3 calendar days or less. We are adopting as final the definition of interrupted stay as proposed, with further clarification that an interruption is 3 consecutive calendar days that begins with the day of discharge and ends on midnight of the third day.

We indicated that when a patient has an interrupted stay, the interrupted stay must be documented on the assessment instrument interrupted stay tracking form. The data recorded on the interrupted stay tracking form must be transmitted to our patient data system within 7 calendar days of the date the patient returns to the IRF.

We proposed that when an interruption of a patient's IRF stay occurs, it may affect the assessment reference dates, completion dates, encoding dates, and transmission dates.

Comment: We received numerous comments stating that the proposed number of assessments was excessive and created an undue burden on the IRF. The commenters stated that they believed that assessing patients only upon the patient's admission and discharge to the IRF was sufficient to fulfill our payment classification and quality of care monitoring goals. Some of the commenters emphasized that the UDSmr patient assessment system requires patient assessment only upon the patient's IRF admission and discharge.

Response: As described more fully in the proposed rule, we believe that a patient assessment at one or more points between a patient's admission and discharge would yield valuable quality of care monitoring data. However, after analyzing the public comments that stated that our proposed method was an undue time burden, we are making changes to reduce the burden associated with our proposed assessment schedule. In this final rule, we are requiring the completion of the patient assessment instrument only upon the patient's admission and discharge, for a total of two assessments (§ 412.610(c)).

In addition to requiring the completion of the patient assessment instrument upon only the patient's admission and discharge, in section IV.D.2. of this final rule, we are specifying that patient assessment data for both the admission and discharge assessment are to be transmitted only once and at the same time (§ 412.614(c)). Thus, there will be only one transmission of all of the patient assessment data. To be consistent with the time requirement for transmission of the patient admission and discharge assessment data, we also are requiring that the interruption in stay data be transmitted only at the same time that the admission and discharge assessment data is transmitted (§ 412.618).

We agree with the commenters who stated that, by collecting IRF patient assessment data only upon the patient's admission and discharge (as approximately 85 percent of IRFs that subscribe to the UDSmr patient assessment system currently do), we can achieve our goals of appropriately classifying a patient into a CMG, and at the same time monitor the quality of care furnished to the IRF patient. In our proposed rule, we stated that we believed that in order to monitor the quality of care furnished to a patient, we needed patient data collected between the admission and discharge assessments. However, we agree with the commenters that obtaining data for quality of care monitoring, using the method employed by approximately 85 percent of IRFs that our data indicate subscribe to the UDSmr patient assessment system, will be sufficient to meet our quality of care monitoring goal. We note that the IRF prospective payment system is a discharge-based system that pays based on the entire episode of the IRF stay. That is in contrast to the SNF prospective payment system which, because it is a per-diem based payment system, needs to have more frequent patient assessment data in order to evaluate if the prior per-diem payment rate that was previously determined based on patient assessment data is still appropriate.

Patient Assessment Instrument Dates Associated with the Admission Assessment. The following Charts 1 and 2 and the accompanying discussion illustrate application of the final patient assessment schedule and associated assessment reference date, assessment instrument completion date, assessment instrument encoding date, and assessment instrument transmission date to the admission assessment.

CHART 1.—PATIENT INSTRUMENT ADMISSION ASSESSMENT SCHEDULE AND ASSOCIATED DATES

Assessment type	Hospitalization time period and observation time period	Assessment reference date	Patient assessment instrument must be completed by:	Payment time covered by this assessment:	Patient assessment data must be encoded by:	Patient assessment instrument data must be transmitted by:**
Admission assessment.	First 3 days	Day 3*	Day 4	Entire Medicare Part A stay time period.	Day 10	See ** below for how to calculate this date.

* Except for some items, as discussed previously in section IV.A.3. of this preamble.

** Because all the assessment data for admission and discharge assessments must be transmitted together after the patient is discharged or stops receiving Medicare Part A services, the admission assessment data must be transmitted at the same time the discharge data are transmitted. That transmission date is by the 7th calendar day in the period beginning with the last permitted *discharge* patient assessment instrument ''encoded by'' date.

CHART 2.—EXAMPLE APPLYING THE PATIENT ASSESSMENT INSTRUMENT ADMISSION ASSESSMENT SCHEDULE AND ASSOCIATED DATES

Assessment type	Hospitalization time period and observation time period	Assessment reference date	Patient assessment instrument must be completed by:	Patient assessment instrument data must be encoded by:	Patient assessment instrument data must be transmitted by:**
Admission assessment	First 3 days (Patient admitted on 7/3/02).	* 7/5/02	7/6/02	7/12/02	See ** below for how to calculate this date.

* Except for some items, as discussed previously in section IV.A.3. of this preamble.

** If the patient is discharged on 7/16/02, the last permitted discharge patient assessment instrument encoding date is 7/26/02, and the admission and discharge assessment data must be transmitted by 8/01/02. See Chart 3 that illustrates how to apply the patient assessment instrument discharge dates. Note that the span of time to complete the admission assessment is different from the time to complete the discharge assessment as discussed in this section IV.D. of the preamble.

Each Medicare Part A fee-for-service patient must be assessed by a clinician(s) using our IRF patient assessment instrument to perform a comprehensive assessment according to the schedule specified above. More than one clinician may contribute to the completion of the patient assessment instrument. We believe that the accuracy of the assessment would be enhanced if the data collected for a patient assessment item were collected by a clinician with specialized training and experience in the area of the data being collected. For example, although a registered nurse could fully assess all aspects of a patient and collect all the patient assessment instrument data, a physical therapist or an occupational therapist has the specialized training that may contribute to a more accurate assessment of some neuromuscular items. Our objective is to have data collected that would best reflect the patient's unique circumstances and clinical status during the assessment observation period, considering the accuracy of patient assessment is contingent on the training and experience of the clinician assessor.

In Chart 6.—Critical Patient Assessment Items in section V.D. of this preamble, we specify the patient assessment instrument items that will be used to classify a patient into a specific CMG.

If an interruption of 3 calendar days or less occurred for the admission assessment observation time period (for example, the days specified in the ''Hospitalization Time Period and Observation Time Period'' column in Charts 1 and 2 illustrated previously), the associated assessment reference date, patient assessment instrument completion date, patient assessment instrument encoded by date, and patient assessment instrument transmitted by date for the admission assessment would be shifted forward by the number of days that the patient was not an inpatient of the IRF. We refer to Chart 2 to help guide the reader during our discussion of the shifting forward of dates. With regard to the admission assessment, assume that the patient's stay began with admission to the IRF on July 3, 2002, but was interrupted on July 4, 2002, which would be day 2 of the patient's IRF hospitalization. The patient returned to the same IRF prior to midnight of July 6, 2002, and had an interrupted stay of 3 calendar days. The assessment reference date observation time period for the admission assessment would be shifted to July 6, 7, and 8. (Without the interrupted stay, the admission assessment reference date observation time period would have been July 3, 4, and 5, with the assessment reference date being July 5, 2002.) Because of the interruption in stay, the admission assessment reference date would be reset to July 8, 2002. The admission assessment completion date would be reset to July 9, 2002. The admission assessment ''patient assessment instrument must be encoded by'' date would be reset to July 15, 2002. The admission assessment ''patient assessment instrument must be transmitted by'' date would be reset to a date calculated according to the footnote for the ''patient assessment instrument must be transmitted by'' column in Chart 2.

In the final rule, we are revising proposed § 412.610 to specify under paragraph (c)(1) the admission assessment reference dates and the admission assessment completion dates.

Patient Assessment Instrument Dates Associated with the Discharge Assessment. In this final rule, we are revising proposed § 412.610(c) to specify under paragraph (2) that the assessment reference date for the discharge assessment is the actual day that one of two events occurs first: (1) The day on which the patient is discharged from the IRF; or (2) the day on which the patient ceases to receive Medicare-covered Part A inpatient rehabilitation services. Note that the day the patient ceases to receive Medicare-covered Part A inpatient rehabilitation services includes a situation when a patient dies. The discharge assessment is performed only at the first point in time that either of these events occurs. There may be cases when a patient ceases receiving Medicare Part A inpatient rehabilitation services, but is not discharged from the IRF.

After the assessment reference date for the discharge assessment is determined, the completion date for the discharge assessment must be set. We are revising proposed § 412.610(c) to include under paragraph (2)(i)(B) that the completion date for the discharge assessment is the 5th calendar day that follows the discharge assessment reference date with the discharge assessment reference date itself being counted as the first day of the 5 calendar day time period. To determine the 5th calendar day, the discharge assessment reference date is counted as day 1 of the 5 calendar days. For example, if the assessment reference date is July 16, 2002, the completion date would be July 20, 2002.

We are not using the method used to determine the completion date for the admission assessment to determine the completion date for the discharge assessment.

The reason for using a different method to determine the discharge completion date is because of the

definition of an interrupted stay. Previously, we specified that, after the patient returns to the IRF after an interrupted stay, another admission assessment is not performed, and the CMG into which the patient classified prior to starting the interrupted stay is still in effect. Therefore, in order to ensure that a clinician does not perform a discharge assessment on a patient who meets the criteria of an interrupted stay, it is necessary to make the completion date of the discharge assessment a date that exceeds the interrupted stay defined time period. This safeguard prevents the performance of unnecessary discharge assessments by the IRF.

In addition, any discharge assessment that is transmitted to the CMS patient data system is used by the system to indicate that a patient is no longer hospitalized in the IRF. Therefore, if a discharge assessment that is associated with an interrupted stay is transmitted to our patient data system, it would result in our patient data system rejecting the subsequent true discharge assessment that would be transmitted when the patient is actually discharged or stops being furnished Medicare Part A inpatient rehabilitation services.

We are revising proposed § 412.610 to remove the contents of paragraph (d) that reference penalties for late completions (as discussed in section IV.D.4. of this preamble); to remove from paragraph (e) the provisions on assessment completion dates (which are now under paragraph (c)); and to specify under new paragraph (d) only encoding dates. (As conforming changes, proposed paragraphs (f) and (g) are redesignated as paragraphs (e) and (f), respectively.)

We are providing that the discharge assessment ''must be encoded by date'' is the 7th calendar day in the period beginning with the determined discharge completion date. To determine the 7th calendar day, count the discharge assessment completion date as day 1 of the 7 calendar days. For example, if the discharge assessment completion date is July 20, 2002, the assessment must be encoded by date would be July 26, 2002.

In this final rule, we also are revising proposed § 412.614(c) to specify that the discharge assessment ''must be transmitted by date'' is the 7th calendar day in the period beginning with the discharge assessment ''must be encoded by date''. To determine the 7th calendar day, count the discharge assessment ''must be encoded by date'' as day 1 of the 7 calendar days. For example, if the discharge assessment ''must be encoded by date'' is July 26, 2002, the assessment ''must be transmitted by date'' would be August 1, 2002.

Chart 3 below illustrates the discharge assessment dates discussed above:

CHART 3.—EXAMPLE APPLYING THE PATIENT ASSESSMENT INSTRUMENT DISCHARGE ASSESSMENT DATES

Assessment type	Discharge date *	Assessment reference date	Assessment Instrument must be completed on:	Assessment instrument data must be encoded by:	Assessment instrument data must be transmitted by:
Discharge assessment	* 7/16/02	** 7/16/02	7/20/02	7/26/02	8/01/02

* This is either: (1) The day the patient is discharged from the IRF; or (2) the day the patient ceases receiving Medicare-covered Part A inpatient rehabilitation services.

** Except for some items, as discussed previously in section IV.A.3. of this preamble.

Comment: Some commenters believed that the IRF prospective payment system policies should only apply to patients admitted to an IRF on or after the implementation date of the IRF prospective payment system. They did not believe that the IRF prospective payment system policies should apply to patients who were admitted prior to implementation of IRF prospective payment system, and are still patients on the day the IRF prospective payment system is effective.

Response: Because the IRF prospective payment system is a discharge-based system, payment is made to the IRF based on the entire episode of stay of the patient in the IRF. Therefore, any IRF that discharges any patient after the IRF prospective payment system is implemented must be paid according to the IRF prospective payment system policies. Consequently, we are adopting as final the ''Assessment Rule to Use if Medicare Beneficiaries Are Receiving IRF Services on the Effective Date of the Regulation'' policy (65 FR 66328) we proposed in the proposed rule.

2. Data Items To Be Collected

In the proposed rule, we specified a list of data items that we were proposing to be collected for Day 4, Day 11, Day 30, and Day 60 of an admission and at discharge (65 FR 66328–66330).

Comment: As stated previously, many commenters urged us to use the FIM as the patient assessment instrument. In addition, the commenters urged us to collect the patient assessment data according to the same schedule as the UDSmr uses for the FIM.

Response: In sections IV.A. and B. of this preamble, we state that the patient assessment instrument we are adopting in this final rule is more similar to the UDSmr patient assessment instrument. We also state under this final rule that we are requiring IRFs to collect patient assessment data in a manner similar to how the UDSmr patient assessment data are collected, that is, only upon the admission and discharge of the patient. However, as we specified in the proposed rule (under proposed § 412.610(c)(5)) and as we are adopting in this final rule under § 412.610(c)(2)(ii), if the patient stops receiving Medicare Part A inpatient rehabilitation services before being discharged from the hospital, for purposes of the discharge assessment, the day that the patient stops receiving Medicare Part A services becomes the discharge day. In other words, in this situation the day that the patient stops receiving Medicare Part A services is the day to use as the discharge day. The net effect is that the patient is still only assessed twice during the patient's IRF stay. We note that the IRF is only required to collect patient assessment data on Medicare Part A fee-for-service patients.

The IRF must record the items in the identification information, admission information, and payer information sections of the patient assessment instrument only once on the assessment instrument, and must transmit these items to the CMS patient data system when all of the admission and discharge assessment data are completed. Once entered into the computerized version of the assessment instrument, that data will be retained in the computerized version, negating the need to enter the same information again. Data for the other sections of the patient assessment instrument will be collected only upon the patient's admission or discharge as

appropriate; the patient assessment instrument clearly delineates which items are collected upon admission and which are collected upon discharge.

The proposed rule contained a table entitled ''Table 7C.—MDS–PAC ITEMS REQUIRED BY TYPE OF ASSESSMENT''. That table specified the data items that would be collected during the admission, update, or discharge assessment. Chart 4 below (a replacement for proposed Table 7C) is a category, sub-category, item name, and item number specification of the data items that are to be collected for the admission assessment and the discharge assessment. As would be expected, the data for all of the items will be recorded during the admission assessment, with the logical exception of the items for which data can only be recorded upon the patient's discharge. The ''X'' in the admission or discharge column indicates if that item is collected upon the admission or discharge assessment. Chart 4 takes into account that the admission assessment items associated with the patient assessment instrument categories of data related to patient identification, admission information, payer information, medical information, medical needs, function modifiers, FIM instrument, and quality indicators will be retained in the data fields of the computerized version (software) of the patient assessment instrument. Therefore, there are many data items that are not collected during the discharge assessment, but because the data items are retained in the patient assessment software, will also be transmitted when the discharge assessment items are completed and the entire assessment instrument is transmitted.

CHART 4.—PATIENT ASSESSMENT ITEMS BY TYPE OF ASSESSMENT

Item category, item sub-category, item name, item no.	Admission assessment	Discharge assessment
Identification Information*		
1. Facility Information:		
A. Facility Name	X	
B. Facility Medicare Provider Number	X	
2. Patient Medicare Number	X	
3. Patient Medicaid Number	X	
4. Patient First Name	X	
5. Patient Last Name	X	
6. Birth Date	X	
7. Social Security Number	X	
8. Gender	X	
9. Race/Ethnicity (Check all that apply):		
American Indian or Alaska Native	X	
Asian	X	
Black or African American	X	
Hispanic or Latino	X	
Native Hawaiian or Other Pacific Islander	X	
White	X	
10. Marital Status	X	
11. Zip Code of Patient's Pre-Hospital Residence	X	
Admission Information*		
12. Admission Date	X	
13. Assessment Reference Date	X	
14. Admission Class	X	
15. Admit From	X	
16. Pre-Hospital Living Setting	X	
17. Pre-Hospital Living With	X	
18. Pre-Hospital Vocational Category	X	
19. Pre-Hospital Vocational Effort	X	
Payer Information*		
20. Payment Source:		
A. Primary Source	X	
B. Secondary Source	X	
Medical Information*		
21. Impairment Group	X	X
22. Etiologic Diagnosis:	X	
23. Date of Onset of Etiologic Diagnosis	X	
24. Comorbid Conditions:		
A	X	X
B	X	X
C	X	X
D	X	X
E	X	X
F	X	X
G	X	X
H	X	X
I	X	X
J	X	X
Medical Needs		
25. Is patient comatose at admission?	X	
26 Is patient delirious at admission?	X	
27. Swallowing Status:	X	X
28. Clinical signs of dehydration	X	X
Function Modifiers*		
29. Bladder Level	X	X
30. Bladder Freq.	X	X
31. Bowel Level	X	X
32. Bowel Freq.	X	X
33. Tub Transfer	X	X
34. Shower Transfer	X	X
35. Distance Walked (feet)	X	X
36. Distance Traveled in Wheelchair (feet)	X	X
37. Walk	X	X
38. Wheelchair	X	X
FIM Instrument*		
Self-care:		
A. Eating	X	X
B. Grooming	X	X
C. Bathing	X	X
D. Dressing—Upper	X	X
E. Dressing—Lower	X	X
F. Toileting	X	X
Sphincter Control:		
G. Bladder	X	X
H. Bowel	X	X
Transfers:		
I. Bed, Chair, Wheelchair	X	X
J. Toilet	X	X
K. Tub, Shower	X	X
Locomotion:		
L. Walk/Wheelchair	X	X
M. Stairs	X	X
Communication:		
N. Comprehension	X	X
O. Expression	X	X
Social Cognition:		
P. Social Interaction	X	X
Q. Problem Solving	X	X
R. Memory	X	X
Discharge Information*		
40. Discharge Date		X
41. Patient discharge against medical advice:		X
42. Program Interruptions		X
43. Program Interruption Dates:		
A. 1st Transfer Date		X
B. 1st Return Date		X
C. 2nd Transfer Date		X
D. 2nd Return Date		X
E. 3rd Transfer Date		X
F. 3rd Return Date		X
44A. Discharge to Living Setting:		X
44B. Was patient discharged with Home Health Services?		X
45. Discharge to Living With:		X
46. Diagnosis for Transfer or Death:		X
47. Complications during rehabilitation stay:		
A		X
B		X
C		X
D		X
E		X
F		X

CHART 4.—PATIENT ASSESSMENT ITEMS BY TYPE OF ASSESSMENT—Continued

Item category, item sub-category, item name, item no.	Admission assessment	Discharge assessment
Quality Indicators		
Respiratory Status:		
48. Shortness of breath with exertion	X	X
49. Shortness of breath at rest	X	X
50. Difficulty coughing	X	X
Pain:		
51. Rate the highest level of pain reported by the patient within the assessment period	X	X
Push Scale:		
Pressure Ulcers:		
52A. Highest current pressure ulcer stage	X	X
52B. Number of current pressure ulcers	X	X
52C. Length multiplied by width (open wound surface area)	X	X
52D. Exudate amount	X	X
52E. Tissue type	X	X
52F. Total Push Score	X	X
Safety		
53. Total number of falls during the rehabilitation stay	.....	X
54. Balance problem	X	X

*The FIM data set, measurement scale and impairment codes incorporated or referenced herein are the property of U B Foundation Activities, Inc. © 1993, 2001 U B Foundation Activities, Inc. The FIM mark is owned by UBFA, Inc.

The IRF must collect the patient assessment data upon admission and discharge, but must transmit the patient assessment data only one time to our patient data system. This transmission will contain all the admission data and the discharge data.

In the proposed rule, we named the patient data system to which the IRF would transmit its patient assessment data the ''HCFA MDS–PAC system''. Because we are using a patient assessment instrument that is different from the MDS–PAC, we are renaming the HCFA MDS–PAC system ''the CMS Patient Data System.'' The IRF will still encode the patient data into a computerized version of the patient assessment instrument. Also, the computer program will use the encoded admission assessment data to classify a patient into a CMG.

3. Data Transmission

a. Computerization of Patient Assessment Data

In the proposed rule, we specified that the data for all MDS–PAC specified assessments must be encoded. Encoding the data means entering the data into the IRF's computer using appropriate software, including performing data edits. In § 412.610(e)(3), we proposed that IRFs encode and edit the data for Medicare patients within 7 calendar days of the date that the MDS–PAC is completed. We proposed to specify a maximum of 7 calendar days because we believed that this is a reasonable amount of time for IRFs to complete these tasks (65 FR 66330).

In § 412.610(f) we proposed that the encoded data must accurately reflect the patient's status at the time the data are collected. Because the patient's clinical status may change over time, the data must accurately represent a patient's clinical status as of a particular assessment reference date. Before transmission, the IRF must ensure that the data items on the paper copy match the encoded data that are sent to our patient data system. We also proposed to require that once the clinician(s) complete the assessment using either a paper copy of the instrument or an electronic version, the IRF must ensure that the data encoded into the computer and transmitted to our system accurately reflect the data collected by the clinician.

b. Transmission of Data

The IRF must have a system that supports dial-up communication for the transmission of the patient assessment instrument data to our system. The patient assessment data will be submitted to our system via the Medicare Data Collection Network (MDCN). The MDCN is a secured private network. Specific instructions and telephone numbers will be provided to the IRFs in order for the IRFs to be able to access the MDCN.

We will utilize the most current technology capable of maintaining the security of the patient data (for example, encryption technology) in order to ensure the security of the information transmitted to and from our system. For security purposes, there are two levels of user authentication required. For the first level, to obtain access to the MDCN, the IRF must obtain an individual network-identification code for each person submitting the data to our system. The CMS system administrator or our agents distribute this identification code. Then, to obtain access to our data system, an IRF must also obtain a facility-identification code from our system administrator. The IRF must transmit the patient assessment data via the MDCN secured lines to our data system. At that time, the data will be checked to ensure it complies with our system data formatting specifications.

