

**Request for a Temporary Waiver of the 75% Rule
and a Limited Waiver from Local Coverage Decisions
for IRFs Participating in Study on the Optimal Post-acute
Placement of Patients with Lower Extremity Joint Replacements**

The National Rehabilitation Hospital (NRH) Research Division and its partner, the Institute for Clinical Outcomes Research (ICOR), are implementing a study protocol to examine the post-acute management and treatment of patients with hip and knee replacements in skilled nursing facilities (SNFs) and inpatient rehabilitation facilities (IRFs). During contacts with prospective IRF participants, the issue of a temporary waiver of the 75% Rule has been raised. There appears to be a risk that, if the compliance thresholds included in the Rule are increased over the next two years as currently planned, we may lose the opportunity to compare SNF- and IRF-based rehabilitation for joint replacement patients because of the narrowing mix of joint replacement admitted to IRFs.

Accordingly, we are requesting a limited waiver for IRFs who participate in the study. Specifically, we are requesting:

- 1. That lower extremity joint replacement patients (Rehabilitation Impairment Group (RIG) 08 or CMG 801-806) accepted into the study count neither for, nor against, an IRF's compliance with the 75% Rule.** In other words, these joint replacement patients would be counted neither in the numerator nor in the denominator in computing a participating IRF's compliance with the 75% Rule in a given year.
- 2. That the two-month period following the discharge of the last study patient not be included in the calculation of a participating facility' compliance with the 75% Rule. This grace period is necessary in order allow participating facilities a reasonable opportunity to adjust patient referral patterns and clinical programs to reduce the volume of lower extremity joint patients in order to resume compliance with the Rule.**
- 3. That the application of Local Coverage Determinations be waived with respect to lower extremity joint replacement patients admitted to the study.**

The Centers for Medicare and Medicaid Services (CMS) has determined that, except in relatively rare instances, joint replacement patients should not be counted on the list of the 13 types of patients used to define an IRF. CMS made this determination in the absence of any large-scale studies. Since the rule was published, the RAND Corporation conducted a large scale study for the Medicare Payment Advisory Commission (MedPAC) comparing outcomes and expenditures for Medicare joint replacement beneficiaries in IRFs and SNFs. Because of the limitations inherent in administrative data, this study proved inconclusive.

IRFs face additional pressures from Medicare fiscal intermediaries (FIs) that have implemented new guidelines, known as local coverage decisions (LCDs), previously known as local medical review policies (LMRPs). These guidelines also limit the types of patients who can be admitted to IRFs. The precise effects of these FI decisions remain unknown but some believe that their effects may eventually supersede the effects of CMS's gradual enforcement of

the 75% Rule. **We are therefore also requesting a waiver of LCD restrictions applicable to lower extremity joint replacement patients accepted into the study.**

We have a limited window of opportunity to determine the optimal post-acute setting for joint rehabilitation patients. In many locations, IRFs are already limiting the types of joint replacement patients they admit because these patients do not count toward meeting the required threshold under the 75% Rule. The risk is that the pool of joint replacement patients seen in IRFs will continually diminish over the next two years among facilities participating in the study. This will make it increasingly difficult to make comparisons across a spectrum of joint replacement patients. Indeed the 75% Rule's effect on the ability to pursue meaningful and usable research was discussed earlier this year during an NIH/CMS-sponsored workshop to discuss possible research agendas.

Several kinds of studies could be initiated to address the issue of SNF- and IRF-based rehabilitation for joint replacement patients—from strong observational cohort studies to randomized trials. In the face of its own limited research budget, CMS has acknowledged the general lack of research on this topic and has urged industry leaders and others to step to the plate and sponsor the kinds of studies needed to answer the questions that plague policy makers with respect to the purchase of post-acute rehabilitation services.¹ The IRF industry has done just that **by sponsoring a full, open, no-bars-held research study** and is encouraging numerous others, including representatives of the SNF industry, to participate.

CMS and health plans want to be prudent purchasers of post-acute services. To some extent, the SNF-IRF dichotomy is a false one and yet it is the way the research question is often framed. Neither IRFs nor SNFs provide uniform packages of services for similar patients. Practice patterns in both post-acute industries are believed to vary widely especially among SNFs. We need to obtain a better understanding of how service settings vary in the types of services they render and how these services vary in terms of timing, intensity, frequency, duration, and cost. We also need to learn which combinations of services are associated with superior outcomes—and the relative cost-effectiveness of these combinations. Without these characterizations, health care payers such as CMS cannot make prudent purchases on behalf of taxpayers, employers, and other groups.

In the accompanying tables and charts we present recent trends in the numbers of lower extremity Medicare patients going to IRFs. We report from two data sources. The first is from eRehabdata, an industry-sponsored database with approximately 180 IRF subscribers. The second is from the Uniform Data System for Medical Rehabilitation (UDS_{MR}), a database with approximately 800 IRF subscribers. Together these two databases include about 80% of all IRFs in the nation. Because the number of IRFs reporting to these databases varies over time, we report only “same-store” numbers, i.e., data from facilities in each database that reported data for the entire period under review. This eliminates fluctuations that may arise because of the changing number of reporting facilities in each database. Thus, we report data from 144 IRFs

¹ See, for example, *Medicare Program; Changes to the Criteria for being Classified as an Inpatient Rehabilitation Facility* (Final “75% Rule” / preamble discussion), 69 Fed. Reg. 25752, 25763 (May 7, 2004). Also see, *Medicare Program: Inpatient