In § 412.614, we proposed to require that the IRF electronically transmit to our patient data system accurate, complete, and encoded data for each Medicare patient. We also proposed that the data must be transmitted in a format that meets the general requirements specified in § 412.614. We believed that once the patient assessment data are encoded and edited, it is a relatively simple procedure to complete the preparation of the data for transmission to our system. Therefore, we proposed that encoded and edited data that have not previously been transmitted, must be transmitted within 7 calendar days of the day by which the data must be encoded as specified in the assessment schedule and associated dates (Charts 1 and 3 in section IV.D. of this preamble). In addition, we proposed that the data must be transmitted in a manner that meets the locked data criteria specified in the proposed rule. At the end of the transmission file, an entry concerning the number of records being transmitted is required to complete the transmission process.

As specified in section IV.D.2. of this preamble, we are changing the proposed patient assessment schedule so that a patient is now assessed only at admission and upon discharge. As a result of this revision, in this final rule we are revising proposed § 412.614(c) to reflect transmission dates that conform to the schedule admission and discharge assessment and encoding dates.

c. Patient Instrument Computer Software

In the proposed rule under § 412.614(c), we proposed that the IRF encode and transmit the MDS-PAC data using the software available from us or other software that conforms to our standard data specifications, data dictionary, and other data requirements specified by us, and that includes the data items that match the most updated version of the patient assessment instrument. We indicated that our Minimum Data Set for Post-Acute Care Tool (MPACT) software would be able to be used for several purposes, such as to encode data, to maintain IRF and patient-specified information, to create export files to submit data, and to test alternative software. The MPACT software would provide comprehensive on-line help to users in encoding,

editing, and transmitting the data. Additionally, there would be a toll-free hotline to support this software product.

Comment: Several commenters requested more information regarding the IRF patient assessment data test transmission that we will conduct.

Response: Because we were not able to publish a final rule prior to February 1, 2001, we were not able to have IRFs conduct a patient data test transmission during February 2001 as stated in the proposed rule. At this time, we have not finalized when the test transmission time period will occur. We will train the IRFs on the CMS IRF patient assessment instrument and the patient assessment process. During that time, we will provide the IRFs with specifics about the patient data test transmission process.

4. Penalties for Late Assessments

In the proposed rule, we proposed that the assessment is late if the assessment is not in accordance with the assessment reference date specification for the Day 4 assessment and outlined the penalties (65 FR 66330; § 412.614(d)). We stated that, if the IRF transmits the patient assessment data late, the IRF would be paid either a reduced CMG-determined payment or no CMG-determined payment. We proposed that the CMG-determined payment be reduced by 25 percent if the IRF transmitted the patient assessment data 10 or less calendar days late. We also proposed that if the IRF transmitted the patient assessment data more than 10 calendar days late, the IRF receives no payment for the Medicare Part A services the IRF furnished.

Comment: Several commenters stated that the penalties associated with late completion and late transmission of the patient assessment data were too harsh.

Response: In the proposed rule, we proposed a penalty for late completion of the MDS–PAC assessment. As specified in section IV.D.2. of this preamble, we are changing the assessment schedule so that the patient is only assessed upon admission and discharge. In addition, in this final rule, we are specifying that both the admission and discharge patient assessment data must be transmitted together. Because of these changes the focus of our patient assessment data monitoring will be the assessment reference date and the data transmission date, instead of the instrument completion date. In addition, as stated previously, we are deleting the proposed assessment attestation section of the patient assessment instrument. The attestation section was the basis for the completion penalty, because it contained the date on the assessment instrument form that specified when the data for all of the assessment instrument items had been recorded on the patient assessment instrument. Thus, the date on the proposed attestation section was the basis for determining the date when the assessment instrument had been completed. The result of eliminating the proposed attestation section is that the completion date that the IRF would record on the assessment instrument form that indicated when all of the assessment items had been completed is also eliminated. In order to have a completion penalty, there must be a completion date specified on the assessment form. For these reasons the completion penalty is eliminated. However, the IRF must still complete the CMS IRF patient assessment instrument in accordance with the calendar date specifications contained in this final rule.

After analysis of the public comments we received, we have decided to revise the transmission penalty. In the proposed rule, we proposed that ''late transmission'' meant the IRF did not transmit MDS'PAC data in accordance with the transmission timeframes specified in Table 4C of section III. of the proposed rule. The payment penalties we proposed are described above under item 4.

As specified in section IV.D.2. of this preamble, we are changing the patient assessment schedule so that a patient is now assessed only at admission and upon discharge. In addition, we are specifying that for each IRF stay, the patient assessment data will be transmitted only once. Because of the change in the patient assessment schedule, we no longer need the data to be transmitted more frequently. This less frequent assessment of the patient and transmission of the patient assessment data will reduce the time burden associated with the assessment process as requested by many commenters. Because of the changes to the patient assessment schedule, we are revising the specifications of what constitutes a late transmission. In this final rule, ''late transmission'' means the IRF did not transmit the patient assessment data in accordance with the transmission timeframes specified in Charts 1, 2, and 3 of section IV.D. of this final rule. In addition, we are persuaded by the commenters that the transmission penalty as proposed in the proposed rule, and described above under item 4, is too harsh. It is appropriate for the IRF to be paid some amount for the treatment the IRF furnished to the patient. To address the commenters' concern, we are reducing the amount of the penalty so that the IRF is paid some of the CMG associated payment for the patient care the IRF furnished (§ 412.614(d)).

In this final rule under § 412.614(d)(2), we are specifying that if the IRF transmits the patient assessment data more than 10 calendar days late, the IRF will be paid a CMG-determined payment that will be reduced by 25 percent. There will not be any other penalty associated with late transmission.

E. Quality Monitoring

Before we present our specific strategies for quality monitoring in IRFs, we want to discuss our conceptual framework for understanding and advancing quality in the setting of IRFs, as well as other post-acute care settings.

The degree of efficiency of any process that produces a service is measured by the span of time, the amount of resources, and the type of resources consumed to produce the service. The degree of effectiveness of the service is measured by the change that occurs when that service process is applied. The concept ''quality of care'' refers to the relationship between patient treatment (a service) efficiency and the resulting effect of that treatment process. Therefore, to measure the relationship (quality of care), we must collect and quantify both before and after treatment patient assessment data so that the correlation or consequences due to the efficiency (time, amount and type of resources used) and the effectiveness (outcomes) of the patient treatment process can be evaluated.

To help promote efficiency in the rehabilitation treatment process, the IRF prospective payment system methodology uses historical data to determine a payment amount that, given the patient's clinical status, is representative of what we consider to be an appropriate use and mix of available treatment resources. To measure the relationship (that is, the quality of the care furnished) between the IRF treatment process resources used (and paid by Medicare) and the effects of the treatment process, we need to use generally acknowledged measures that indicate the results that are due to the treatment the patient was furnished. At a minimum, these measures must indicate that the patient's health and safety are being fostered. In addition, the measures should reveal changes in the patient's capabilities, with the changes reflecting the impact of the treatment process. The changes can be measured by changes in the patient's functional (motor), cognitive, and emotional status.

The CMS IRF patient assessment instrument can be used to record (code) the patient's diseases and injuries. The patient assessment instrument focuses on generalized changes in a patient's functional, cognitive, and emotional status in response to the treatment furnished, as opposed to focusing on the impact of the application of a specific disease or injury treatment process. We note that we are exploring the potential for developing disease-specific quality of care measures.

When measuring changes in the patient's functional, cognitive, emotional, or lifestyle status, a determination must be made if the changes reflect good or bad patient care. Therefore, the changes must be compared to either a predetermined standard or, because we believe that facility comparison promotes competitiveness which leads to enhanced quality, to similar patients treated in other but similar treatment facilities.

Determining if a predetermined generally accepted standard of good care has been met means that the quality of care indicators must demonstrate that the patient care techniques used promoted a positive change in the patient's health. Examples of such patient care techniques include ensuring that the patient consumes appropriate amounts and types of food and fluid, the prevention of patient injury (for example, falls and pressure ulcers), the prevention of the exacerbation of existing injuries (for example, pressure ulcers), or enhancing the caliber of patient's lifestyle (for example, by preventing or mitigating pain). Therefore, to measure the relationship (quality of the care furnished) between the treatment resources used and resulting patient outcomes, we need to: (1) Be able to compare similar patients in similar facilities; and (2) have the ability to determine if some basic patient care, patient safety, and lifestyle enhancement measures are being implemented during the patient's treatment.

From the above discussion, it is clear that quality of care is complex, sometimes difficult to define, and is multidimensional in nature. One dimension is that the care achieve its intended result, which in the context of the IRF setting is most often to improve the patient's functioning in order to foster more independent living. A second dimension of quality is the prevention of avoidable complications or other adverse events and minimizing the effects of adverse events. A third related dimension is to improve management of the patient's medical impairments, with the goal being to promote ''improved'' health as well as function, or at least to improve the management of the patient's medical conditions. In addition, it is important to use data to identify other sentinel events. Identifying these potentially negative impacts to care allows us to perform root cause analysis and determine solutions to prevent them from reoccurring. Our specific quality monitoring processes should be developed in a way that supports this multidimensional view of quality.

The consequences of detecting possible quality of care problems through IRF data are varied and could include— (a) increasing educational efforts to beneficiaries to help them make better informed selections of providers; and (b) improving the survey and oversight of IRFs and accrediting organizations. An IRF's staff may use quality of care information from our patient assessment instrument for their own quality assurance and, ultimately, quality improvement activities. We also have the potential to develop refinements to the case-mix methodology which provide incentives for improving quality.

As our payment policies continue to evolve, our objective is to move forward with a quality assessment and improvement agenda that is based on standardized data, beneficiaries' clinical characteristics, and patient care outcomes. To achieve that objective, we need to collect common data elements and develop standardized assessment tools that will enable us to focus on beneficiary care needs rather than the characteristics of the provider. We believe that the most important short-term goal of post-acute care quality monitoring is to assess the effects of implementing the changes in the payment system on the quality of care furnished in post-acute care settings.

We are aware of MedPAC's concern that we may have only a limited ability to assess the impact of Medicare payment changes that either have been implemented or will soon be initiated— for example, the IRF prospective payment system. There is a need to enhance our ability to assess this impact in order to improve the policies associated with our Medicare prospective payment systems.

In its March 2000 Report to Congress, MedPAC states that ''Quality monitoring systems could help ensure that payment systems are designed correctly and that providers are responding appropriately to the systems' incentives, and could also be used to accomplish several other important objectives.'' (page 62) MedPAC believes that such information ''could assist in tracking trends over time, or provide an early warning of impending problems in quality'', and further indicated that ''Attaining any of these ends requires routine, systematic measurement of health care quality.'' (page 62) We believe that our current patient assessment instrument is another step in the development of the process for monitoring quality of care in IRFs.

The nonpayment-related items in our instrument are necessary to provide an inventory of patient factors that are necessary to monitor quality and assess risk. These data can be used by facilities to identify patients at risk for adverse outcomes. In addition, our patient assessment instrument data may contribute to development of the patient care plan. Information collected can identify patients at risk for adverse outcomes, such as weight loss, aspiration, or pressure ulcers, and support the monitoring of these patients to prevent outcomes that might negatively impact patients' likelihood of optimal rehabilitation.

We believe that the data collected by our patient assessment instrument can be used to monitor the impact of the IRF prospective payment system upon IRFs and beneficiaries, including beneficiary access to care. Section 125 of the BBRA directs the Secretary to conduct a monitoring study, and to submit a report to the Congress no later than 3 years from the date that the IRF prospective payment is implemented. To both monitor the impact of the IRF prospective payment system on IRFs and beneficiaries, and support this BBRA-mandated report to the Congress, we need a data-driven monitoring system that will give us the capability to acquire objective (as opposed to anecdotal) data for analysis.

The discharge assessment will provide data about a patient's clinical status at discharge and give us the ability to compare a patient's clinical status at discharge with the patient's clinical status at the admission assessment. Comparison of the patient's clinical status at admission and at discharge will give us the data to analyze the relationship between any changes in the patient's clinical status and the quantity and effectiveness of the services the IRF furnished to the patient. That comparison will provide us with data that will indicate the quality of the IRF services furnished, and if an IRF was not furnishing the level of Medicare-covered services the patient needed.

Many studies have examined overall and condition-specific functional gain

from admission to discharge as a measure of the effectiveness of a rehabilitation program. National benchmarks of functional gain have been used by providers to measure their performance relative to other facilities. In addition, some work has also been devoted to understanding providers' efficiency by linking measures of length of stay and functional gain.

The data associated with each patient assessment item will enhance our ability to monitor and, thus, safeguard the quality of care that beneficiaries receive. A quality of care improvement monitoring system that is based on our IRF patient assessment instrument data is consistent with other information-based quality monitoring programs, such as the ORYX process used by the JCAHO.

While only some assessment items will be used to determine the CMG, we believe that the data provided by all assessment items are an essential first step in developing the type of quality monitoring system that both MedPAC and our favor. Possible uses of the data include: (1) strengthening existing quality assurance mechanisms; (2) generating indicators that will allow providers to assess their performance, and to compare it against benchmarks derived from standards of care or the performance of peers; and (3) creating a system that assists beneficiaries in making informed decisions when choosing among providers. In addition, the patient assessment items may be useful in developing core measures that provide meaningful information on patient characteristics and outcomes across post-acute care settings.

1. Monitoring the IRF Prospective Payment System

We are planning a system that can be used to monitor access to rehabilitation facilities as well as to monitor the quality of the care delivered in these facilities. This will be done through the monitoring of payment for the care and the associated cost of the delivered care. Monitoring will include variables such as length of IRF stay, percent of IRF discharges to SNF, long-term care hospital, or intensive outpatient rehabilitation programs, change in motor function between admission and discharge, and the case-mix distribution of the facility. We plan to examine changes within ''market areas'' as well as individual facilities.

In addition, we will be developing a variety of methods for monitoring the impact of the IRF prospective payment system. Monitoring may describe changes in access to rehabilitation, in payments to rehabilitation facilities, in quality of care, and in the cost of rehabilitation care. This monitoring will also help to identify unintended changes in the operations of providers, and help to identify refinements needed in the IRF prospective payment system. In addition, because the IRF prospective payment system may have effects on non-IRF providers, and because changes in the payment systems for other providers may affect IRFs once common core data elements are required across post-acute care providers and linked with other data, the monitoring system could also describe changes in access, utilization, quality, and cost of care in different types of post-acute care sites, including, but not limited to HHAs and SNFs. We could start these activities in approximately 2 years.

2. Quality Indicators

Quality indicators are markers that indicate either the presence or absence of potentially poor facility care practices or outcomes. The development of quality indicators depends on the collection and analysis of sufficient patient assessment data from a representative national sample. We are attempting to design a monitoring system that would not only describe quality indicators, but also show how they can be used together to obtain a clear description of access, outcomes, and cost in IRFs. Quality indicators will be developed around the different dimensions of quality discussed earlier in this section. We believe that quality indicators developed for individual IRFs would help identify the IRFs that require attention because they may be coding incorrectly or providing lower quality care. Analysis of the distribution of hospital indicators within specific classes of hospitals (for example, teaching hospitals and rural hospitals) will help us to evaluate whether facility level adjustments are warranted.

We will decide which quality indicators we will use to evaluate IRF quality of care outcomes based on the results of a contractor's analysis of patient assessment instrument data. Quality indicators are not direct measures of quality but rather point towards potential areas that require further investigation. Quality indicators identify the percent of a patient population with a certain condition and compare this percent to a state level and a national level. If a facility ''flags'' for scoring ''high'' on a particular quality indicator, this does not necessarily mean that the facility has a quality of care problem but simply that further focused review of care practices may be required. Quality indicators have already been developed by the University of Wisconsin for use in SNFs and are being effectively used by State surveyors to target facilities for closer onsite review of care practices as well as by some nursing homes to identify potential problems within their facility.

We have already begun consideration of quality indicators that may be created from IRF patient assessment data to evaluate care delivered in IRFs. However, we note that, due to the quality monitoring developmental process and the time needed to develop quality indicators and benchmarking information, quality monitoring based on the patient assessment instrument will not be implemented for at least 2 years. We agree with MedPAC's view that quality monitoring efforts be closely coordinated across different types of post-acute care providers. We expect to develop measures to be applied across different settings. We anticipate that measures of functional improvement from admission to discharge will be examined. In addition, during calendar year 2001, the infrastructure to collect the data to identify quality indicators for IRFs will be under development. Field validation of these indicators is expected to begin in FY 2003. Once the indicators have been field tested, we can begin to utilize these data to monitor quality. The next step will be validation of the assessment data. Piloting the reporting of data will be ongoing during this time period. ''Tool kits'' will be developed for targeted interventions to address common quality issues in IRFs. Examples of quality indicators currently being considered for IRFs are described below.

a. Functional Independence

The main goal of an IRF is to assist the patient in regaining his or her prior level of functional ability. A measure of the quality of a rehabilitation program is the patient's ability to function independently upon discharge to the community. Using our IRF patient instrument assessment data, we believe it will be possible to measure the percent of all cases discharged to the community who are functionally independent or whose functional status has improved at the time of discharge.

Functional independence on the patient assessment instrument would be measured using the functional modifiers and FIM instrument sections of the instrument. A patient's progress can be evaluated with respect to thresholds or milestones, developed after analysis of data collected during rehabilitation stays rather than based upon theoretical assumptions. The data also will assist in the development of quality indicators to predict the types of patients who have

the best prognosis for improvement in rehabilitation programs. In addition, this information may encourage referrals to IRFs for patients who might otherwise not have been referred. The data derived from functional information may also serve to better match patients with program characteristics to ''fine tune'' the delivery of rehabilitation services.

Additional items on our patient assessment instrument will allow the facility to consider factors that may affect a patient's ability to return to his or her previous level of functional ability or live independently in the community. Indicators based on functional gain will be useful in public reporting to help beneficiaries make more educated decisions about the facility from which they choose to receive care. In addition, PROs may be able to use the data from successful IRFs to identify factors that are better at assisting patients in achieving functional independence and returning to the community. This information can be shared with other IRFs to help improve their success rate as well.

b. Incidence of Pressure Ulcers

Pressure ulcers (also known as decubitus ulcers) are a problem in IRFs as well as in other post-acute care and acute care settings. Pressure ulcers will be documented using the PUSH scale developed by the National Ulcer Advisory Panel. Many facilities are already using this scale and laud its ability to present a true picture of the pressure ulcer status in a facility. In some situations, the patient is admitted with these ulcers. IRFs cannot be held responsible for ulcers that were present upon admission, but if these ulcers increase in size or grade, or if new ulcers develop, this can be an indicator of poor quality of care. Information about pressure ulcers would be collected in the quality indicators section of our patient assessment instrument. Information about bed mobility and transfer ability, bladder incontinence, and nutritional status is useful in identifying patients at high risk for developing new pressure ulcers. A pressure ulcer quality indicator could be used by the facility to institute such measures as staff training or more attention to techniques and equipment intended to prevent the development of pressure ulcers (such as frequent change of position of patients unable to move themselves and use of pressure relieving devices). In addition, quality indicators at the facility and State level can be compared to national averages for a better understanding of a facility's performance relative to its peers. Focused review will help identify which factors are contributing to the higher incidence of pressure ulcers. Analysis of patient assessment data can also be used to identify facilities that are successful in resolving and treating existing pressure ulcers. These facilities may have effective pressure ulcer reduction programs in place that can be shared with other facilities that are experiencing difficulty treating and reducing the incidence of pressure ulcers. Public reporting of the rate of pressure ulcers based on quality indicator information may help consumers make more informed choices when choosing a facility.

c. Falls Prevention

Falls prevention is an important component of a rehabilitation program and is critical to avoiding repeat hospitalizations which, in turn, delay return to independence. Items in our patient assessment instrument such as balance, dizziness, and falls provide critical information regarding fall risk to help facilities identify patients who may be at risk for falls. This indicator may also be used to identify facilities with poorer track records in fall avoidance. Information about falls prevention also provides information so that facilities serving different types of patients can be distinguished. PROs may also use these data to teach facilities how to better identify patients at risk for falls and set up programs to reduce the incidence of falls through such methods as low beds or better monitoring of at-risk patients.

As illustrated by these examples, there are several ways the quality information gathered through our patient assessment instrument may be used. As noted, quality indicator data do not necessarily illustrate that a facility is providing a lower level of care, but this information can be useful in targeting facilities for closer review of their patient care practices and facility layout. Quality indicators can also be used to identify facilities with best practices. Identifying how these facilities maintain a high-quality level of care may provide valuable information to assist facilities.

3. Quality Improvement

Quality assurance involves the establishment of standards and having a system to enforce compliance with these standards. Quality improvement fosters and facilitates continuous enhancement of whatever service or product an organization is engaged in or produces. The JCAHO require facilities to have quality improvement programs. Currently, the Medicare conditions of participation require hospitals to do quality assurance, which we believe can be supported with the information obtained from the IRF patient assessment instrument. The proposed change in these conditions for hospitals would require hospitals, including IRFs, to have quality improvement programs (62 FR 66726, December 19, 1997). Also, we are identifying opportunities in which PROs can use their expertise and skill mix to provide valuable information on quality improvement to post-acute care providers. For example, PROs have been working with SNFs for the past year, and feedback from the SNFs has indicated that the information shared by the PRO in a penalty-free environment has been valuable in helping the SNFs learn how to use the MDS to identify their own opportunities for quality improvement. In addition, many IRFs already have data-based quality improvement systems addressing some aspects of quality. PROs may build on their experience in SNFs and on the experience of IRFs and become a resource on how to use information derived from our patient assessment instrument to identify potential quality concerns. Quality improvement activities may include providing each facility with information derived from its submissions of its patient assessment data for use in self-monitoring, providing facilities with information comparing their performance with that of their peers, and maintaining a clearinghouse of ''best practices'' that can be used by facilities to improve the quality of care they deliver.

IRFs may also use data from our patient assessment instrument to generate quality indicators on their own, and use this information to help them target specific problems within their facility, or identify areas where quality improvement projects may be most effective. IRFs can also use the data from our patient assessment instrument to perform their own monitoring of changes in quality of care within the facility.

Comment: Many commenters questioned the reliability and validity of the patient assessment items that we had proposed to use for quality of care monitoring.

Response: The patient assessment items that we had proposed for monitoring quality of care in IRFs were (1) being used by us to monitor quality of care in other post-acute settings; (2) the items that resulted from our extensive MDS-PAC pilot and field testing; or (3) the result of the consensus of the Technical Expert Panel. However, in accordance with our statement in the proposed rule that we would conduct

further study of the patient assessment instrument, after publishing the proposed rule we conducted additional field testing of all the MDS–PAC items.

In order to reduce the burden imposed by our patient assessment instrument, we have greatly decreased the number of items. The CMS IRF patient assessment instrument is now very similar to the UDSmr patient assessment instrument, because we used the UDSmr patient assessment instrument as the foundation for our assessment instrument. Our data indicate that approximately 85 percent of IRFs currently use the UDSmr patient assessment instrument to assess their patients.

As stated in the proposed rule, an independent panel of technical experts highlighted areas of concern regarding the FIM's accuracy in predicting costs for patient care. Panelists were concerned that the scoring of some items, such as cognitive functioning, gave raters a great deal of discretion in determining what evidence was used in the assessment and how often the behavior had occurred. These technical experts also agreed that a functional status assessment for payment purposes should be based on clinical observation of performance rather than on the rater's assessment of the patient's capacity to perform the task.

In order to address these and other concerns, a special study was completed to assess the validity and reliability of the MDS–PAC and the FIM instruments. This special study was also completed in accordance with our statement in the proposed rule that we would be conducting additional testing of the MDS–PAC and the FIM.

In the proposed rule, we proposed to use the MDS–PAC as the patient assessment instrument for payment purposes. We qualified our proposal by indicating that we were in the process of performing a special study to assess the reliability and validity of both these instruments. We further indicated that the findings of this study would inform our final decisionmaking process regarding the instrument of choice for implementing the inpatient rehabilitation payment system.

Our study was in a sample of facilities that are currently using UDSmr's FIM patient assessment instrument. These facilities completed the UDSmr instrument and the MDS–PAC on the same patient at the same time. We then compared the results of this paired assessment to determine the capability of the MDS–PAC instrument to accurately and consistently assign CMGs and whether the MDS–PAC assigns the same CMGs as the UDSmr instrument would.

The purpose of this study was not only to assess the accuracy of the MDS–PAC for classifying cases into CMGs, but also to determine the time it would take clinicians to administer the FIM and the MDS–PAC, the accuracy of coding of comorbidities, and a comparison of the validity, reliability, and consistency of the FIM and the MDS–PAC. The following summarizes the findings from this study:

- Interrater reliabilities were higher on the FIM than on the MDS–PAC.
- The FIM and MDS–PAC functional and cognitive scores were able to produce the same case-mix groups 53 percent of the time and a comparison of a more FIM-like version of the MDS–PAC and the FIM increased the case-mix group match to 57 percent.
- The study found that payment differences between the two instruments varied by RIC. While overall the payment differences (using the two instruments) were small, 20 percent of the hospitals could see revenue differences of 10 percent or more depending on which instrument was used.
- The administrative burden associated with the MDS–PAC, that is, 120 minutes compared with 23 minutes to complete the FIM, was found to be substantial.

As stated in the proposed rule, if the tests showed that patients are classified differently using the MDS–PAC, we would incorporate the phrasing and definitions of the FIM to replace sections of the MDS–PAC. This would meet our objective to field a more extensive instrument to provide a more complete picture of the condition of the patient and of the care provided in the IRF, while also retaining confidence in the validity of the CMG classification of the patient. Using the phrasing and definitions of many of the UDSmr patient assessment instrument items will minimize the effect on reliability and validity inherent in the design of new data collection instruments. Based upon our study findings, the comments received on the proposed rule, the earlier research and analysis supporting the design of the prospective payment system for inpatient rehabilitation facilities, and after conferring with UDSmr staff, we decided to use a majority of the UDSmr patient assessment instrument items and some other quality of care items to collect the information needed for implementation of the IRF prospective payment system.

Comment: Many commenters indicated that they believed that using only the items on the UDSmr patient assessment instrument could fulfill our goals to classify patients into payment groups and monitor quality of care.

Response: We believe that, in order to adequately monitor quality of care, we need to add quality items to the UDSmr patient assessment instrument. Therefore, we have added to the basic UDSmr patient assessment instrument a few items we believe are critical to monitor quality of care. Also, in response to the recommendations following additional data analysis by our contractor, RAND, and in consultation with and with the agreement of UDSmr, we have added functional independence measure modifiers to our patient assessment instrument. We will use the functional independence measure modifiers, and other items as specified in Chart 7.—Critical Patient Assessment Items in section V.E. of this preamble, to classify patients into CMG payment groups. We also will use the functional independence measure modifiers items and some other items as specified in the ''Critical Items'' chart to monitor quality of care.

We used items similar to MDS–PAC items to modify the UDSmr patient assessment instrument because the MDS–PAC covers several topics, such as nutrition, swallowing, and pain, that are either not included in the FIM or not covered in sufficient detail in the FIM for clinical assessment purposes. Therefore, we decided to retain some of the nonpayment items from the MDS–PAC. The MDS–PAC items that we have chosen to retain in our patient assessment instrument are the items that we believe will yield significant quality of care data and will be used to direct and define development of quality indicators for use in IRFs.

4. Consumer Information

We plan to use the quality information derived from our patient assessment instrument in our public reporting strategy. Our patient assessment data, after appropriate evaluation and validation, can be used to inform consumers about the performance of facilities in their area so that they can make informed decisions when selecting a rehabilitation facility. In addition, information derived from our patient assessment instrument and the comparable information available in SNFs and other settings will help us understand which patients fare better in which types of post-acute care settings, or even within subsets of IRFs, thus informing and shaping future long-term care quality initiatives.

As part of our efforts in designing a monitoring system, in the November 3,

2000 proposed rule we solicited comments on whether we should also collect data related to medications and medication administration.

Comment: One commenter stated that because data related to medications and medication administration will have no bearing on how the CMG is determined, collecting this information would be an unnecessary burden on the IRF.

Response: Considering the consequences of both medication administration errors and the incorrect prescribing of medications, we believe that data on these issues are of benefit in monitoring quality of care. However, these data are contained in the patient's clinical record or in some other documentation maintained about the patient. Therefore, at this time we will not use the IRF patient assessment instrument to collect these data.

F. Training and Technical Support for IRFs

We will provide educational and technical resources to IRFs to support both implementation of the CMS IRF patient assessment instrument and the computerization and transmission of the patient assessment data. We will provide training and technical support on the use of our patient assessment instrument by clinical staff and on the use of software to encode and transmit the patient assessment data.

Although we will be providing both initial and ongoing training and technical support, IRFs will probably find it advantageous to designate a staff member as an IRF trainer, in order to have in-house capability both to train newly hired staff, and to have a designated person who can serve as the in-house resource for other staff.

We will train and support the IRFs in the implementation of the IRF prospective payment system and automation of our patient assessment instrument by—

- Training IRFs on our patient assessment data set;
- Answering questions on the clinical aspects of our patient assessment instrument and providing information to IRFs on the use of the instrument to determine CMGs;
- Providing training to State agency staff in using our patient assessment data for survey activities;
- Training IRFs in interpreting validation reports;
- Providing information relative to hardware and software requirements; and
- Providing support for transmission of test data, supporting callers who request technical assistance, providing passwords to IRFs, and answering questions about the computer edits and reports.

Comment: One commenter stated that having an IRF clinician that we [CMS] have trained to be the trainer of other clinicians at an IRF may lead to incorrect information being disseminated, because the clinician that we have trained might unintentionally distort the information when that clinician trains other clinicians. Other commenters stated that we underestimated the time needed to train clinicians, and the number of clinicians that need to be trained. One commenter indicated that only 5 to 6 hours are needed by UDSmr to train IRF clinicians in how to perform a patient assessment using the UDSmr patient assessment instrument.

Response: We, along with other organizations, have successfully used the ''train the trainer'' technique, in which the person trained then trains others. We acknowledge that there is the possibility that an IRF staff member trained by us might inadvertently train another IRF staff member incorrectly in some aspect of the IRF patient assessment process that is specified in our final rule. However, we note that all IRF staff will have the patient assessment instrument item-by-item guide available to them as a resource in how to perform the patient assessment. In addition, all staff members may refer to this final rule and call our contractors or us if they have questions about the patient assessment process.

We are still in the process of finalizing our plans for training IRFs on the patient assessment process. However, we are aware that UDSmr estimates that it only takes a day to train IRF clinicians in how to perform a patient assessment using the UDSmr patient assessment instrument. We believe that ''a day'' means approximately 8 hours. Our patient assessment instrument is a slightly modified version of the UDSmr patient assessment instrument. Therefore, we believe that our estimate of 16 hours of initial training, in order to train the IRF lead clinician on our patient assessment instrument and assessment process, is a reasonable estimate. We believe that our estimate of 12 hours of initial training to train the nonlead IRF clinicians also is a reasonable estimate. In addition, we believe that 5 hours to initially train clerical personnel is reasonable, because their tasks under the IRF patient assessment process are not as complicated as the tasks that the clinicians must perform. We note that the training hours specified in the rule, both for the initial training and for ongoing training, are estimates, and we will adjust the hours as needed when we finalize our training plans and schedules. In addition, due to the wide variety of the sizes of IRFs, we have no way of knowing how many clinicians are employed by an IRF. Therefore, we could only give estimates of how many clinicians would need to be trained. When we have a final training schedule, we will publish it on our IRF prospective payment system website.

G. Release of Information Collected Using the Patient Assessment Instrument

As in the proposed rule under § 412.616, in this final rule we are providing that the IRF and its agents must ensure the confidentiality of the information collected using the assessment instrument in the same manner as all other information in the medical record, in accordance with the hospital conditions of participation at § 482.24(b)(3). While the conditions of participation include confidentiality requirements that apply broadly to all patient information used and disclosed by the IRF, in this final rule we are establishing additional requirements that apply specifically to data collected using the patient assessment instrument. Specifically, we are establishing a requirement to inform patients of their rights regarding collection of the patient assessment (§ 412.608), as well as requirements governing release of patient-identifiable information to IRF agents (§ 412.616(b)). The facility must ensure that information may be released only to authorized individuals and must ensure that unauthorized individuals cannot gain access to or alter patient records. The original medical record must be released by the facility or its agent only in accordance with Federal or State laws, court orders or subpoenas. In addition, we are providing that an agent acting on behalf of an IRF in accordance with a written contract with that IRF may only use the information for the purposes specified in the contract. We believe that these provisions will ensure that access to patient assessment data (paper copy as well as electronic data) is secured and controlled by the IRF, in accordance with Federal and State laws.

On December 28, 2000, the Department of Health and Human Services published a final rule adopting standards for the privacy of certain individually identifiable health information (65 FR 82462) (Privacy Rule). The Privacy Rule is the second in a series of rules mandated by provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104–191. In part, the Privacy

Rule establishes a new Subpart E under 45 CFR Part 164. Subpart E establishes standards that entities covered by the statute—health plans, health care clearinghouses, and certain health care providers—are required to comply with in order to protect the privacy of certain individually identifiable health information. The standards establish requirements relating to the use and disclosure of protected health information, the rights of individuals with respect to that information, and the procedure for exercising those rights.

On February 26, 2001, the Department published a final rule (66 FR 12434) correcting the effective date of the December 28, 2000 final rule. The new effective date is now April 14, 2001. In accordance with the requirements set forth in the Privacy Rule, we are proceeding with an implementation plan that will result in full compliance with these standards on or before April 14, 2003. This plan includes compliance with the standards as they relate to information collected as part of the IRF patient assessment instrument set forth in this final rule. Accordingly, as we proceed with its compliance efforts associated with the Privacy Rule, we may be making future changes in the regulations adopted in this final rule.

In the proposed rule, we indicated that, as with other regulations that result in the creation of a new system of records, we are in the process of developing a notice describing the new system of records that is unique to MDS-PAC. We have typically issued notices describing new systems of records in conjunction with the issuing of a final rule. The notices, required by the Privacy Act of 1974, describe both the entities to whom identifiable and nonidentifiable data can be routinely disclosed, as well as the safeguards that will protect the privacy and the security of the data. While each system of records notice is unique to the system and the data instrument, readers interested in understanding a recent approach are referred to the notice of the new system of records published June 18, 1999 (64 FR 32992) for the ''Home Health Agency Outcome and Assessment Information Set (OASIS).''

We solicited comments on issues germane to the notice that we would develop for the patient assessment records.

Comment: Several commenters believed that the great number of items in the MDS–PAC are not necessary to determine that a payment is excessive. In the commenters' view, the excessive number of these nonpayment items is both of dubious value in monitoring quality of care and amount to a violation of the patient's privacy.

Response: Our patient assessment instrument is now closely modeled on the UDSmr patient assessment instrument. The items that we have added to the UDSmr instrument either improve the capability of the instrument to determine a patient's CMG or collect quality of care data. We believe that the number of items we have added to the basic UDSmr patient assessment instrument is not excessive, especially considering the vital data these items will yield. The quality of care data items are few, especially when the number of these items are compared to all the nonpayment items in the MDS–PAC. In addition, the quality of care items now in our instrument collect basic data that we have found to be of significant value in monitoring quality of care. Therefore, we are only collecting data needed to appropriately classify a patient into a CMG and data that benefit the patient by helping monitor the quality of the services furnished. We will be publishing a system of records notice in the **Federal Register** that will detail our efforts to safeguard the privacy of the data that we collect using our inpatient rehabilitation facility patient assessment instrument in this final rule.

H. Patient Rights

We are adopting the provision of the proposed rule under § 412.608 that in order to receive payment for the Medicare IRF services furnished, a clinician must inform the Medicare inpatient of the following rights with respect to the assessment prior to performing the assessment. These rights include—

- The right to be informed of the purpose of the patient assessment data collection;

The right to have any patient assessment information that is collected remain confidential and secure;

- 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;
- The right to refuse to answer patient assessment data questions; and
- The right to see, review, and request changes on the patient assessment instrument.

We are requiring the IRF to ensure that a clinician documents in the Medicare patient's clinical record that the patient has been informed of the above patient rights. IRFs should note that the above patient rights are in addition to the patient rights specified under the conditions of participation for hospitals in § 482.13.

Our statements of patient rights with regard to the IRF patient assessment instrument will be available via our Inpatient Rehabilitation Facility Prospective Payment System website. These statements may be revised in accordance with the Office of Management and Budget Paperwork Reduction Act reapproval process. Future revisions to these statements will be available via our Inpatient Rehabilitation Facility Prospective Payment System website, and in other instructional materials that we issue.

Comment: Commenters asked what the IRF should do if the patient refuses to answer questions when the IRF clinician tries to collect patient assessment data, and how this would be indicated on the electronic version of the patient assessment instrument.

Response: In the proposed rule, we proposed that data that are not obtained by direct observation by an IRF clinician of an activity performed by the patient can be obtained from the patient, the patient's clinical record, other patient documents or the patient's family. In addition to the patient's family, we are including in this final rule the provision that the data can be obtained from someone personally knowledgeable about the patient's clinical conditions or capabilities. Data that are obtained from the patient's clinical record, other patient documents, the patient's family, or someone personally knowledgeable about the patient's clinical conditions or capabilities do not have to be specially indicated or annotated on the paper or electronic version of the patient assessment instrument. However, the clinician has the discretion to note in the patient's clinical record that the information recorded for an item was obtained from one of these other sources, and not directly from the patient.

We believe that the data for the items associated with observation by the clinician of a particular activity performed by the patient will always be recorded on the patient assessment instrument, because these items allow for the recording of the data in different ways, including recording that the activity did not occur. We reiterate that, for the patient assessment observational items, the clinician assessor should not require a patient to perform an activity that, in the clinician's professional judgment, is clinically contraindicated or hazardous to the patient.

I. Medical Review Under the IRF Prospective Payment System

Under a discharge-based prospective payment system, IRFs might have financial incentives to miscode information on the patient assessment instrument in order to gain a higher CMG and, therefore, payment (that is, case-mix upcoding for payment). Data analysis may be conducted to identify program payment vulnerabilities or areas of risk, and medical review may be conducted to ensure that appropriate payment is being made for services furnished by IRFs.

V. Case-Mix Group Patient Classification System

A. Background

1. Statutory Authority for the Establishment of a Patient Classification System

Section 1886(j)(2)(A)(i) of the Act, as amended by section 125 of the BBRA, requires the Secretary to establish ''classes of patient discharges of rehabilitation facilities by functional-related groups (each referred to * * * as a 'case mix group'), based on impairment, age, comorbidities, and functional capability of the patient, and such other factors as the Secretary deems appropriate to improve the explanatory power of functional independence measure-function related groups.'' In addition, the Secretary is required to establish a method of classifying specific patients in IRFs within these groups. (These provisions are implemented in § 412.620 of this final rule.)

2. Development of the Proposed Case-Mix Groups

In the November 3, 2000 proposed rule, we proposed a methodology to establish a patient classification system using case-mix groups called CMGs (65 FR 66337). The proposed CMGs are based on the FIM–FRG methodology and reflect refinements to that methodology. In addition, we described in the proposed rule the process to classify a patient into a CMG.

In general, a patient is first placed in a major group called a RIC based on the patient's primary reason for inpatient rehabilitation, such as a stroke or a hip fracture. Next, the patient is placed into a CMG within the RIC, based on the patient's ability to perform specific activities of daily living, and sometimes the patient's cognitive ability and/or age. Other special circumstances, such as the occurrence of very short stays or cases where the patient expired, would be considered in determining the appropriate CMG.

In the proposed rule, we stated that our analysis of 1996 and 1997 FIM and Medicare data validated our proposal to establish 21 RICs and 92 CMGs based on the FIM–FRG methodology. The data also supported the establishment of five additional special CMGs that improved the explanatory power of the FIM–FRGs. That is, we proposed to establish one additional special CMG to account for very short stays and four additional special CMGs to account for cases where the patient expired. In addition, we proposed to pay an additional amount with the presence of at least one relevant comorbidity for certain CMGs.

Comment: Several commenters suggested that we use the term ''FIM–FRGs'' rather than ''CMGs'' to describe the patient classification groupings.

Response: The FIM–FRGs' ability to predict resource use has been improved since their original development with the recognition of comorbidities and other special circumstances. We believe that identifying the groups as CMGs avoids any confusion that the basis of the CMGs is not only the original FIM–FRG methodology, but that it also includes improvements to that methodology. In addition, we believe that the statutory language also recognized that improvements have been made and may be made in the future to the original FIM–FRG methodology by referring to the groups as ''case mix groups.'' Accordingly, the patient classification system that we are implementing under § 412.620(a) of these final regulations will classify patients into case-mix groups called CMGs.

3. Refinements to the Proposed CMGs

We explained in the proposed rule that further analysis of FIM and Medicare data and our review of the comments received may result in refinements to some proposed CMGs. For this final rule, we use the most recent FIM and Medicare data from 1998 and 1999 as described in section III. of this preamble. Developing the CMGs with the 1998 and 1999 data results in 95 CMGs based on the FIM–FRG methodology rather than the 92 CMGs described in the proposed rule. In addition, in the following subsections, we will describe the results of analyzing these later data that validate the use of the same 21 RICs and five special CMGs as proposed.

B. Description of Methodology Used To Develop the CMGs Based on the FIM–FRG Methodology for the Final Rule

1. Rehabilitation Impairment Categories

In the first step to develop the CMGs, the FIM data from 1998 and 1999 were used to group patients into RICs. Specifically, the impairment code from the assessment instrument used by clients of UDSmr and Healthsouth indicates the primary reason for the inpatient rehabilitation admission. This impairment code is used to group the patient into a RIC. Chart 5 below (a replacement for Table 1D in the proposed rule) shows each RIC and its associated impairment code.

The earlier RAND research using 1994 data resulted in 20 RICs. We initially used RAND's statistical analysis of 1997 data which showed that the 1997 data generally performed as well as the 1994 data in predicting resource use in RICs 01 through 20. Based on this analysis, the impairment code 14.9 ''Status post major multiple fractures'' appeared to fit more appropriately into RIC 17. Also, based on the 1997 data, we created a separate RIC for burn cases.

For this final rule, we will continue to use the 21 RICs described in the proposed rule and shown in Chart 5 below.

CHART 5.—REHABILITATION IMPAIRMENT CATEGORIES (RICS) AND ASSOCIATED IMPAIRMENT GROUP CODES

Rehabilitation impairment category	Associated impairment group codes
01 Stroke (Stroke)	01.1 Left body involvement (right brain) 01.2 Right body involvement (left brain) 01.3 Bilateral Involvement 01.4 No Paresis 01.9 Other Stroke
02 Traumatic brain injury (TBI)	02.21 Open Injury 02.22 Closed Injury

CHART 5.—REHABILITATION IMPAIRMENT CATEGORIES (RICS) AND ASSOCIATED IMPAIRMENT GROUP CODES—Continued

Rehabilitation impairment category	Associated impairment group codes
03 Nontraumatic brain injury (NTBI)	02.1 Non-traumatic 02.9 Other Brain
04 Traumatic spinal cord injury (TSCI)	04.210 Paraplegia, Unspecified 04.211 Paraplegia, Incomplete 04.212 Paraplegia, Complete 04.220 Quadriplegia, Unspecified 04.2211 Quadriplegia, Incomplete C1–4 04.2212 Quadriplegia, Incomplete C5–8 04.2221 Quadriplegia, Complete C1–4 04.2222 Quadriplegia, Complete C5–8 04.230 Other traumatic spinal cord dysfunction
05 Nontraumatic spinal cord injury (NTSCI)	04.110 Paraplegia, unspecified 04.111 Paraplegia, incomplete 04.112 Paraplegia, complete 04.120 Quadriplegia, unspecified 04.1211 Quadriplegia, Incomplete C1–4 04.1212 Quadriplegia, Incomplete C5–8 04.1221 Quadriplegia, Complete C1–4 04.1222 Quadriplegia, Complete C5–8 04.130 Other non-traumatic spinal cord dysfunction
06 Neurological (Neuro)	03.1 Multiple Sclerosis 03.2 Parkinsonism 03.3 Polyneuropathy 03.5 Cerebral Palsy 03.8 Neuromuscular Disorders 03.9 Other Neurologic
07 Fracture of LE (FracLE)	08.11 Status post unilateral hip fracture 08.12 Status post bilateral hip fractures 08.2 Status post femur (shaft) fracture 08.3 Status post pelvic fracture
08 Replacement of LE joint (Rep1LE)	08.51 Status post unilateral hip replacement 08.52 Status post bilateral hip replacements 08.61 Status post unilateral knee replacement 08.62 Status post bilateral knee replacements 08.71 Status post knee and hip replacements (same side) 08.72 Status post knee and hip replacements (different sides)
09 Other orthopedic (Ortho)	08.9 Other orthopedic
10 Amputation, lower extremity (AMPLE)	05.3 Unilateral lower extremity above the knee (AK) 05.4 Unilateral lower extremity below the knee (BK) 05.5 Bilateral lower extremity above the knee (AK/AK) 05.6 Bilateral lower extremity above/below the knee (AK/BK) 05.7 Bilateral lower extremity below the knee (BK/BK)
11 Amputation, other (AMP–NLE)	05.1 Unilateral upper extremity above the elbow (AE) 05.2 Unilateral upper extremity below the elbow (BE) 05.9 Other amputation
12 Osteoarthritis (OsteoA)	06.2 Osteoarthritis
13 Rheumatoid, other arthritis (RheumA)	06.1 Rheumatoid Arthritis 06.9 Other arthritis
14 Cardiac (Cardiac)	09 Cardiac
15 Pulmonary (Pulmonary)	10.1 Chronic Obstructive Pulmonary Disease 10.9 Other pulmonary
16 Pain Syndrome (Pain)	07.1 Neck pain 07.2 Back pain 07.3 Extremity pain 07.9 Other pain
17 Major multiple trauma, no brain injury or spinal cord injury (MMT–NBSCI).	08.4 Status post major multiple fractures 14.9 Other multiple trauma
18 Major multiple trauma, with brain or spinal cord injury (MMT–BSCI)	14.1 Brain and spinal cord injury 14.2 Brain and multiple fractures/amputation

CHART 5.—REHABILITATION IMPAIRMENT CATEGORIES (RICS) AND ASSOCIATED IMPAIRMENT GROUP CODES—Continued

Rehabilitation impairment category	Associated impairment group codes
	14.3 Spinal cord and multiple fractures/amputation
19 Guillian Barre (GB)	03.4
20 Miscellaneous (Misc)	12.1 Spina Bifida 12.9 Other congenital 13 Other disabling impairments 15 Developmental disability 16 Debility 17.1 Infection 17.2 Neoplasms 17.31 Nutrition (endocrine/metabolic) with intubation/parenteral nutrition 17.32 Nutrition (endocrine/metabolic) without intubation/parenteral nutrition 17.4 Circulatory disorders 17.51 Respiratory disorders-Ventilator Dependent 17.52 Respiratory disorders-Non-ventilator Dependent 17.6 Terminal care 17.7 Skin disorders 17.8 Medical/Surgical complications 17.9 Other medically complex conditions
21 Burns (Burns)	11 Burns

In the proposed rule, we stated in the footnote to Table 1D that we were analyzing the effect of moving the few cases with an impairment code of 12.1 (Spina Bifida) to one of the other spinal cord RICs (RIC 05 or 04). Based on our analysis of the 1998 and 1999 data, there were a combined total of 45 cases with an impairment code for Spina Bifida for both years. With such a small sample of cases, the results of our analysis of the effects of moving these cases to another RIC were inconclusive. Therefore, in this final rule, we are retaining the 12.1 impairment code in RIC 20 (Miscellaneous). We will continue our analysis of these cases in the future with later data to determine if moving them to another RIC would be appropriate.

2. Functional Status Measures and Age

After using the RIC to define the first split among the inpatient rehabilitation groups, we used functional status measures and age to partition the cases further. For this final rule, we used more recent data (1998 and 1999 Medicare bills with corresponding FIM data) to create the CMGs and more thoroughly examine each item of the motor and cognitive measures. Based on this analysis, we found that we could improve upon the CMGs by making a slight modification to the motor measure. We modify the motor measure by removing the transfer to tub/shower item because we found that an increase in a patient's ability to perform functional tasks with less assistance for this item is associated with an increase in cost, whereas an increase in other functional items decreases costs. We describe below the statistical methodology (Classification and Regression Trees (CART)) that we used to incorporate a patient's functional status measures (modified motor score and cognitive score), and age into the construction of the CMGs in this final rule.

We used the CART methodology to split the rehabilitation cases further within each RIC. In general, CART can be used to identify statistical relationships among data and, using these relationships, construct a predictive model for organizing and separating a large set of data into smaller, similar groups. Further, in constructing the CMGs, we analyzed the extent to which the independent variables (motor score, cognitive score, and age) help predict the value of the dependent variable (the log of the cost per case).

The CART methodology creates the CMGs that classify patients with clinically distinct resource needs into groups. CART is an iterative process that creates initial groups of patients and then searches for ways to split the initial groups to decrease the clinical and cost variances further and to increase the explanatory power of the CMGs. (Further information regarding this methodology can be found in the seminal literature on CART (Classification and Regression Trees, Leo Breiman, Jerome Friedman, Richard Olshen, Charles Stone, Wadsworth Inc., Belmont CA, 1984: pp. 78–80).)

As a result of this analysis, Chart 6 lists 95 CMGs and their respective descriptions, including the motor and cognitive scores and age that will be used to classify discharges into CMGs in the IRF prospective payment system.

Comment: One commenter suggested that spinal cord injury (SCI) patients who are ventilator-dependent should have their own CMG and an associated payment. The commenter stated that, under the proposed CMGs, an SCI ventilator-dependent patient would always result in an outlier payment. The commenter further noted that while there is not a large number of these patients, the outlier payment could result in a large financial loss to providers.

Response: We are not including a separate CMG for ventilator-dependent, spinal cord injury patients in this final rule. We will consider analyzing this group of patients for future refinements. Our current CMGs are based on historical data. In order to develop a separate CMG, we need to have data on a sufficient number of cases to develop coherent groups. As the commenter noted, the data that RAND analyzed did not have a sufficiently large number of these patients. The cost of caring for ventilator-dependent spinal cord injury patients is reflected in the relative weights for the CMGs in which these cases fall. Ventilator-dependent spinal cord injury cases will be classified to comorbidity tier 1. We grouped these types of cases only with other very expensive spinal cord injury patients, and the relative weights set forth in this final rule reflect the average cost for these cases. Therefore, we believe that the standard IRF prospective payment

plus the outlier payment (which addresses the marginal cost of care beyond the applicable threshold) will pay adequately for these cases. It is certainly possible that, for a given case, the total payment for the case might be lower than the cost for the case, but for other cases, the total payment might be higher than costs.

Comment: A few commenters believed that payment for burns was insufficient.

Response: For the proposed rule, we created one case-mix group, CMG 2101, for all burn cases. For CMG 2101, we calculated an average length of stay of 18.5 days and a relative weight of 1.2863 as described in the proposed rule. However, for the CMGs set forth in this final rule, we use the latest available data as described in Appendix A. These data include more burn cases compared to the data used to create the CMGs in the proposed rule. We created two CMGs with the more recent data using the CART methodology described earlier in this preamble. The costs of providing care for patients with the lowest motor scores (those patients needing more assistance with tasks such as transferring, bathing, and dressing) are more on average than the costs for patients with higher motor scores. When we use the most recent data, we find that the CMG for a burn patient with the lower motor score, from 12 to 45 (CMG 2102 with no comorbidities) has an average length of stay of 29 days and a relative weight of 1.8226. The CMG for a burn patient with a higher motor score of 46 to 84 (CMG 2101) who can perform self-care task with less assistance reflects the lower costs of caring for these patients. The average length of stay for patients classified to CMG 2101 with no comorbidities is 16 days and the relative weight is .8387. It is possible that, for a given case, the total payment for a burn case might be lower than the costs for the case, but for other burn cases, the total payment might be higher than costs. For burn cases with extremely high costs, outlier payments may be made as well. Therefore, we believe payment for burn cases will be sufficient.

3. Comorbidities

A comorbidity is considered in the context of the principal diagnosis. That is, a comorbidity is a specific patient condition that is secondary to the patient's principal diagnosis or impairment that is used to place a patient into a RIC. A patient could have more than one comorbidity present during the inpatient rehabilitation stay.

Our analysis found that the presence of a comorbidity could have a major effect on the cost of furnishing inpatient rehabilitation care. For the proposed rule, we found that the effect of comorbidities varied across RICs, significantly increasing the costs of patients in some RICs, while having no effect in others.

We linked frequently occurring comorbidities to impairment categories in order to ensure that all of the chosen comorbidities are not an inherent part of the diagnosis that assigns the patient to the RIC. For example, providing rehabilitation services to a beneficiary with a total hip replacement can become both more complex and more costly if the beneficiary also has pneumonia. In contrast, hemiparesis paralysis of one side of the body would not have an impact on patients in RIC 01, stroke.

In the proposed rule, we found comorbidities to affect cost per case for some of the CMGs, but not all. When comorbidities substantially increased the average cost of the CMG and were determined to be clinically relevant (not inherent in the diagnosis in the RIC), we developed CMG relative weights adjusted for comorbidities (§ 412.620(b)).

In this final rule (as we had proposed in the November 3, 2000 proposed rule), we are specifying that a payment adjustment will be made if one of the comorbidities listed in Appendix C of this final rule is present during the patient's stay.

Comment: We received a number of comments suggesting that we take into account the existence of multiple comorbidities.

Response: We have completed considerable analysis on how to account for the severity of each comorbidity that may be present during an inpatient rehabilitation stay. Further discussion of the results of this analysis appears in section VI. of this final rule.

C. Description of Methodology Used to Develop CMGs for Special Cases for the Final Rule

As we did with the proposed rule, for this final rule, we analyzed the payment-to-cost ratios for special types of cases that were not typical cases to determine if costs could be predicted. (We define typical cases as those that stay more than 3 days, receive a full course of inpatient rehabilitation care, and are discharged to the community.) From this analysis, we believe that IRFs would be paid substantially more for cases in which the patient expires and cases with a length of stay of 3 days or less (not including transfer cases) than for the costs of these cases if facilities received the full CMG payment. To improve the explanatory power of the groups, we added four CMGs to account for cases in which the patient expires and one CMG for all cases that have a length of stay of 3 days or less (not including transfer cases). We explain these five types of special cases in greater detail in section VI. of this final rule.

D. Final Set of CMGs

Chart 6 below shows the final set of 95 CMGs based on the FIM–FRG methodology and 5 special CMGs and their description. In section V.E. of this preamble, we discuss the process of how to classify a patient into a RIC and a CMG.

CHART 6.—DEFINITION OF CASE MIX GROUPS (CMGS)

CMG No.*	CMG description
0101	Stroke with motor score from 69–84 and cognitive score from 23–35.
0102	Stroke with motor score from 59–68 and cognitive score from 23–35.
0103	Stroke with motor score from 59–84 and cognitive score from 5–22.
0104	Stroke with motor score from 53–58.
0105	Stroke with motor score from 47–52.
0106	Stroke with motor score from 42–46.
0107	Stroke with motor score from 39–41.
0108	Stroke with motor score from 34–38 and patient is 83 years old or older.
0109	Stroke with motor score from 34–38 and patient is 82 years old or younger.
0110	Stroke with motor score from 12–33 and patient is 89 years old or older.
0111	Stroke with motor score from 27–33 and patient is between 82 and 88 years old.
0112	Stroke with motor score from 12–26 and patient is between 82 and 88 years old.
0113	Stroke with motor score from 27–33 and patient is 81 years old or younger.
0114	Stroke with motor score from 12–26 and patient is 81 years old or younger.

CHART 6.—DEFINITION OF CASE MIX GROUPS (CMGS)—Continued

CMG No.*	CMG description
0201	Traumatic brain injury with motor score from 52–84 and cognitive score from 24–35.
0202	Traumatic brain injury with motor score from 40–51 and cognitive score from 24–35.
0203	Traumatic brain injury with motor score from 40–84 and cognitive score from 5–23.
0204	Traumatic brain injury with motor score from 30–39.
0205	Traumatic brain injury with motor score from 12–29.
0301	Non-traumatic brain injury with motor score from 51–84.
0302	Non-traumatic brain injury with motor score from 41–50.
0303	Non-traumatic brain injury with motor score from 25–40.
0304	Non-traumatic brain injury with motor score from 12–24.
0401	Traumatic spinal cord injury with motor score from 50–84.
0402	Traumatic spinal cord injury with motor score from 36–49.
0403	Traumatic spinal cord injury with motor score from 19–35.
0404	Traumatic spinal cord injury with motor score from 12–18.
0501	Non-traumatic spinal cord injury with motor score from 51–84 and cognitive score from 30–35.
0502	Non-traumatic spinal cord injury with motor score from 51–84 and cognitive score from 5–29.
0503	Non-traumatic spinal cord injury with motor score from 41–50.
0504	Non-traumatic spinal cord injury with motor score from 34–40.
0505	Non-traumatic spinal cord injury with motor score from 12–33.
0601	Neurological with motor score from 56–84.
0602	Neurological with motor score from 47–55.
0603	Neurological with motor score from 36–46.
0604	Neurological with motor score from 12–35.
0701	Fracture of lower extremity with motor score from 52–84.
0702	Fracture of lower extremity with motor score from 46–51.
0703	Fracture of lower extremity with motor score from 42–45.
0704	Fracture of lower extremity with motor score from 38–41.
0705	Fracture of lower extremity with motor score from 12–37.
0801	Replacement of lower extremity joint with motor score from 58–84.
0802	Replacement of lower extremity joint with motor score from 55–57.
0803	Replacement of lower extremity joint with motor score from 47–54.
0804	Replacement of lower extremity joint with motor score from 12–46 and cognitive score from 32–35.
0805	Replacement of lower extremity joint with motor score from 40–46 and cognitive score from 5–31.
0806	Replacement of lower extremity joint with motor score from 12–39 and cognitive score from 5–31.
0901	Other orthopedic with motor score from 54–84.
0902	Other orthopedic with motor score from 47–53.
0903	Other orthopedic with motor score from 38–46.
0904	Other orthopedic with motor score from 12–37.
1001	Amputation, lower extremity with motor score from 61–84.
1002	Amputation, lower extremity with motor score from 52–60.
1003	Amputation, lower extremity with motor score from 46–51.
1004	Amputation, lower extremity with motor score from 39–45.
1005	Amputation, lower extremity with motor score from 12–38.
1101	Amputation, non-lower extremity with motor score from 52–84.
1102	Amputation, non-lower extremity with motor score from 38–51.
1103	Amputation, non-lower extremity with motor score from 12–37.
1201	Osteoarthritis with motor score from 55–84 and cognitive score from 34–35.
1202	Osteoarthritis with motor score from 55–84 and cognitive score from 5–33.
1203	Osteoarthritis with motor score from 48–54.
1204	Osteoarthritis with motor score from 39–47.
1205	Osteoarthritis with motor score from 12–38.
1301	Rheumatoid, other arthritis with motor score from 54–84.
1302	Rheumatoid, other arthritis with motor score from 47–53.
1303	Rheumatoid, other arthritis with motor score from 36–46.
1304	Rheumatoid, other arthritis with motor score from 12–35.
1401	Cardiac with motor score from 56–84.
1402	Cardiac with motor score from 48–55.
1403	Cardiac with motor score from 38–47.
1404	Cardiac with motor score from 12–37.
1501	Pulmonary with motor score from 61–84.
1502	Pulmonary with motor score from 48–60.
1503	Pulmonary with motor score from 36–47.
1504	Pulmonary with motor score from 12–35.
1601	Pain syndrome with motor score from 45–84.
1602	Pain syndrome with motor score from 12–44.
1701	Major multiple trauma without brain or spinal cord injury with motor score from 46–84.
1702	Major multiple trauma without brain or spinal cord injury with motor score from 33–45.
1703	Major multiple trauma without brain or spinal cord injury with motor score from 12–32.
1801	Major multiple trauma with brain or spinal cord injury with motor score from 45–84 and cognitive score from 33–35.
1802	Major multiple trauma with brain or spinal cord injury with motor score from 45–84 and cognitive score from 5–32.
1803	Major multiple trauma with brain or spinal cord injury with motor score from 26–44.

CHART 6.—DEFINITION OF CASE MIX GROUPS (CMGS)—Continued

CMG No.*	CMG description
1804	Major multiple trauma with brain or spinal cord injury with motor score from 12–25.
1901	Guillian Barre with motor score from 47–84.
1902	Guillian Barre with motor score from 31–46.
1903	Guillian Barre with motor score from 12–30.
2001	Miscellaneous with motor score from 54–84.
2002	Miscellaneous with motor score from 45–53.
2003	Miscellaneous with motor score from 33–44.
2004	Miscellaneous with motor score from 12–32 and patient is 82 years old or older.
2005	Miscellaneous with motor score from 12–32 and patient is 81 years old or younger.
2101	Burns with motor score from 46–84.
2102	Burns with motor score from 12–45.
5001	Short-stay cases, length of stay is 3 days or fewer.
5101	Expired, orthopedic, length of stay is 13 days or fewer.
5102	Expired, orthopedic, length of stay is 14 days or more.
5103	Expired, not orthopedic, length of stay is 15 days or fewer.
5104	Expired, not orthopedic, length of stay is 16 days or more.

* The first two digits of the CMG number from 01 to 21 correspond with a specific RIC number shown on Chart 5.

E. Methodology to Classify Patients Into CMGs

Data from the patient assessment instrument, described in section IV.A. of this preamble and specified in § 412.620(a)(3) of the final regulations, will be used to classify a patient into a RIC and CMG. In Chart 7, we have identified the impairment code needed to classify a patient into a RIC and specific items that must be completed on the instrument in order to classify a patient into a CMG. The items from the instrument will be used to establish a motor score, a cognitive score, and age of the patient that corresponds with a specific CMG description.

CHART 7.—CRITICAL PATIENT ASSESSMENT ITEMS

Item category, item sub-category, item name, item number	Admission assessment	Discharge assessment
Identification Information *		
1. Facility Information:		
A. Facility Name	X	
B. Facility Medicare Provider Number	X	
2. Patient Medicare Number	X	
3. Patient Medicaid Number	X	
4. Patient First Name	X	
5. Patient Last Name	X	
6. Birth Date**	X	
7. Social Security Number	X	
8. Gender	X	
9. Race/Ethnicity (Check all that apply):		
American Indian or Alaska Native	X	
Asian	X	
Black or African American	X	
Hispanic or Latino	X	
Native Hawaiian or Other Pacific Islander	X	
White	X	
10. Marital Status	X	
11. Zip Code of Patient's Pre-Hospital Residence	X	
Admission Information*		
12. Admission Date	X	
13. Assessment Reference Date	X	
14. Admission Class	X	
15. Admit From	X	
16. Pre-Hospital Living Setting	X	
17. Pre-Hospital Living With	X	
18. Pre-Hospital Vocational Category	X	
19. Pre-Hospital Vocational Effort	X	
Payer Information*		
20. Payment Source:		
A. Primary Source	X	
B. Secondary Source	X	
Medical Information*		
21. Impairment Group**	X	X
22. Etiologic Diagnosis	X	
23. Date of Onset of Etiologic Diagnosis	X	
24. Comorbid Conditions:**		
A.	X	X
B.	X	X
C.	X	X
D.	X	X
E.	X	X
F.	X	X
G.	X	X
H.	X	X
I.	X	X
J.	X	X
Medical Needs		
25. Is patient comatose at admission?	X	
26. Is patient delirious at admission?	X	
27. Swallowing Status	X	X
28. Clinical signs of dehydration	X	X
Function Modifiers*		
29. Bladder Level**	X	X
30. Bladder Freq.**	X	X
31. Bowel Level**	X	X
32. Bowel Freq.**	X	X
33. Tub Transfer**	X	X
34. Shower Transfer**	X	X
35. Distance Walked (feet)**	X	X
36. Distance Traveled in Wheelchair (feet)**	X	X
37. Walk**	X	X
38. Wheelchair**	X	X
FIM Instrument*		
Self-Care:		
A. Eating**	X	X
B. Grooming**	X	X
C. Bathing**	X	X
D. Dressing—Upper**	X	X
E. Dressing—Lower**	X	X
F. Toileting**	X	X
Sphincter Control		
G. Bladder**	X	X
H. Bowel**	X	X

CHART 7.—CRITICAL PATIENT ASSESSMENT ITEMS—Continued

Item category, item sub-category, item name, item number	Admission assessment	Discharge assessment
Transfers		
I. Bed, Chair, Wheelchair **	X	X
J. Toilet **	X	X
K. Tub, Shower	X	X
Locomotion		
L. Walk/Wheelchair **	X	X
M. Stairs **	X	X
Communication		
N. Comprehension **	X	X
O. Expression **	X	X
Social Cognition		
P. Social Interaction **	X	X
Q. Problem Solving **	X	X
R. Memory **	X	X
Discharge Information *		
40. Discharge Date		X
41. Patient discharge against medical advice		X
42. Program Interruptions		X
43. Program Interruption Dates:		
A. 1st Transfer Date		X
B. 1st Return Date		X
C. 2nd Transfer Date		X
D. 2nd Return Date		X
E. 3rd Transfer Date		X
F. 3rd Return Date		X
44A. Discharge to Living Setting		X
44B. Was patient discharged with Home Health Services?		X
45. Discharge to Living With		X
46. Diagnosis for Transfer or Death		X
47. Complications during rehabilitation stay: **		
A.		X
B.		X
C.		X
D.		X
E.		X
F.		X
Quality Indicators		
Respiratory Status:		
48. Shortness of breath with exertion	X	X
49. Shortness of breath at rest	X	X
50. Difficulty coughing	X	X

CHART 7.—CRITICAL PATIENT ASSESSMENT ITEMS—Continued

Item category, item sub-category, item name, item number	Admission assessment	Discharge assessment
Pain		
51. Rate the highest level of pain reported by the patient within the assessment period	X	X
Push Scale		
Pressure Ulcers		X
52A. Highest current pressure ulcer stage	X	X
52B. Number of current pressure ulcers	X	X
52C. Length multiplied by width (open wound surface area)	X	X
52D. Exudate amount	X	X
52E. Tissue type	X	X
52F. Total Push Score	X	X
Safety		
53. Total number of falls during the rehabilitation stay		X
54. Balance problem	X	X

* The FIM data set, measurement scale, and impairment codes incorporated or referenced herein are the property of UB Foundation Activities, Inc. "1993, 2001 UB Foundation Activities, Inc. The FIM mark is owned by UBFA, Inc.

** Denotes the items from the patient assessment instrument that must be recorded by item number to classify a patient into a CMG. All other items in this Chart will be used to administer, monitor, and analyze possible refinements to the IRF prospective payment system. The items identified will be further explained and may be refined in the manual associated with our patent assessment instrument.

Case Example

The following is an example of how data from the admission patient assessment will be used to code the functional independence measure items of the IRF patient assessment instrument.

Note: This is a fictitious patient.

Martin P. is an 84-year-old left-handed male who was admitted to an acute care hospital at 11:00 A.M. An initial medical history was obtained from his wife. He is English speaking. Martin is retired and lives with his 72-year-old wife in a townhouse with three levels. He has been an adult-onset diabetic for 10 years, who has been treated with oral medication which provides adequate control of his blood glucose. He has a history of hypertension. He has, nevertheless, been actively traveling with his wife and actively involved with his daughter and her family who live a few blocks away. His wife explained that Martin complained of heaviness in his right arm and an overall tired or weak feeling prior to the onset and asked his wife to call the doctor. When his speech was affected, she called an ambulance.

On admission to the hospital, Martin's speech was garbled, but he was able to follow simple commands. His right arm and leg were weak with diminished sensation.

Diagnosis on admission: Ischemic stroke involving the left middle cerebral artery.

Four days after admission to an acute care hospital, Martin was medically stable. He was alert, cooperative, and had the support of his family. He was transferred to an IRF for intensive inpatient rehabilitation. Functional assessment during the first 3 days after admission to the rehabilitation unit is as follows:

Eating

Martin eats by himself after the helper provides setup assistance, such as opening milk and juice containers and cutting meat.

Grooming

Martin performs grooming activities at the sink. He washes his face, combs his hair, rinses his dentures, and shaves himself after the helper provides setup assistance.

Bathing

Martin washes, rinses, and dries just less than half of his body while sitting on a tub bench. Specifically, he bathes his chest, abdomen, and his left and right thighs. The helper then bathes Martin's arms, lower legs, buttocks, and perineal area.

Dressing—Upper Body

Martin typically wears a sweatshirt to therapy. The helper threads the left and right sleeves of the sweatshirt. Martin pulls the shirt over his head and down over his trunk. Martin performs just over half of the effort.

Dressing—Lower Body

Martin typically wears underwear, sweatpants, antiembolic stockings, and shoes on his lower body. The helper performs most of the lower body dressing tasks, with Martin performing just over one-fourth of the effort.

Toileting

Martin uses a urinal to void and the toilet for bowel movements. The helper manages his clothing before and after using the toilet or urinal. Martin

cleanses himself after voiding and moving his bowels. Martin performs approximately one-third of the toileting effort.

Bladder Management

Martin uses a urinal to void. The helper places the urinal within reach on the bedside table and empties it for Martin. He has had two bladder accidents during the past week.

Bowel Management

Martin has not had any episodes of bowel incontinence. He does not use any assistive devices related to bowel management, but does take a stool softener every day.

Transfers: Bed, Chair, Wheelchair

The helper provides lifting assistance to transfer Martin from the wheelchair to the bed. Although Martin assists during the transfer, he performs less than half of the effort.

Transfers: Toilet

The helper provides lifting assistance to get Martin from a sitting position in the wheelchair to a standing position. Although Martin assists during the transfer, he performs less than half of the effort.

Locomotion: Walk/Wheelchair

The therapist expects Martin to be ambulating at discharge. At admission, Martin travels in the wheelchair over 150 feet requiring supervision and cueing only. He walks only 15 feet at a time in therapy with one person assisting. Note: Since patient is expected to walk at discharge, record walking score.

Locomotion: Stairs

Martin has not attempted going up or down stairs.

Comprehension

Martin understands directions and questions about his daily activities. Martin indicates food and beverages preferences when someone reads the hospital menu. He does not understand more abstract information such as humor or discharge planning. Overall, Martin understands just over 90 percent of the basic information presented to him.

Expression

During the day, Martin expresses basic daily information such as asking for pain medication and food preferences. His speech is slurred, but understandable. He does not express more complex information.

Social Interaction

Martin interacts appropriately with the hospital staff, other patients and family members.

Problem Solving

Martin recognizes and solves basic problems as he performs his daily activities such as asking for help as he tries to thread his shirt without success, and asking for assistance to wash his lower body. He has more trouble with unfamiliar tasks. For example, he is unable to solve more complex problems such as managing his medications.

Memory

Martin recognizes people frequently encountered, and remembers his daily therapy schedule and directions in most situations. He has difficulty remembering under stressful situations, and requires prompting less than 10 percent of the time.

In order to classify a patient into a CMG, the IRF will use the IRF patient assessment instrument admission assessment data to score a patient's functional independence measures that consist of what are termed ''motor'' items and the ''cognitive'' items. In addition to the functional independence measures, the patient's age will also influence the CMG into which the patient is classified. The motor items are generally indications of the patient's physical functioning level. The cognitive items are generally indications of the patient's mental functioning level, and are related to the patient's ability to process and respond to empirical factual information, use judgment, and accurately perceive what is happening. The motor items are eating, grooming, bathing, dressing upper body, dressing lower body, toileting, bladder management, bowel management, transfer to bed/chair/wheelchair, transfer to toilet, walking or wheelchair use, and stair climbing. The cognitive items are comprehension, expression, social interaction, problem solving, and memory. (The CMS IRF patient assessment instrument manual will include more information on these items.) Each item is generally recorded on our patient assessment instrument and scored on a scale of 1 to 7, with a 7 indicating complete independence in this area of functioning, and a 1 indicating that a patient is very impaired in this area of functioning.

Under the current instructions for completing the FIM instrument, a 1 is recorded if an activity did not occur indicating that the patient needs total assistance to perform the activity. For our patient assessment instrument, an 8 will be recorded to indicate that the activity did not occur. This will enable us to distinguish between patients who needed total assistance from patients who did not perform an activity. However, for the purpose of classifying a patient into a CMG, a recorded score of 8 will be recoded as a 1. This scoring methodology will then be consistent with the scoring methodology for the FIM data used to construct the CMGs in this final rule. The methodology to determine the score will be further explained in the manual associated with our patient assessment instrument.

The coding of this patient's functional independence measures on the IRF patient assessment instrument is reflected in the chart below:

Item	Rating	Rationale *
Eating	5	The helper provides assistance such as opening containers—Setup.
Grooming	5	The helper provides setup assistance—Setup.
Bathing	2	Martin washes less than half of his body—Maximal Assistance.
Dressing-Upper Body.	3	The helper threads both sweatshirt sleeves. Martin threads his neck through the sweatshirt and pulls the sweatshirt over his trunk—Moderate Assistance.
Dressing-Lower Body.	2	Martin performs just over one-fourth of the effort—Total Assistance.
Toileting	2	Martin does his own perineal hygiene. The helper manages Martin's clothing before and after toilet/urinal use—Maximal Assistance.

Item	Rating	Rationale*
Bladder Management.	3	Martin has had two bladder accidents (wetting linen/clothing) during the past week (level 3). The helper provides setup assistance for bladder management. Record the lower rating—Moderate Assistance.
Bowel Management.	6	Martin is not incontinent of stool (level 7) and does not use any assistive devices. He takes a stool softener (medication—level 6)—Record the lower rating—Modified Independence.
Transfer: Bed, Chair, Wheelchair.	2	Martin performs between 25 and 49 percent of the effort—Maximal Assistance.
Transfer: Toilet ..	2	Martin performs between 25 and 49 percent of the effort—Maximal Assistance.
Walk/Wheelchair	1	Martin travels in a wheelchair more than 150 feet with supervision (level 5), but is expected to walk by discharge. Record the rating based on Martin's walking: Level 1—Total Assistance.
Stairs	1	Martin has not attempted stairs. Activity Did Not Occur—Code 8 on form, and recode to 1 for CMG assignment.
Comprehension	5	Martin understands over 90 percent of the basic information presented to him, but not complex information—Standby Prompting.
Expression	5	Martin expresses basic information, not complex information—Standby Prompting.
Social Interaction	7	Martin interacts appropriately with the staff—Complete Independence.
Problem Solving	5	Martin recognizes and solves routine problems only (not complex)—Supervision
Memory	5	Martin remembers more than 90 percent of the time. He only has difficulty during stressful situations—Supervision.

*The use of the rationale and the methodology to determine the rating (score) will be further explained in the manual associated with the patient assessment instrument.

The patient's motor score (the sum of the scores for eating; grooming; bathing; dressing; toileting; bladder and bowel management; transfer: bed, chair, wheelchair; transfer: toilet; locomotion: walk/wheelchair; and locomotion: stairs) equals 34. The patient's cognitive score (the sum of comprehension; expression; social interaction; problemsolving; and memory) equals 27. Based on this patient's reason for rehabilitation (ICD–9 coding: Cerebral artery occlusion—434.91, hemiplegia—342.9, aphasia—784.3), he is first classified into RIC 01 for stroke. He is then classified into CMG 0108 because his motor score is between 34–38 and he is more than 83 years old. (The cognitive score does not affect this CMG assignment.)

F. Adjustment to the CMGs

In accordance with § 412.620(c) of the final regulations and section 1886(j)(2)(C)(i) of the Act, we adjust the CMGs periodically to reflect changes in treatment patterns, technology, number of discharges, and other factors affecting the relative use of resources. 191

VI. Payment Rates

The IRF prospective payment system in this final rule utilizes Federal prospective payment rates across 100 distinct CMGs. The Federal payment rates are established using a standard payment amount (referred to as the budget neutral conversion factor). A set of relative payment weights that account for the relative difference in resource use across the CMGs is applied to the budget neutral conversion factor and, finally, a number of facility-level and case-level adjustments may apply. The facility-level adjustments include those that account for geographic variation in wages (wage index), disproportionate share hospital (DSH) percentages, and location in a rural area. Case-level adjustments include those that apply for interrupted stays, transfer cases, short-stays, cases in which patients expire, and outlier cases, as described later in this section.

The budget neutral conversion factor provides the basis for determining the CMG-based Federal payment rates. It is a standardized payment amount that is based on average costs from a base period and also reflects the combined aggregate effects of the payment weights, various facility-level and case-level adjustments, and other policies discussed in this section. Consequently, in discussing the methodology for development of the Federal payment rates, we begin by describing the various adjustments and factors that serve as the inputs used in establishing the budget neutral conversion factor.

We developed prospective payments for IRFs using the following major steps:

- Develop the CMG relative weights.
- Determine the payment adjustments.
- Calculate the budget neutral conversion factor.
- Calculate the Federal CMG prospective payments.

A description of each step and a discussion of our final policies follow.

A. Development of CMG Relative Weights

Section 1886(j)(2)(B) of the Act requires that an appropriate relative weight be assigned to each CMG. Relative weights are a primary element of a case-mix adjusted prospective payment system that account for the variance in cost per discharge and resource utilization among the payment groups. The establishment of relative weights will help ensure that beneficiaries have access to care and receive the appropriate services that are

commensurate to other beneficiaries that are classified to the same CMG. In addition, prospective payments that are based on relative weights encourage provider efficiency and, hence, help ensure a fair distribution of Medicare payments. Accordingly, under § 412.620(b)(1) of the final regulations, we calculate a relative weight for each CMG that is proportional to the resources needed by an average inpatient rehabilitation case in that CMG. For example, cases in a CMG with a relative weight of 2, on average, will cost twice as much as cases in a CMG with a relative weight of 1. We discuss the details of developing the relative weights below.

As indicated in section III. of this final rule, we believe that the RAND analysis has shown that CMGs based on functional-related groups (adjusted for comorbidities) are effective predictors of resource use as measured by proxies such as length of stay and costs. The use of these proxies is necessary in developing the relative weights because data that measure actual nursing and therapy time spent on patient care, and other resource use data, are not available. Throughout this section of the final rule, we describe how we used these proxy measures of resource use to develop the relative weights for each CMG and the specific case-level adjustments.

1. Overview of Development of the CMG Relative Weights

To calculate the relative weights, we estimate operating (routine and ancillary services) and capital costs of IRFs. For the payment rates set forth in this final rule, we use the same method for calculating the cost of a case as we did for the proposed rule; however, we have used the most recent data available. Specifically, for the relative weights set forth in this final rule, we obtained cost-to-charge ratios for ancillary services and per diem costs for routine services from the most recent available cost report data (FYs 1998, 1997, and/or 1996). We obtained charges from calendar year 1999 Medicare bill data and derived corresponding functional measures from the FIM data. We omitted data from rehabilitation facilities that are classified as all-inclusive providers from the calculation of the relative weights, as well as from the parameters that we use to define transfer cases, because these facilities are paid a single, negotiated rate per discharge and they do not maintain a charge structure.

For ancillary services, we calculate both operating and capital costs by converting charges from Medicare claims into costs using facility-specific, cost-center specific cost-to-charge ratios obtained from cost reports. Our data analysis showed that some departmental cost-to-charge ratios were missing or found to be outside a range of statistically valid values. For anesthesiology, a value greater than 10, or less than 0.01, was found not to be statistically valid. For all other cost centers values greater than 10 or less than 0.5 were found not to be statistically valid. As with the proposed rule, we replace individual cost-to-charge ratios outside of these thresholds. The replacement value that we use for these aberrant cost-to-charge ratios is the mean value of the cost-to-charge ratio for the cost-center within the same type of hospital (either freestanding or unit).

For routine services, per diem operating and capital costs are used to develop the relative weights. In addition, per diem operating and capital costs for special care services are used to develop the relative weights. (Special care services are furnished in intensive care units. We note that fewer than 1 percent of rehabilitation days are spent in intensive care units.) Per diem costs are obtained from each facility's Medicare cost report data. We use per diem costs for routine and special care services because, unlike for ancillary services, we cannot obtain cost-to-charge ratios for those services from the cost report data. To estimate the costs for routine and special care services included in developing the relative weights, we sum the product of routine cost per diem and Medicare inpatient days and the product of the special care per diem and the number of Medicare special care days.

In this final rule, we use a hospital-specific relative value method to calculate relative weights as described in the proposed rule. We use the following basic steps to calculate the relative weights for this final rule:

The first step in calculating the CMG weights is to estimate the effect that comorbidities have on costs. The second step is to adjust the cost of each Medicare discharge (case) to reflect the effects found in the first step. In the third step, the adjusted costs from the second step are used to calculate ''relative adjusted weights'' in each CMG using the hospital-specific relative value method. The final steps are to calculate the CMG relative weights by modifying the ''relative adjusted weight'' with the effects of the existence of the comorbidity tiers (explained below) and normalize the weights to 1.

We describe each of these steps in greater detail below.

2. Steps for Calculating the Relative Weights

Step 1—Estimate the effect of comorbidities on costs.

We use regression analyses to determine if we should establish a separate relative weight for cases in a CMG with comorbidities meeting the appropriate criteria described in section V.B. of this preamble. In the proposed rule, we indicated that a higher payment would be made for cases that have at least one relevant comorbidity from the list included in Appendix C of the proposed rule. Under the proposed policy, payment for a case with one relevant comorbidity would be the same as a case with multiple relevant comorbidities.

Comment: Several commenters suggested that additional payments should be made for more than one comorbidity. Further, some commenters suggested that payment for comorbidities should be based on a tiered approach. Specifically, a tiered approach provides for different payments based on the cost of the comorbidity.

Response: In response to these comments, for this final rule we analyzed the use of a tiered approach that consists of three weighting levels that account for variations in severity of relevant comorbidities. The data indicate that arraying comorbidities into three categories based on whether the costs associated with the comorbidities are considered high, medium, or low improves the extent to which payment matches cost. As described later in this final rule, separate relative weights for three tiers will now be calculated for each CMG using the weighting methodology. Then, separate payment rates will be calculated by multiplying the relative weights by a standardized payment amount which is also discussed later in this final rule. The result is variations in payment for CMGs based on differences in costs among relevant comorbidities for each tier. When a case has more than one comorbidity, the applicable CMG payment rate will be determined by the comorbidity that results in the highest payment. We believe the use of this 3-tiered approach will improve the extent to which the IRF prospective payments accurately reflect case costs. Therefore, we will use the 3-tiered approach for the payment rates set forth in this final rule.

Comment: Several commenters suggested that the list of comorbidities in the proposed Appendix C should be expanded to include specific diagnoses. In contrast, some commenters recommended that certain diagnoses

should be excluded from the list of comorbidities because they suggested these codes were inappropriate for care furnished in an inpatient rehabilitation setting.

Response: We analyzed the comorbidities listed in Appendix C in the proposed rule extensively to determine the appropriateness of the diagnoses and improve the list. Based on the results of the analyses described below, we are modifying the list of comorbidities in Appendix C of this final rule. Specifically, we applied the following general criteria to refine the comorbidity list further: We deleted codes that we found to be irrelevant to the inpatient rehabilitation population and added codes that we found to be associated with higher costs in the inpatient rehabilitation population. We removed from the list those comorbidities that we determined to be preventable by good medical care. An example would be not to pay extra for urinary tract infections, many of which can be prevented by removing unnecessary Foley catheters. In addition, as we proposed, conditions that we determined to be inherent to a specific RIC were excluded from the list of relevant comorbidities for that RIC.

We will continue to examine the appropriateness of the comorbidities and may refine the list in the future if warranted. We used the final list of comorbidities in Appendix C of this final rule to construct the payment rates effective with this final rule. This list of comorbidities will help determine which comorbidity tier may be appropriate for payment.

To compute payments for the comorbidity tiers, we performed a regression analysis to determine if the comorbidity tiers affect costs per case by RIC. In the analysis, we found that each comorbidity tier does not have the same effect on each RIC. Therefore, if coefficients by RIC are positive and significant and the comorbidity is deemed to be relevant clinically to the CMG, we calculate separate relative weights for cases for each comorbidity tier in Step 3 below.

Comment: One commenter requested clarification regarding why the CMGs that depicted expired patients were not affected by comorbidities.

Response: The process of determining the effects of comorbidities excludes cases that end in death. The number of cases used to calculate the relative weights for cases that end in death is too small to develop different payments based on comorbidities. However, the effects of comorbidities are still accounted for in the payments. To the extent that comorbidities occur with cases ending in death, the costs of comorbidities are included in the average cost and, thus, the relative weight for these cases reflects comorbidities for these cases.

Step 2—Adjust the costs of each discharge for the effects of comorbidities.

The second step in the calculation of the weights is to adjust the resource use for each case to eliminate the effect of comorbidities. The adjusted cost (A) for a discharge is calculated as follows: Let x be a vector (a quantity completely specified by a magnitude and a direction) with three elements, one for each comorbidity tier. Each element of x will be 1 if the case is in that tier and 0 otherwise. The a is the transposed vector of coefficients corresponding to each tier in the RIC for the case. Then A = cost per discharge/exp(a*x). These adjusted costs for each discharge are then used to calculate the adjusted relative weight for each CMG, thereby eliminating the effect of comorbidities from the weight (signified by wk in the formula described in step 3 below).

Step 3—Calculate the CMG relative weights adjusted for comorbidity tiers, on an iterative basis.

The process of calculating the CMG relative weights is iterative. First, we give an initial case-mix index (CMI) value of 1 to each facility. Then, for each case, we calculate a facility-specific relative value by dividing the comorbidity-adjusted cost of the case by the average comorbidity-adjusted cost of all cases at the facility, and multiplying the result by the facility's CMI. We then set the CMG-adjusted weights in proportion to the average of the facility-specific relative values. The result is a new CMI for each facility and, therefore, new facility-specific, relative values. The process continues until there is convergence between the weights produced at adjacent steps, for example, when the maximum difference is less than 0.0001. After the first iteration, we remove statistical outlier—cases that differ from the CMG mean by more than three standard deviations in the log scale of standardized cost. We believe this method is a reasonable statistical approach to remove aberrant values that could skew the remainder of the data. We treat discharges that meet the definition of a transfer case as a fraction of a case. (See discussion of transfers in section VI.B. of this preamble.) We calculate relative weight for each relevant combination of CMG ''without comorbidity'', ''tier 1'', ''tier 2'', and ''tier 3'', using the following formula:

$$W(k, x) = \exp(a*x)w_k$$

where x and a are the vectors described in step 2 (all elements of x are 0 if no comorbidities were present, so exp(a*x) = 1 when no comorbidities are present). The variable (w_k) equals the comorbidity adjusted weight. If the coefficient (a) is not positive and significant as previously discussed in Step 1, then (a) will be set to equal 0 in the formula. This results in exp(a*x), in the formula, to equal 1 and the weight (W) will equal (w_k).

Step 4—Calculate the weight by modifying the relative adjusted weight with the effects of comorbidity and normalizing the weights to 1.0.

This step entails calculating a relative weight for each relevant combination of CMG and comorbidity tier. In this step, we determine the average cost per discharge for all the cases and use that value as the divisor to calculate the relative weights. For example, if the average cost per discharge across all discharges is $12,000, then the relative weight for a CMG with an average cost of $12,000 is 1, and the relative weight for a CMG with an average cost per discharge of $20,000 is 1.67. If ''r'' is the relative adjusted weight for a case in a CMG with a comorbidity given by:

$$w = k\ r\ \exp(a*x),$$

then k is determined so that the average value of w is 1.

Table 1 in the Addendum to this final rule lists the CMGs, the comorbidity tiers, and their respective relative weights. The relative weights reflect the inclusion of cases with a very short interruption (return on day of discharge or either of the next 2 days). Information obtained from the first assessment will be used to determine the appropriate CMG and corresponding payment.

Comment: A few commenters suggested that additional payments should be made if the comorbidity develops at any time during the course of the inpatient stay, rather than only if the condition is recorded on the admission assessment.

Response: For the proposed rule, we stated that we proposed to pay an additional amount with the presence of a relevant comorbidity based on the initial assessment. In this final rule, we are using a modified version of the UDSmr patient assessment instrument, the FIM. For the FIM instrument, comorbidity data are not coded until the discharge assessment. Because we are modifying our patient assessment instrument to reflect more closely the items and data collection methods from the FIM, we will obtain information regarding comorbidities from the discharge assessment. However, we will not use any comorbidities identified on the day prior to the day of discharge or the day of discharge to determine a comorbidity tier. We believe increasing payment for comorbidities that occur at the end of a beneficiary's stay is

inappropriate because these comorbidities have less effect on the resources consumed during the entire stay. Often, the occurrence of a comorbidity at the end of the stay may be part of the reason the rehabilitation stay was ended. Comorbidities that are identified on the day prior to the day of discharge or the day of discharge should not be listed on the discharge assessment; we will reevaluate the appropriateness of this type of coding in the future. Therefore, in order to determine the appropriate comorbidity, we will use the ICD–9–CM codes (item 24 on the patient assessment instrument) obtained from the discharge assessment.

If a relevant comorbidity is indicated on the discharge assessment, payment will be based on the relative weight from the appropriate comorbidity tier column in Table 1 in the Addendum to this final rule.

Comment: Several commenters expressed concern regarding relative weight compression in the proposed classification system.

Response: Subsequent to issuance of the proposed rule our analysis showed that the proposed CMG relative weights exhibited weight compression and suggested a methodology for addressing it. Weight compression may exist when payment for ''high weighted'' cases is less than the cost of the case and payment for ''low weighted'' cases is more than the cost of the case. Similarly, CMI compression may exist when facilities with high CMIs have higher standardized costs relative to their CMG than facilities with low CMIs.

To measure compression, we use regression analysis to assess the relationship of the log of the average cost minus outlier payments at a facility and the log of the CMI. The coefficient on the CMI illustrates how much cost increases with increasing the CMI. If the weights are neither compressed or decompressed, the coefficient will be 1. A value greater than 1 indicates compression. The relative weights computed for this final rule also exhibited CMI compression with a coefficient of about 1.10. In other words, a facility with a case-mix index that is 10 percent higher than another facility will, on average, cost about 11.0 percent more.

In light of the coefficient, we explored possible reasons for compression. Analysis of the data supports an assumption that the use by IRFs of a single uniform per diem charge for routine services may be a major cause of the observed compression. This results in data on IRF claims that may not fully reflect the relative resource requirements for nursing and other routine services. Further analysis also indicates that the likely causes for the compression may be due to the bundling of ancillary services into routine costs and varying nursing intensity across CMGs. However, at the present time, there is a lack of data to resolve these issues directly. When staff time measurements become available in the future (as discussed in section III. of this final rule), we will analyze these data in terms of potential explanation of compression and modify the relative weights or payment methodologies, if warranted.

We believe it is important to alleviate compression to the extent that payment for higher cost cases is lower than costs, and payment for lower cost cases is higher than costs. If the weights are not adjusted, inappropriate incentives will exist to admit the lower cost cases. Limiting access to higher cost cases is not a desirable outcome. In order to adjust the relative weights for this final rule, we developed an algorithm using the relationship of IRF average costs and CMI. We believe that using this algorithm to adjust the relative weights will, to the extent possible, eliminate CMI compression and result in weights that are a better measure of costs than the compressed weights. Therefore, we adjust the relative weights using the following basic formula:

$$nw(i) = w(i) + 0.10(w(i)-1)$$

where nw(i) is the new relative weight and w(i) is the relative weight prior to the adjustment.

The adjusted relative weights result in average payments per IRF that vary directly with average costs at the IRF. Although this formula is used to adjust the relative weights for each CMG, we do not apply it to the short-stay CMG because the result would be a negative relative weight. Instead, we reduce the case weight by 15 percent, which we believe based on our analysis is an appropriate amount to offset the increase in the relative weights at the high end (that is, over 1.0) and results in weights that we find are a better measure of costs than the compressed weights.

B. Transfer Payment Policy

1. Background

In the November 3, 2000 proposed rule, we proposed a transfer policy under § 412.624(f) to provide for payments that more accurately reflect facility resources used and services delivered. This reflected our belief that it is important to minimize the inherent incentives specifically associated with the early transfer of patients in a discharge-based payment system. Discharging patients early can be profitable in that IRFs can receive the full CMG payment without providing a complete course of treatment. As we previously stated, length of stay has been shown to be a good proxy measure of costs. Thus, in general, reducing lengths of stay will be profitable under the IRF prospective payment system. We are concerned that incentives might exist for IRFs to discharge patients prematurely, as well as to admit patients that may not be able to endure intense inpatient therapy services. Even if patients were transferred before receiving the typical, full course of inpatient rehabilitation, the IRF could still be paid the full CMG payment rate in the absence of a transfer policy. Accordingly, we proposed a transfer policy that reduces the full CMG payment rate when a Medicare beneficiary is transferred.

2. Definition of Site of Care

In the proposed rule, for the purposes of our transfer policy, we proposed to define site of care as an ''institutional site'', although we were considering the option to extend the definition of site of care to the ''provider site'' definition. In addition, we solicited comments regarding the inclusion of nursing homes in the definition of site of care.

3. Criteria for Defining Transfer Cases

In the proposed rule, we proposed that in order for a discharge from an IRF to be classified as an early transfer, the length of stay for the discharge must be less than the average length of stay for the given CMG (as shown in section XII. of the proposed rule), and the patient must be discharged to another rehabilitation facility, a long-term care hospital, an inpatient hospital, or a nursing home that accepts payment under either the Medicare program or the Medicaid program, or both (65 FR 66346).

Comment: Some commenters suggested that we limit or completely eliminate the transfer policy. Specifically, some commenters noted that a prospective payment system, by design, is based on averages, making adjustments for transfer cases unnecessary. Other commenters suggested that nursing homes be removed from the definition of transfer cases. Another commenter focused on potential access barriers for patients who use a nursing home as their residence.

Response: With the development of each new prospective payment system, analysis of the inherent incentives is necessary to determine what factors will

motivate providers to optimize their payments inappropriately. As we stated in the proposed rule, a discharge-based payment system based on national average costs contains the inherent incentive to discharge patients prematurely and admit patients inappropriately. If these incentives are not addressed, Medicare funds will not be distributed in the most equitable manner possible or, more specifically, to those IRFs that are providing the full course of rehabilitative services. We note that a transfer policy for IRFs is contemplated under the statute. Specifically, section 1886(j)(1)(E) of the Act states: ''Nothing in this subsection shall be construed as preventing the Secretary from providing for an adjustment to payments to take into account the early transfer of a patient from a rehabilitation facility to another site of care.''

Some commenters suggested that applying our transfer policy to cases discharged to nursing homes will pose access barriers to patients whose permanent residence is a nursing home because discharge prior to the average length of stay for a CMG will always involve a transfer payment. Thus, IRFs may decide to not admit nursing home patients because they want to avoid the risk of receiving a transfer payment for their services. We believe that payments for such cases (which include an additional half day payment for the first day) are adequate to cover costs of care and should mitigate any potential incentives not to admit these patients (see comment and response regarding increasing payment for transfer cases). Accordingly, we are not adopting the commenters' recommendation to eliminate or narrow the focus of the transfer policy.

In the November 3, 2000 proposed rule, we stated that we were analyzing claims data to determine the extent to which we could distinguish among services that could be considered a substitution of care rather than an extension of the normal progression for inpatient rehabilitation care, and to determine the frequency and intensity of both home health and outpatient therapy services. We noted that estimating the potential substitution of home health therapy services was made more challenging because we had just developed the HHA prospective payment system, and it was difficult to anticipate how therapy services would be delivered after implementation of that system.

We indicated in the proposed rule that we were not proposing to include home health services, outpatient therapy, and ''day programs'' in our transfer policy. However, we were considering including these services to the extent that we could distinguish when home health and outpatient therapy services are more intensive and used as a substitution for inpatient rehabilitation care. We proposed that if we could determine that the care is used as a substitution rather than just the normal progression of care, then we believed that these types of intensive home health and outpatient therapy services should be included as part of the transfer policy. We specifically solicited comments on this option.

Comment: Several commenters recommended that the transfer policy should not be extended to include home health and outpatient rehabilitation services. Specifically, the commenters noted that many Medicare beneficiaries need and benefit from some short-term home health or outpatient therapy following discharge from an IRF. They also observed that home health and outpatient therapy services are the most appropriate and cost effective way to continue their care.

Response: To date, claims data are not available to determine the extent to which we can distinguish those services that represent a substitution of care rather than an extension of the normal progression for inpatient rehabilitation care, and to determine the frequency and intensity of both home health and outpatient therapy services. Therefore, we believe it would be inappropriate to expand the transfer policy at this time to include discharges of patients who will receive home health and outpatient therapy services. We acknowledge that many patients will require some form of therapy after discharge from the IRF. However, we remain concerned about incentives to discharge patients prematurely under the IRF prospective payment system, and as part of the monitoring system we will analyze data to compare practice patterns prior to and after its implementation. Based on future analysis of practice patterns, we may refine payments in the future, if warranted.

In the November 3, 2000 proposed rule, we also solicited comments on a monitoring system that includes transfers or discharges from an IRF to ''provider sites.'' This would have included transfers or discharges from an IRF to a SNF, a long-term care facility, an HHA, or an inpatient hospital. The monitoring system would include discharges and transfers from one IRF to a different IRF, including situations where the transfer occurs between organizations of common ownership. We indicated that although it does not currently appear that this type of transfer occurs frequently, further analysis of data regarding this type of transfer between IRFs may warrant an adjustment to payments. We did not receive any comments in response to our solicitation, and we will continue to develop a monitoring system that will allow us to assess the impact of the IRF prospective payment system on these types of situations.

4. Transfer Case Payment

For the November 3, 2000 proposed rule, we proposed to compute the per diem-based payment for a transfer case as follows: first, calculate the unadjusted per diem amount for each CMG (except the short-stay CMG) by dividing the average length of stay for nontransfer cases (those cases discharged to the community with a length of stay exceeding 3 days) in the CMG into the Federal prospective payment (with or without comorbidities) for that CMG. Next, multiply the CMG per diem payment from the first step by the number of days that the beneficiary was in the IRF prior to his or her transfer. The result equals the proposed unadjusted Federal prospective payment for the transfer case. We solicited comments on the appropriateness of our proposed methodology for computing payments for transfer cases.

Comment: Several commenters suggested that there are additional costs associated with the initial day in comparison to each additional day a patient is in the IRF, and therefore recommended that we pay transfer cases at a higher rate. Further, the commenters noted the additional costs of the initial day are related to: processing the patient through the admissions department; integrating the patient into the facility; assessing the patient; and providing appropriate diagnostic tests, pharmaceuticals, and supplies. Most of the commenters recommended an additional half day payment for the first day to account for the higher costs incurred at the beginning of the stay. Some commenters recommended a transfer payment methodology similar to the acute transfer payment methodology, where the initial day is paid two times the per diem and each additional day at the per diem.

Response: In light of these comments, we analyzed cost data for each day of stay to determine if per diem costs were significantly higher for the first day relative to subsequent days. The data support the commenters' recommendations to include an additional half day payment for the first day of a stay for transfer cases. However,

the data do not support payment at two times the per diem for the first day. Therefore, under § 412.624(f) of these final regulations, we will pay transfer cases a per diem amount and include an additional half day payment for the first day. As with other adjustments, this payment will be made in a budget neutral manner. We are concerned that this more precise matching of payment to average historical costs has the potential to provide an incentive for IRFs to admit patients who are not appropriate for an intensive inpatient rehabilitation program. These patients may be less expensive to care for than patients requiring intensive rehabilitation and, thus, may be more profitable to hospitals even though these patients are soon transferred to another setting. We will monitor the appropriateness of admissions for patients who have shorter than average stays and are then transferred to another setting. We may make future payment refinements based on the extent to which this type of case increases.

Comment: Several commenters suggested that the proposed payments did not account for long-stay transfers. The commenters stated that long-stay transfers would not receive adequate payments and suggested an increase in payment for these cases.

Response: Based on the comments received, we believe it is necessary to clarify which cases were included in the construction of the CMGs, and also to identify the types of cases that were included in the construction of the relative weights for the CMGs. The cases included in the construction of the CMGs were those cases in which the patient returned home and had a length of stay greater than 3 days (short-stay and expired CMGs were created based on the remainder of the cases). For the proposed rule, we also used these data to determine the average length of stay for the groups based on these cases. Once we constructed the CMGs for the proposed rule, we then calculated the relative weights for each group using cases in which the patient returned home and had a length of stay greater than 3 days in addition to the long-stay transfer cases. Therefore, long-stay transfer cases were included for cases other than short stays and expired cases in the construction of the relative weights for the CMGs.

For this final rule, we calculate the average length of stay for the CMGs which included those cases in which the patient returned home and had a length of stay greater than 3 days as well as long-stay transfer cases. We calculate the average length of stay in this manner so that the inputs are consistent with those used to develop the relative weights. For CMGs that have a very small number of cases (less than 10 cases), we use a model to estimate the average length of stay for that CMG. To do this, we estimate the average length of stay from an analysis of variance using the log of the length of stay as the dependent variable. The independent variables are the CMG and the comorbidity tier coefficient for each RIC. It is possible that payment for an individual case might be lower than the cost of the case, but for other cases, the total payment might be higher than costs.

C. Special Cases That Are Not Transfers

Section 1886(j)(3)(A)(v) of the Act permits us to adjust the payment rates by such factors as the Secretary determines are necessary to properly reflect variations in necessary costs of treatment among rehabilitation facilities. There are three types of special cases that are not transfers. The special cases include short-stay outliers, cases in which the patient expires, and interrupted stays.

1. Short-Stay Outliers

We proposed under § 412.620(b)(2) of the proposed rule to develop separate weighting factor(s) for patients who are discharged (and not transferred) within a specified number of days after admission. We proposed to define a short-stay outlier as a case that has a length of stay of 3 days or less (regardless of the CMG) and that does not meet the definition of a transfer (as discussed in section VI.B. of this final rule). Payment-to-cost ratios for these cases show that, if facilities received a full CMG payment, the payment would substantially exceed the resources the IRF had expended.

We proposed to pay short-stay outliers a relative weight of 0.1908. We computed this relative weight for short-stay outlier discharges by identifying all cases in which the length of stay is 3 days or less and the discharge does not meet the policy criteria to be considered a transfer. In the proposed rule, we calculated the relative weight for short-stay cases using the hospital-specific relative value methodology. For this final rule, we will pay short-stay cases a relative weight of 0.1651. This amount also was derived using the hospital-specific relative value method. However, we use the most recent data available (calendar year 1999 Medicare bills with corresponding FIM data) and we adjust the weight due to the results of the regression analyses described earlier in this preamble which measured the extent to which the relative weights reflect case costs.

In addition, in the proposed rule we specifically solicited comments on the appropriate time period for our short-stay criteria. We proposed that the considerations underlying the short-stay policy might also apply to cases with a length of stay greater than 3 days. More specifically, we noted that some beneficiaries may have longer lengths of stay, and yet may not require intensive inpatient rehabilitative care, or may lack the capacity to participate in an intensive rehabilitation program. Thus, we were also considering a short-stay policy that could encompass certain cases with a length of stay longer than 3 days. We indicated that we were in the process of further analyzing claims data for Medicare beneficiaries to determine the most appropriate number of days to use in the definition of a short-stay case. We stated that if analysis of the data supported increasing the number of days for the short-stay criteria, we might adopt in the final rule a definition covering a longer timeframe than the 3-day period.

Comment: One commenter suggested that adjustments for short-stay outliers are unnecessary, because the prospective payment system is based on averages; some patients have a longer length of stay, while others have a shorter length of stay.

Response: Section 1886(j)(3)(A)(v) of the Act provides us with broad authority to adjust the payment rates under the IRF prospective payment system by such factors as the Secretary determines are necessary to properly reflect variations in necessary costs of treatment among rehabilitation facilities. Because the prospective payment system is based on a system of averages, certain cases could be paid significally more than their cost if the facility receives the full CMG payment. Due to the budget neutrality provision, excessive payment for short-stay outlier cases that do not actually entail the full course of rehabilitative care results in reducing payment for those cases that warrant full payment based on the rehabilitation services delivered. Adjusting for short-stay outlier cases is a means of matching payment as closely to cost as possible. Therefore, we are not adopting the suggestion to eliminate the short-stay outlier policy.

Comment: Some commenters maintained that the time period used to define the short-stay outlier policy (3 days or less) is appropriate. Other commenters disagreed with increasing the short-stay outlier policy to encompass cases with a length of stay of longer than 3 days.

Response: In developing the short-stay CMG for the proposed rule, we performed extensive analyses using the frequency distribution of existing claims data to determine the most appropriate length of stay for the short-stay CMG. Specifically, we found that a length of stay of 3 days or less will capture the majority of those cases in which the beneficiary is unlikely to receive and benefit from a full course of rehabilitative treatment. Further, based on consultation with clinical experts, we determined the minimum length of time needed to acclimate a beneficiary to an IRF before intensive rehabilitation can begin. In view of administrative processes and the initial assessment activities, we believe that 3 days is appropriate. Based on these analyses, we are not expanding the 3-day period for the short-stay outlier policy. However, we will monitor the extent to which practice patterns change as a result of implementing this policy, and we may make refinements in the future, if warranted.

2. Cases in Which the Patient Expires

In general, payment for cases that end in death might substantially exceed the costs if facilities received the full CMG payment for these cases. Even excluding all of the short-stay cases with a length of stay of 3 days or fewer, payment for the remaining expired cases as a whole would still be substantially more than the costs.

In the proposed rule, we indicated that we had analyzed payment-to-cost ratios and found that we could improve the accuracy of the payments if we split expired cases into two categories based on the RIC—one for orthopedic cases and one for all other types of RICs. We further found that splitting these cases based on length of stay also improves the accuracy of the payment system. Therefore, under proposed § 412.620(b)(3), we proposed to determine weighting factor(s) for patients who expired within a specified number of days after admission. We proposed that expired cases in which a beneficiary dies within 3 days after admission are classified into the short-stay CMG. Expired cases with a length of stay greater than 3 days are classified into one of four CMGs, based on length of stay and whether the discharge falls within an orthopedic RIC (RICs 07, 08, and 09). More specifically, one group includes orthopedic discharges with a length of stay of more than 3 days but less than or equal to the average length of stay for expired cases classified within the orthopedic RIC. The second group includes orthopedic discharges with a length of stay greater than the average length of stay for expired cases classified within the orthopedic RIC. The third group includes nonorthopedic discharges with a length of stay of more than 3 days but less than or equal to the average length of stay of expired cases that are not classified within the orthopedic RIC. The fourth group includes nonorthopedic discharges with a length of stay greater than the average length of stay of expired cases that are not classified within the orthopedic RIC. We calculated the proposed relative weights for each expired CMG using the hospital-specific relative value methodology discussed previously in this preamble.

Comment: A few commenters suggested that adjustments for cases that end in death are not necessary in the IRF prospective payment system. Specifically, one commenter indicated that, since the system is based on averages, it should account for atypical cases.

Response: Section 1886(j)(3)(A)(v) of the Act permits us to adjust the payment rates by such factors as the Secretary determines are necessary to properly reflect variations in necessary costs of treatment among rehabilitation facilities. In the proposed rule, we noted that certain cases (such as cases in which the patient expires) that receive less than the full course of treatment for a specific CMG would be paid inappropriately if the facility received the full CMG payment. In general, cases in which the patient expires might be paid substantially more than costs if we did not create separate CMGs for these cases. Further, other cases that warrant full payment because they receive the full course of rehabilitative care would instead receive reduced payments, due to the budget neutrality provision of the statute. Adjusting for cases in which the patient expires is a means of matching payment more closely to the cost of the case. Expired cases may also warrant additional outlier payments if the estimated cost of the case exceeds the adjusted CMG payment amount and the adjusted loss threshold amount. Therefore, in this final rule we are adopting as final the provision at proposed § 412.620(b)(3), which provides for the development of weighting factor(s) for cases in which patients expire within the number of days after admission that we specify.

3. Interrupted Stay

In proposed § 412.602, we proposed to define an interrupted stay as a stay in which the beneficiary is discharged and returns to the same IRF within 3 consecutive calendar days. We proposed to pay one discharge payment for these cases. The assessment from the initial stay would be used to determine the appropriate CMG.

Comment: Several commenters expressed concern about the proposed interrupted stay policy. Some commenters recommended that the interrupted stay policy be eliminated or limited to a 24-hour time period.

Response: We believe that, in the absence of an interrupted stay policy, incentives might exist for facilities to attempt to inappropriately receive more than one CMG payment for the same patient by moving the patient out of the IRF, only to return the patient to the same IRF, solely to maximize payments. We believe this would be an undesirable outcome of the IRF prospective payment system. Therefore, we are not adopting the recommendation to eliminate or reduce the interrupted stay policy. In addition, in this final rule, we are clarifying in § 412.602 that the duration of the interruption of stay of 3 consecutive calendar days begins with the day of discharge from the IRF and ends on midnight of the third day.

Comment: One commenter suggested that we include the interrupted stay policy in the codified regulations text.

Response: In response to this comment, we are adding language to the regulation text at § 412.624(g).

Comment: Other commenters requested clarification regarding how services during the interruption of the IRF stay would be paid.

Response: As stated above, in this final rule we are adding a paragraph (g) to proposed § 412.624 to specify special payment provisions for interrupted stays when a beneficiary is discharged from the IRF to an acute care hospital. Under § 412.624(g), there will be no separate DRG payment to the acute care hospital when the beneficiary is discharged and returns to the same IRF on the same day. However, if a beneficiary receives inpatient acute care hospital services, the acute care hospital can receive a DRG payment if the beneficiary is discharged from the IRF and does not return to that IRF by the end of that same day.

D. Adjustments

Section 1886(j)(6) of the Act requires an adjustment to the Federal prospective payments to account for geographic area wage variation. Section 1886(j)(3)(A)(v) of the Act confers broad discretion on the Secretary to adjust prospective payments ''by such other factors as the Secretary determines are necessary to properly reflect variations in necessary costs of treatment among rehabilitation facilities.'' Section 1886(j)(4) of the Act authorizes (but

does not require) the Secretary to make specified payment adjustments (including an adjustment for outlier cases).

Consistent with what we proposed in the November 3, 2000 proposed rule, in this final rule we will adjust payments for facilities located in rural areas, in addition to the geographical wage adjustment. Further, we will adjust payments to reflect the percentage of low-income patients. We discuss these adjustments and the final payment methodologies below.

1. Area Wage Adjustment

Section 1886(j)(6) of the Act specifies that payment rates under the IRF prospective payment system must be adjusted to account for geographic area wage variation. The statute requires the Secretary to adjust the labor-related portion of the prospective payment rates for area differences in wage levels by a factor reflecting the relative facility wage level in the geographic area of the rehabilitation facility compared to the national average wage level for these facilities. In accordance with § 412.624(e)(1) of this final rule, we will adjust payment rates for geographic wage variations using the following methodology:

To account for wage differences, we first identify the proportion of labor and nonlabor components of costs. In general, the labor-related share is the sum of relative importance of wages, fringe benefits, professional fees, postal services, labor-intensive services, and a portion of the capital share from an appropriate market basket. We use the excluded hospital market basket with capital costs to determine the labor-related share. The excluded hospital market basket with capital costs is derived from available cost data for rehabilitation hospitals, long-term care hospitals, psychiatric hospitals, cancer hospitals, and children's hospitals. In the proposed rule, we estimated the labor-related share for FY 2001. However, because implementation of the IRF prospective payment system is effective with cost reporting periods beginning on or after January 1, 2002 and before October 1, 2002, we are now estimating the labor-related share for FY 2002.

The labor-related share is the sum of the weights for those cost categories contained in the excluded hospital with capital market basket that are influenced by local labor markets. These cost categories include wages and salaries, employee benefits, professional fees, labor-intensive services and a 46-percent share of capital-related expenses. The labor-related share for FY 2002 is the sum of the FY 2002 relative importance of each labor-related cost category, and reflects the different rates of price change for these cost categories between the base year and FY 2002. The sum of the relative importance for FY 2002 for operating costs (wages and salaries, employee benefits, professional fees, and labor-intensive services) is 68.821 percent, as shown in the chart below. The portion of capital that is influenced by local labor markets is estimated to be 46 percent, which is the same percentage used for the hospital inpatient capital-related prospective payment system. Because the relative importance for capital is 7.770 percent of the excluded hospital with capital market basket in FY 2002, we take 46 percent of 7.770 percent to determine the labor-related share for FY 2002. The result is 3.574 percent, which we add to 68.821 percent for operating cost to determine the total labor-related share for FY 2002. Thus, the labor-related share that we will use for rehabilitation facilities in FY 2002 is 72.395 percent, as show in the chart below.

TOTAL LABOR-RELATED SHARE

Cost category	Relative Importance—FY 2002 (percent)
Wages and salaries	50.038
Employee benefits	11.285
Professional fees	2.045
Postal services	0.245
All other labor intensive services	5.208
Subtotal	68.821
Labor-related share of capital costs	3.574
Total	72.395

Comment: A few commenters requested clarification of references to different labor-related shares in the proposed rule.

Response: In the proposed rule, we described the methodology for computing the labor-related share for FY 2001 (71.301 percent). We proposed a wage adjustment using an estimated FY 2001 labor-related share which was appropriate given that the IRF prospective payment system was proposed to be implemented on or after April 1, 2001. However, in this final rule, we use the estimated FY 2002 labor-related share of 72.395 to develop the impacts among the various classes of IRFs, as well as for determining the payment rates set forth in this final rule. We use the estimated FY 2002 labor-related share for these purposes because the payment system will be implemented during FY 2002, and we updated the payments used in the impact analysis in section VIII. of this final rule to the midpoint of FY 2002.

In the proposed rule as well as in this final rule, we apply an estimated labor-related share of 70.5 percent (FY 1998) in order to determine the facility-level adjustments other than the wage adjustment. For purposes of determining facility-level adjustments (other than the wage adjustment), the FY 1998 labor-related share continues to be appropriate, given that, for the proposed rule, the labor-related share was applied to FY 1998 cost report and cost per case data. Although we obtained more recent Medicare bill and FIM data in developing the payment rates set forth in this final rule, the cost report data are still primarily from FY 1998. Therefore, we believe the estimated labor-related share for FY 1998 remains most appropriate to apply to the data used in the regression analyses to determine the facility-level adjustments other than the wage adjustment.

The labor-related portion of the unadjusted Federal payment is multiplied by a wage index value to account for area wage differences. We use inpatient acute care hospital wage data to compute the wage indices.

The inpatient acute care hospital wage data that we use include the following categories of data associated with costs paid under the inpatient acute care hospital prospective payment system (as well as outpatient costs): salaries and hours from short-term, acute care hospitals, home office costs and hours, certain contract labor costs and hours, and wage-related costs. The wage data exclude the wages for services provided by teaching physicians, interns and residents, and nonphysician anesthetists under Medicare Part B, because these services are not covered under the IRF prospective payment system.

Consistent with the wage index methodologies in other prospective payment systems, we divide hospitals into labor market areas. For purposes of defining labor market areas, we define an urban area as a Metropolitan Statistical Area (MSA) or New England County Metropolitan Area (NECMA), as defined by the Executive Office of Management and Budget. We define a rural area as any area outside an urban area. For the purposes of computing the wage index for IRFs, we determine the wage index values for urban and rural areas without regard to geographic reclassification under section 1886(d)(8) or 1886(d)(10) of the Act.

Comment: One commenter questioned how we would compute the wage index for providers with more than one MSA. Also, a few commenters requested that we use ''post-reclassification'' wage data, that is, wage data that reflects any geographic reclassification, to compute the IRF wage index.

Response: We believe the actual location of an IRF as opposed to the location of affiliated providers is most appropriate for determining the wage adjustment because the data support the premise that the prevailing wages in the area in which a facility is located influence the cost of a case. Further, IRFs provide services that are considered part of the post-acute continuum of care. In order to be consistent with the area wage adjustments made to other post-acute care providers (that is, under the existing SNF and HHA prospective payment systems), we are using the inpatient acute care hospital wage data without regard to any approved geographic reclassifications under section 1886(d)(8) or 1886(d)(10) of the Act. Therefore, we are not adopting the use of ''post-reclassification'' wage data and the wage index used by an IRF will be based on the facility's actual location, as shown in Tables 3A and 3B in the Addendum to this final rule, without regard to the urban or rural designation of any affiliated or related providers.

In the November 3, 2000 proposed rule, we proposed to use an IRF wage index that was based on FY 1996 inpatient acute care hospital wage data (65 FR 66349). These data were also used to compute the FY 2000 hospital inpatient prospective payment system wage indices. In the proposed rule, we also indicated that we proposed to use FY 1997 inpatient acute care hospital wage data to develop the wage index for IRFs for this final rule. Because these are the most recent final data available, for this final rule, we used the FY 1997 inpatient acute care hospital wage data to develop the wage index for the IRF prospective payment system.

Comment: Some commenters recommended that we research the development of a separate wage index for rehabilitation facilities. Further, commenters stated that the acute care hospital wage structure and labor classification are not necessarily representative of rehabilitative staffing and wages.

Response: At this time, we are unable to develop a separate wage index for rehabilitation facilities. There is a lack of specific IRF wage and staffing data necessary to develop a separate IRF wage index accurately. Further, in order to accumulate the data needed for such an effort, we would need to make modifications to the cost report. In the future, we will continue to research a wage index specific to IRF facilities. Because we do not have an IRF specific wage index that we can compare to the hospital wage index, we are unable to determine at this time the degree to which the acute care hospital data fully represent IRF wages. However, we believe that a wage index based on acute care hospital wage data is the best and most appropriate wage index to use in adjusting payments to IRFs, since both acute care hospitals and IRFs compete in the same labor markets.

The final IRF wage indices are computed as follows:

- Compute an average hourly wage for each urban and rural area.
- Compute a national average hourly wage.
- Divide the average hourly wage for each urban and rural area by the national average hourly wage—the result is a wage index for each urban and rural area.

To calculate the adjusted facility payments for the payment rates set forth in this final rule, the prospectively determined Federal prospective payment is multiplied by the labor-related percentage (72.395) to determine the labor-related portion of the Federal prospective payments. This labor-related portion is then multiplied by the applicable IRF wage index shown in Table 3A for urban areas and Table 3B for rural areas in the Addendum to this final rule.

The resulting wage-adjusted labor-related portion is added to the nonlabor-related portion, resulting in a wage-adjusted payment. The following example illustrates how a Medicare fiscal intermediary would calculate the adjusted facility Federal prospective payment for IRF services with a hypothetical Federal prospective payment of $10,000 for services provided in the rehabilitation facility located in Heartland, USA. The rehabilitation wage index value for facilities located in Heartland, USA is 1.0234. The labor-related portion (72.395 percent) of the Federal prospective payment is $7,239.50 = ($10,000*72.395 percent), and the nonlabor related portion (27.605 percent) of the Federal prospective payment is $2,760.50 = ($10,000*27.605 percent). Therefore, the wage-adjusted payment calculation is as follows: $10,169.40 = ($7,239.50*1.0234) + $2,760.50

2. General Specifications to Determine Other Adjustments

As indicated earlier, section 1886(j)(3)(A)(v) of the Act confers broad authority on the Secretary to adjust prospective payments ''by such other factors as the Secretary determines are necessary to properly reflect variations in necessary costs of treatment among rehabilitation facilities.'' To determine whether other payment adjustments are warranted for the IRF prospective payment system, we conducted extensive regression analyses of the relationship between IRF costs (including both operating and capital costs per case) and several facility characteristics such as percentage of low-income patients, geographic location, and other factors that may affect costs. The appropriateness of potential payment adjustments is based on both cost effects estimated by regression analysis and other factors, including simulated payments that we discuss in section VIII.B.2. of this final rule.

Our analyses for developing the payment adjustments set forth in this final rule included 714 facilities for which cost and case-mix data were available. We estimated costs for each case by taking facility specific, cost-center specific cost-to-charge ratios and multiplying them by charges. We obtained cost-to-charge ratios from FYs 1996, 1997, and/or 1998 cost report data, and obtained charges from the calendar years 1998 and 1999 Medicare claims data. We calculated the cost per case by summing all costs and dividing by the number of equivalent full cases. After calculating the cost per case for both years, we combined the number of cases and total costs for both years. For this final rule, we did not adjust the 1998 cost per case by the case-weighted average change in cost per case between 1998 and 1999 because the difference is less than 0.2 percent and adjusting the 1998 costs would have such a small effect. Using the data from both years should provide more stability in the payment adjustments than would using data for a single year. When data for only one year are available, we use the costs and number of equivalent cases for that year.

Multivariate regression analysis is a standard way to examine facility cost variation and analyze potential payment adjustments. We looked at two standard models: (1) Fully specified explanatory models to examine the impact of all relevant factors that might potentially affect facility cost per case; and (2) payment models that examine the impact of those factors specifically used

to determine payment rates. The general specification for the multi-variate regression is that the estimated average cost per case (the dependent variable) at the facility can be explained or predicted by several independent variables, including the CMI, the wage index for the facility, and a vector of additional explanatory variables that affect a facility's cost per case, such as its teaching program or the proportion of low-income patients. The CMI is the average of the CMG weights derived by the hospital-specific relative value method for each facility. We give transfer cases a partial weight based on the ratio of the length of stay for the transfer to the average length of stay for the CMG, in addition to an increase to account for the half-day payment for the first day. We count interrupted stay cases as a single stay. Using the regression coefficients, we then simulated payments and calculated payment-to-cost ratios for different classes of hospitals, for specific combinations of payment policies.

For the proposed rule, we used payment variables from the hospital inpatient prospective payment system, including DSH patient percentage, both capital and operating teaching variables (resident-to-average daily census and resident-to-bed ratios, respectively) as well as the teaching variable (resident-to-adjusted average daily census ratio) used in the analyses for the hospital outpatient prospective payment system, and variables to account for location in a rural or large urban area.

For this final rule, we updated the variables described above based on the availability of more recent data and refined some of the independent variables based on suggestions from the comments received. A discussion of the major payment variables and our findings for this final rule appears below.

3. Adjustments for Rural Location

We examined costs per case for both large urban and rural IRFs. In the regression models, both explanatory and payment, the variable for rural IRFs was positive and significant ($p<0.05$). The standardized cost per case for rural IRFs is almost 16 percent higher than the national average. On average, rural IRFs tend to have fewer cases, a longer length of stay, and a higher average cost per case. The difference in costs becomes more evident when the average cost per case is standardized for the CMI and the wage index. In the regression models, large urban IRFs were not significantly different from other urban facilities. Under § 412.624(e)(3) of this final rule, we adjust for rural IRFs by multiplying the payment by 1.1914. This adjustment was determined by using the coefficients derived from the regressions.

Comment: Two commenters suggested that we consider the patient's residence to determine eligibility for the rural adjustment, as opposed to the physical location of the IRF.

Response: Our analysis of the IRF data has shown that the physical location of IRFs corresponds with the cost of a case, with rural IRFs experiencing higher costs other things being equal. Rural IRFs have higher costs because they exhibit practice patterns that contribute to increased expense relative to other facilities, such as lower transfer rates for longer lengths of stay. Further, if any effects in costs are associated with beneficiaries who reside in rural locations, the relative weights should address these differences. The purpose of the relative weights is to account for the level of severity of a given case. If beneficiaries who reside in rural locations require more costly care, the relative weights should account for these costs. Therefore, we are not adopting the recommendation to consider the beneficiary's place of residence to determine eligibility for the rural adjustment.

4. Adjustments for Indirect Teaching Costs

In general, facilities with major teaching programs tend to be located in large urban areas and have more cases, a higher case mix, and a higher proportion of low-income patients. For the proposed rule, we found that when the regression models used only the payment variables that might warrant an adjustment under the prospective payment system (that is, percentage of low-income patients or rural/urban status, rather than for-profit and not for-profit), the indirect teaching cost variable was not significant. Accordingly, we did not propose an adjustment for indirect teaching costs.

For the proposed rule, we looked at different specifications for the teaching variable. We used a resident-to-average daily census ratio and a resident-to-bed ratio that we based on the estimated number of residents assigned to the inpatient area of the rehabilitation facility. We also used a resident-to-adjusted average daily census ratio based on the total number of residents at the hospital complex and outpatient as well as inpatient volume.

For this final rule, we assessed the extent to which we could improve the variable used to measure indirect teaching intensity in order to reassess the appropriateness for an adjustment. However, developing an appropriate measure is complicated by differences in reporting resident counts for freestanding rehabilitation hospitals and units.

To determine if an adjustment for indirect teaching costs is warranted for this final rule, we use the same approach that we used in the proposed rule to calculate the number of full-time equivalent (FTE) residents. That is, we use the number of residents reported for the rehabilitation units of acute care hospitals. For freestanding hospitals, we estimate the number of residents assigned to the routine area (that is, room and board and direct nursing care) based on the ratio of resident salaries apportioned to those areas to total resident salaries for the facility. We define teaching intensity as the ratio of FTE residents-to-average daily census. As in the proposed rule, the indirect teaching variable was insignificant in the payment regressions. Therefore, we will not adjust payments for costs associated with indirect teaching.

Comment: A few commenters requested that we reconsider an adjustment for costs associated with indirect teaching.

Response: As we previously stated, the results of the regression analyses for the proposed rule showed that the indirect teaching variable was significant only with the fully specified regression, and not with the payment regression. However, in the analyses conducted for this final rule, the indirect teaching variable was not significant for either the fully specified regression or the payment regression. Also, the impacts among the various classes of facilities reflecting the fully phased-in IRF prospective payment system in section VIII. of this final rule illustrate that IRFs with the highest measures of indirect teaching lose approximately 2 percent of estimated payments under the IRF prospective payment system. Further, these impacts among the various classes of facilities do not account for changes in behavior that facilities will likely adopt in response to the inherent incentives of the IRF prospective payment system. Accordingly, IRFs can change their behavior in ways to mitigate any potential losses. In considering the impacts among these types of facilities and the results of the regression analyses, we will not adjust payments for indirect teaching because we believe that this type of adjustment is not supported by our regression analyses or impact analyses.

5. Adjustments for Low-Income Patients

We assessed the appropriateness of adjustments for facilities serving low-

income patients. For the proposed rule, we limited our analysis to the effects of serving low-income patients on costs per case rather than a subsidy for uncompensated care.

Also, in the proposed rule, we evaluated a facility-level adjustment that takes into account both the percentage of Medicare patients who are receiving Supplemental Security Income (SSI) and the percentage of Medicaid patients who are not entitled to Medicare. We proposed to use the same measure of the percentage of low-income patients currently used for the acute care hospital inpatient prospective payment system, which is the DSH variable. The low-income payment adjustment we chose improves the explanatory power of the IRF prospective payment system because as a facility's percentage of low-income patients increases, there is an incremental increase in a facility's costs. We proposed to adjust payments for each facility to reflect the facility's percentage of low-income patients using the DSH measure.

Comment: One commenter suggested that the payment for the percentage of low-income patients adjustment should reflect all low-income patients, including uninsured patients.

Response: While we recognize that an adjustment accounting for the costs of serving uninsured patients may be desirable, we do not currently have access to data that would allow us to measure uncompensated care. However, we analyzed the performance of other measures of low-income patients, in addition to DSH, such as the SSI ratio, dual eligibles (Medicare beneficiaries entitled to Medicaid), and self-pay/charity cases (determined by UDSmr non-Medicare data by primary and secondary payer) in order to determine the measure that most accurately matches payment to costs. To do this, we used data for the IRFs for which we had all payer information. These data indicate that the DSH variable improves the explanatory power of the groups better than the other measures, with an r-squared of .0529. The measure of dual eligibles, self-pay/charity, and the SSI ratio did not predict costs as well as DSH. Further, the SSI ratio measure was not significant in our regression analyses. After examining the use of these alternative low-income measures, we found the DSH variable explained costs more fully than the other variables that we examined. Therefore, we are not adopting the commenter's suggestion and will use the DSH variable as the basis of the adjustment for low-income patients.

Comment: A few commenters noted that the adjustment for low-income patients was not consistent with the name of the adjustment, ''disproportionate'' share adjustment. In general, one commenter stated that if all IRFs are eligible to receive this adjustment, then the adjustment is not applicable only to those IRFs that treat a ''disproportionate'' share of low-income patients.

Response: In response to this comment, in this final rule, we will refer to the adjustment for low-income patients as the LIP adjustment. However, we will use the term DSH when we refer to the measure used to compute IRF's percentage of low-income patients because it is the same measure used to measure low-income patients in acute care hospitals.

Comment: Some commenters suggested that the LIP adjustment have a threshold similar to the inpatient acute care hospital prospective payment system.

Response: We analyzed different specifications for the LIP adjustment. One option had a threshold of 5 percent. In general, under this option, a facility would not be allowed to receive the LIP adjustment unless its DSH was greater than 5 percent. Although we considered this option, we favored the use of a LIP adjustment that matches payment as closely to cost as possible. The LIP adjustment we chose improves the explanatory power of the IRF prospective payment system because as a facility's percentage of low-income patients increases, there is an incremental increase in a facility's cost. It is also important to note that the thresholds established under the inpatient acute care hospital prospective payment system were statutorily mandated. Thus, we have decided to adjust the IRF payments set forth in this final rule for the percentage of low-income patients, but the adjustment does not have a threshold amount.

As we stated in the proposed rule, section 4403(b) of the BBA requires us to develop a Report to the Congress containing a formula for determining additional payment amounts to hospitals under section 1886(d)(5)(F) of the Act. In light of our current study of a new payment formula for determining adjustments for hospitals serving low-income patients and MedPAC's related recommendation, in the November 3, 2000 proposed rule, we indicated that we would consider these study results and other information as they become available and potentially refine the LIP adjustment in the future to ensure that we pay facilities in the most consistent and equitable manner possible.

Comment: One commenter requested clarification of whether all facilities will receive a LIP adjustment.

Response: All IRFs are eligible to receive a LIP adjustment. There is not a required threshold for a minimum number of beds or a minimum amount of DSH in order to receive the adjustment.

In accordance with proposed § 412.624(e)(2), which we are adopting as final, for the payment rates set forth in this final rule, we multiply each IRF's payment by the following formula to account for the cost of furnishing care to low-income patients:

(1+DSH) raised to the power of .4838

$$\text{Where DSH} = \frac{\text{Medicare SSI Days}}{\text{Total Medicare Days}} + \frac{\text{Medicaid, Non-Medicare Days}}{\text{Total Days}}$$

Comment: One commenter stated that the calculation of the LIP adjustment should exclude the data that we imputed for 46 IRFs. The commenter indicated that the regressions are extremely sensitive to these imputed values.

Response: In light of this comment, we analyzed the data to assess the extent to which the results of the multivariate regressions are sensitive to the imputed DSH values used to calculate the proposed adjustments. For the proposed rule, we used a 2-step process to impute missing values for our low-income patient measures: (1) For rehabilitation units where we were missing only the Medicaid days, we estimated the Medicaid rehabilitation days by applying the ratio of Medicaid acute care days to total acute care inpatient days to the total inpatient rehabilitation days. (2) If we were missing the SSI days or if we were also missing Medicaid days for the hospital, we imputed low-income variable values by assigning the State average DSH percentage for large urban and other facilities as appropriate. Our regression analyses indicated that the facilities

with missing values were significantly different from other facilities. The findings indicate that the results are sensitive to the imputation methodology described above.

In this final rule, we have modified the imputation methodology for imputing DSH values for the LIP adjustments. To impute, we estimate the proportion of non-Medicare days in the rehabilitation facility that are attributable to Medicaid patients as a function of two variables: the facility's percentage of Medicare patients who are entitled to SSI and the State in which the facility is located. The results of the regressions are not sensitive to this methodology (r-squared = .4159). We believe the value of including the imputations is that it allows us to address other concerns the industry expressed in its comments. Specifically, these concerns referred to the number of facilities used to calculate the payment rates. Using an imputation method allows us to include more facilities than we could have otherwise if we had not imputed DSH values for this final rule. In order for an IRF to be included in the analysis for the facility-level adjustment, all values of the independent variables examined under the regression must exist. For example, if we are missing the DSH value for certain facilities, even if we know the remainder of the independent variables (such as the wage index), we cannot include these facilities in the regression. Therefore, in this final rule we use an improved imputation methodology for the DSH variable that does not influence the results of the adjustments.

Comment: Several commenters expressed concern about the data used to measure DSH for purposes of calculating the LIP adjustment. Specifically, some commenters preferred the use of a DSH measure that better reflected the inpatient rehabilitation units, while others preferred the use of the overall acute care hospital DSH measure for the units.

Response: We constructed the DSH variable, as described above, using the latest data available at the time that we developed the proposed rule. Specifically, we used the ratio of Medicaid days to total days specific to the rehabilitation unit when the facility identified this information on its cost report. When the unit-specific information was unavailable, we used the overall Medicaid days and total days for the entire facility. For the SSI portion of the DSH variable, we used the acute care hospitals' ratio of SSI days to total Medicaid days for the rehabilitation units.

For purposes of constructing the LIP adjustment for this final rule, we obtained unit specific measures of the ratio of the SSI days to the total number of Medicare days. Further, we used the ratio of Medicaid (non-Medicare days) to total days when this information was available on the cost reports, in addition to the improved imputation methodology described above. Therefore, to the extent possible, the LIP adjustment set forth in this final rule is based on data specific to inpatient rehabilitation units, as well as freestanding inpatient rehabilitation hospitals. We believe data that are most reflective of the characteristics of the inpatient rehabilitation setting are most appropriate in determining payments under the IRF prospective payment system.

Comment: Some commenters suggested that differences in Medicaid coverage rules would disadvantage IRFs in certain States because of the LIP adjustment.

Response: In order to evaluate these concerns, we examined the feasibility of making an adjustment for the percentage of low-income patients using only the ratio of SSI to Medicare days. The results of this analysis indicated that the ratio of SSI to Medicare days would not predict the cost of a case as well as using the DSH variable. Specifically, the r-square value for the DSH variable is .0609 compared to the r-square value of .0525 for the SSI variable. Therefore, using the DSH variable enables us to develop a payment system that better predicts IRF costs compared to using the SSI variable. We acknowledge that Medicaid coverage rules may vary from State to State. However, based on considerable analysis, we believe that the DSH variable is the best current predictor of costs associated with treating low-income patients in IRFs. In addition, it is unclear whether certain IRFs in States are disadvantaged in the context of the entire payment (reflecting all adjustments). Further, analysis of the ''new payment to current payment ratios'' illustrated in Table II of section VIII. of this final rule indicates that the IRFs with the lowest DSH percentages gain approximately 2 percent of estimated payments under the IRF prospective payment system, while IRFs with moderate levels of DSH lose approximately 1 or 2 percent of estimated payments under the IRF prospective payment system. Therefore, if an IRF has a DSH amount that is lower than average due to Medicaid coverage rules for its State, the IRF may still experience a gain in payments under the IRF prospective payment system. In the future, we will assess the extent to which DSH continues to measure the percentage of low-income patients adequately. This future analysis may include the effect of the LIP adjustment on IRFs in various States.

Comment: Some commenters requested clarification of how new providers would receive DSH payment adjustments.

Response: New providers will receive a LIP adjustment when cost report data are available to determine a DSH amount. Until information from the cost report is available, the information used to calculate DSH is unknown and we will not be unable to determine the LIP adjustment. Once we have the information from the cost report, we will make final payments for the previous appropriate year in a lump sum and we will use these data in the calculation of future interim payments. We will issue further instructions in a Medicare program memorandum regarding the details of implementing this policy.

Comment: One commenter suggested that the LIP adjustment is beyond our legislative authority and stated that the LIP adjustment fulfills no policy objectives.

Response: Section 1886(j)(3)(A)(v) of the Act gives the Secretary broad authority to adjust the prospective payment rates by ''such other factors as the Secretary determines are necessary to properly reflect variations in necessary costs of treatment among rehabilitation facilities.'' Through the multivariate regression analyses described above, we found that providing a LIP adjustment would allow us to match payment more closely to cost. Therefore, as a matter of policy, the purpose of the LIP adjustment for the payment rates set forth in this final rule is to pay IRFs more accurately for the incremental increase in Medicare costs associated with the facility's percentage of low-income patients.

6. Adjustments for Alaska and Hawaii

Section 1886(j)(4)(B) provides that the Secretary is authorized, but not required, to take into account the unique circumstances of IRFs located in Alaska and Hawaii. There are currently three IRFs in Hawaii and one in Alaska. However, for the proposed rule, we had cost and case-mix data for only one of the facilities in Hawaii (982 cases) and the facility in Alaska (117 cases). Due to the small number of cases, analyses of the simulation results were inconclusive regarding whether a cost-of-living adjustment would improve payment equity for these facilities. Therefore, we did not propose to make an adjustment

for rehabilitation facilities located in Alaska and Hawaii.

Comment: A few commenters suggested that a cost-of-living adjustment for Hawaii and Alaska should be revisited.

Response: As with the proposed rule, in determining the adjustments for the final rule, we had cost and case-mix data for only one of the facilities in Hawaii and the facility in Alaska. Further, the total number of cases in the 1999 data (783) is smaller. Due to the small number of cases, analyses of the simulation results were inconclusive regarding whether a cost-of-living adjustment would improve payment equity for these facilities. Therefore, we are not making an adjustment under section 1886(j)(4)(B) of the Act for rehabilitation facilities located in Alaska and Hawaii for the payment rates set forth in this final rule.

7. Adjustments for Cost Outliers

Section 1886(j)(4) of the Act specifies that the Secretary is authorized, but not required, to provide for additional payments for outlier cases. Further, section 1886(j)(4)(A)(iii) of the Act specifies that the total amount of the additional payments for outliers cannot be projected to exceed 5 percent of the total Medicare payments to IRFs in a given year. Providing additional payments for costs that are beyond a facility's control can strongly improve the accuracy of the IRF prospective payment system in determining resource costs at the patient and facility level. In general, outlier payments reduce the financial risk that would otherwise be substantial due to the relatively small size of many rehabilitation facilities. These additional payments reduce the financial losses caused by treating patients who require more costly care and, therefore, will reduce the incentives to underserve these patients.

In the November 3, 2000 proposed rule (65 FR 66357), we considered various outlier policy options. Specifically, we examined outlier policies using 3, 4, and 5 percent of the total estimated payments. In order to determine the most appropriate outlier policy, we analyzed the extent to which the various options reduce financial risk, reduce incentives to underserve costly beneficiaries, and improve the overall fairness of the system. We proposed an outlier policy of 3 percent of total estimated payments because we believed this option would optimize the extent to which we could protect vulnerable facilities, while still providing adequate payment for all other cases.

We proposed under § 412.624(e)(4) to make outlier payments for discharges whose estimated cost exceeds an adjusted threshold amount ($7,066 multiplied by the facility's adjustments) plus the adjusted CMG payment. We would adjust both the loss threshold and the CMG payment amount for wages, rural location, and disproportionate share. We proposed to calculate the estimated cost of a case by multiplying an overall facility-specific cost-to-charge ratio by the charge. Based on analysis of payment-to-cost ratios for outlier cases, and consistent with the marginal cost factor used under section 1886(d) of the Act, we proposed to pay outlier cases 80 percent of the difference between the estimated cost of the case and the outlier threshold (the sum of the CMG payment and the loss amount of $7,066, as adjusted). We calculated the outlier threshold by simulating aggregate payments with and without an outlier policy, and applying an iterative process to determine a threshold that would result in outlier payments being equal to 3 percent of total payments under the simulation.

Comment: Some commenters suggested that adjusting the outlier threshold by the rural adjustment and the LIP adjustment would be inappropriate.

Response: In the proposed rule, we stated that the outlier threshold of $7,066 was to be multiplied by the facility-level adjustments reflecting facility characteristics such as geographic location and LIP. Before the above calculation can be done, we must first determine if any facility characteristics affect the cost of a case. Then we determine adjustments for these characteristics. As we previously discussed, the data showed that wage variation, IRFs located in rural areas, and the percentage of low-income patients affect case costs. Further, we calculate an IRF standardized budget neutral conversion factor that eliminates the effects of the IRF adjustments. We then determine the appropriate outlier percentage based on analyses of the data. As in the proposed rule, in this final rule we calculate the standardized threshold amount by eliminating the effects of the various adjustments. The standardized outlier threshold for the payment rates set forth in this final rule is $11,211. In this final rule, as with the proposed rule, the standardized outlier threshold is then adjusted for each IRF to account for its wage adjustment, its LIP adjustment, and its rural adjustment, if applicable. Using this facility-specific adjusted threshold amount to determine eligibility for outlier payments results in facility payments that do not unduly harm any particular class of IRFs and appears to distribute payments more equitably among the various cases as shown in section VIII. of this final rule. Therefore, we believe applying the facility-level adjustment to the threshold amount is appropriate.

Comment: Some commenters, including MedPAC, suggested increasing the outlier provision from the proposed 3 percent to the full 5 percent allowed under the BBA. One commenter suggested that if we address the issue of compression with the relative weights (which we discuss in response to an earlier comment in this section VI. of this final rule), the increase to 5 percent may not be necessary.

Response: Since outlier payments are a redistribution of payment, it is important to set the outlier percentage so that it maximizes resources available for all types of cases while still protecting a facility from the financial risk associated with extremely high-cost cases. As we stated earlier, section 1886(j)(4) of the Act authorizes, but does not require, us to provide for additional payments for outlier cases. Further, section 1886(j)(4)(A)(iii) of the Act provides that the total amount of the additional payments cannot be projected to exceed 5 percent of the total payments projected or estimated to be made to prospective payment units in a given year. The outlier policy options specified in the proposed rule were evaluated by analyzing financial risk, accuracy of payment at the case level, and accuracy of payment at the hospital level.

We measure financial risk of an IRF using the standard deviation of annual profit as a fraction of expected annual revenue. The outlier payment decreases the financial risk of an IRF as the outlier percentage increases. However, financial risk decreases at a declining rate of improvements as the outlier percentage increases. These results indicate that an outlier percentage lower than the statutory maximum amount of 5 percent of total estimated payments would allow us to pay more appropriately for both outlier and nonoutlier cases.

Increasing the percentage of the outlier policy would leave less payments available to cover the costs of nonoutlier cases, due to the budget neutral provision of the statute. Specifically, an increase in the outlier percentage would decrease the budget neutral conversion factor and reduce payment for all nonoutlier cases. Although the purpose of outlier payments is to funnel more payments to high-cost cases in which the IRF

prospective payment system payment would be substantially less than the cost of the case, it is possible that in some instances the IRF total prospective payment, including the outlier payment, will exceed the cost of the case. Paying cases more than costs may occur with outlier payments because an IRF's overall cost-to-charge ratio, which is used to derive the estimated cost of the case to determine if the case is an outlier may differ substantially from an actual department (for example, a physical therapy cost center) cost-to-charge ratio in which the services are delivered. Specifically, analysis of the various outlier percentage options for the proposed rule illustrated that the amount by which payment is more than cost increases substantially as the outlier percentage increases. Simulating payments using the 1997 data, the 1-percent outlier payment policy option resulted in an estimated total ''overpayment'' of approximately $300,000. When we simulated a 3-percent outlier percentage, estimated ''overpayments'' were at $1.0 million, and when we simulated outlier payments at 5 percent, ''overpayments'' almost doubled to $1.9 million.

Outlier payments funnel more resources to the most costly cases, which improves accuracy of payment at the case level. This is evident in the analysis of r-squared values, a statistical measure of how well the outlier payment matches the costs of the case. The percent improvement of the predictive r-squared value decreases as the outlier payment percentage increases. Using the 1997 cost data, going from the ''no outlier'' policy option to setting the outlier policy at 1 percent increases the r-squared value by 30.7 percent, while going from a 4-percent to a 5-percent outlier payment percentage increases the r-squared value by only 4.2 percent.

To evaluate an outlier policy at the hospital level, we compared payment-to-cost ratios over each outlier percentage option. Because outliers in the data sample appeared to be widely distributed across all types of hospitals, we found that the amount of the outlier payment has little effect on the payment-to-cost ratio for any specific group at the hospital level.

In summary, the results of financial risk, accuracy at the case level, and accuracy at the hospital level suggest that there should be a limit on the outlier percentage that is less than the statutory limit and that balances the need to compensate accurately for high-cost care while still maximizing remaining resources to improve the payment accuracy of nonoutlier cases. The 3-percent outlier policy set forth in the proposed rule reflected a careful analysis of the previously discussed issues and research that supported this policy. Therefore, under § 412.624(e)(4) of this final rule, we are adopting the outlier policy that we had proposed. Accordingly, we are establishing an outlier policy to adjust payments under § 412.624(d)(1) of this final rule. This outlier policy reflects 3 percent of estimated aggregate payments under the IRF prospective payment system.

Comment: Some commenters requested clarification of how new facilities will be able to qualify for outlier payments, since these facilities will not have the historical cost reports needed to compute the estimated cost that determines if the case is an outlier.

Response: We will calculate national average cost-to-charge ratios for urban and rural areas. We will apply these cost-to-charge ratios to new facilities based on the facility's urban or rural status.

Comment: Some commenters requested clarification of whether we will pay more or less for outlier cases retrospectively based on actual cost-to-charge ratios once they exist.

Response: We will not make any retrospective adjustments for outlier payments.

Comment: A few commenters suggested that we adjust payments in the initial 5 years of the IRF prospective payment system in order to provide a financial cushion for hospitals that experience significant losses.

Response: We developed the adjustments described in this final rule based on an analysis of empirical data, as well as consideration of numerous comments. The impacts of the IRF prospective payment system among the various classes of providers are shown in section VIII. of this final rule. In general, the new payment to current payment ratios in Table II of section VIII. of this preamble illustrate that most groups of providers will benefit under the IRF prospective payment system. Further, based on these impacts, there is no strong indication that any particular group of providers will experience significant losses under the IRF prospective payment system. Therefore, we are not adopting the suggestion to provide an additional adjustment for those facilities that may be paid less than their costs under the IRF prospective payment system.

Comment: Some commenters requested clarification regarding the order in which the case-level and facility-level payment provisions apply to a case.

Response: First, we will discuss the order in which the case-level adjustments (excluding outlier payments) may apply to a case. Then we will describe the order in which the facility-level adjustments apply. Lastly, we will discuss the possible application of outlier payments.

The first case-level adjustment that needs to be considered for possible application is whether or not the case meets the definition of an interrupted stay. If the case meets the definition of an interrupted stay, then one CMG payment will be made based on the assessments from the initial stay. Also, if the case meets the definition of an interrupted stay, the total number of days the beneficiary was in the IRF, both prior to and after the interruption, is counted in order to determine if the case meets the definition of a transfer case or the short-stay CMG.

The next case-level adjustment considered for application is the transfer policy. To do this, the length of stay is considered, as well as the discharge destination. Specifically, if the length of stay of the case is less than the average length of stay for the given CMG and the patient is transferred to another IRF, long-term care hospital, inpatient hospital, or nursing home that accepts Medicare or Medicaid, then the case will be considered to be a transfer. If the case is not a transfer, then we determine whether or not the case falls under the short-stay CMG where the length of stay is 3 days or less, irrespective of whether the beneficiary expired. If the beneficiary's length of stay is more than 3 days and he or she expires, one of the four CMGs for expired cases will be applicable, depending on the length of stay and whether the beneficiary is classified to an orthopedic RIC or not. If none of the above case-level adjustments are applicable to a given case, then the case is classified to the appropriate CMG.

After the appropriate case-level adjustments and the CMG is assigned, facility-level adjustments will be applied. First, the wage adjustment is applied by taking the labor-related share of the payment, multiplying by the appropriate wage index, and adding the results to the nonlabor-related portion of the payment. Then the adjustment for low-income patients is determined and multiplied by the wage adjusted payment. Also, if the IRF is a rural facility, the payment will be further multiplied by 1.1914. After all the adjustments described above, both case-level and facility-level, are applied to a case, a determination can be made as to whether or not an outlier payment is warranted.

E. Calculation of the Budget Neutral Conversion Factor

1. Overview of Development of the Budget Neutral Conversion Factor

Prior to BIPA, section 1886(j)(3)(B) of the Act specified that, for prospective payment units during FYs 2001 and 2002, the amount of total payments, including any payment adjustments under sections 1886(j)(4) and (6) of the Act, must be projected to equal 98 percent of the amount of payments that would have been made during these fiscal years for operating and capital-related costs of rehabilitation facilities had section 1886(j) of the Act not been enacted. We proposed to incorporate this provision in proposed § 412.624(d).

Under proposed § 412.624(c)(1) and (c)(3), we proposed to calculate the budget neutral conversion factor using the following steps:

Step 1—Update the latest cost report data to the midpoint of the fiscal year 2001.

Step 2—Estimate total payments under the current payment system.

Step 3—Calculate the average weighted payment per discharge amount under the current payment system.

Step 4—Estimate new payments under the proposed payment system without a budget neutral adjustment.

Step 5—Determine the budget neutral conversion factor.

These same steps are used in developing the payment rates set forth in this final rule.

However, in this final rule, we update the latest cost report data to the midpoint of the FY 2002 because the IRF prospective payment system will be implemented on or after January 1, 2002 and before October 1, 2002.

2. Steps for Developing the Budget Neutral Conversion Factor

• *Data Sources*

In the November 3, 2000 proposed rule, the data sources that we proposed under § 412.624(a)(1) to construct the budget neutral conversion factor included the cost report data from FYs 1995, 1996, and 1997, a list obtained from the fiscal intermediaries of facility-specific target amounts applicable for providers that applied to rebase their target amount in FY 1998, and calendar year 1996 and 1997 Medicare claims with corresponding UDSmr or COS (FIM) data. We used data from 508 facilities to calculate the budget neutral conversion factor. These facilities represented those providers for which we had cost report data available from FYs 1995, 1996, and 1997. We used the 3 years of cost report data to trend the data to the midpoint of the year 2001 based on the facilities' historical relationship of costs and target amounts.

In the proposed rule, we indicated that we were unable to calculate payment under the current payment system for some IRFs because cost report data were unavailable. We stated that we would attempt to obtain the most recent payment amounts for these IRFs through their Medicare fiscal intermediaries and we would consider using these data to construct the payment rates for the final rule. We also indicated that we would examine the extent to which certain IRFs (such as new facilities) are not included in the construction of the budget neutral conversion factor, and would consider the appropriateness of an adjustment to reflect total estimated payments for IRFs more accurately.

In addition, because we did not have FIM data for all rehabilitation facilities, we indicated that for the final rule we would further analyze the extent to which the data used to construct the budget neutral conversion factor accurately reflect the relationship between case-mix and cost. We stated that we were considering the use of weighted averages to account more fully for those types of facilities that might be underrepresented with the given data.

Comment: Some commenters suggested that the sample of IRFs used to develop the budget neutral conversion factor was not representative of all IRFs in terms of size, location, and case-mix. They added that a nonrepresentative sample would skew the development of a budget neutral conversion factor.

Response: To address these concerns, for the final rule we used more IRFs in the construction of the budget neutral conversion factor. To do this, we modified the update methodology to include newer IRFs for which we were unable to obtain cost report data for FYs 1996, 1997, and 1998. We explain the modifications to the update methods below.

For IRFs that did not have cost report data for FYs 1996, 1997, and 1998, we updated their cost report data by applying the excluded hospital operating market basket update. For instance, if an IRF was new in FY 1997, we applied the excluded hospital operating market basket to update its cost report data to FY 1999. If the IRF was new in FY 1998, we used the excluded hospital operating market basket update to update its cost report data for FY 1999 and FY 2000. For IRFs that were not considered ''new,'' we used cost report data from FYs 1996, 1997, and 1998 to trend the data to the midpoint of the year 2001 based on the IRF's historical relationship of costs and target amounts. The FY 1996 cost report data were used to determine the update to be used for FY 1999; the FY 1997 cost report data were used to determine the update to be used for FY 2000; and the FY 1998 cost report data were used to determine the update for FY 2001.

In the proposed rule, we discussed the methodology for developing the budget neutral conversion factor in which we used data from only those IRFs that we had matching bill and FIM data and historical cost report data. In the proposed rule, we stated our intent to further analyze the extent to which the data used to construct the budget neutral conversion factor accurately reflects the relationship between case-mix and cost. Through this further analysis, we are able to include more IRFs into the data used to construct the budget neutral conversion factor. Including more IRFs with characteristics, as well as more cases in addition to the data for which we have Medicare bills matched with FIM data, allows for the development of prospective payments that will better reflect the IRF population.

The CMI for an IRF is computed as the average of the CMG relative weights for all rehabilitation cases for that particular facility. The CMI reflects resource use and can be regarded as a measure of the average relative cost of each IRF's cases. Because case payment under the IRF will be a function of the budget neutral conversion factor as well as case-level and facility-level adjustments, the conversion factor can be influenced by each facility's historical CMI.

In an attempt to include IRFs, as well as cases, with missing FIM data in the calculation of the budget neutral conversion factor, we developed a technique to estimate CMI data for these facilities. By utilizing the relationship between case-level and facility-level characteristics and their predictive power of an IRF's CMI, we can include more IRFs in the calculation of the budget neutral conversion factor, which should better reflect the characteristics of all types of facilities. We are able to estimate the CMI because we can obtain pertinent information regarding the characteristics of all IRFs, such as the facility's TEFRA payment, the facility's adjustment factor(s), (the wage adjustment, the LIP adjustment, and, if applicable, the rural adjustment) and other facility characteristics (for example, freestanding/unit status). We also use pertinent information regarding the characteristics of a case (even those cases for which we do not have matched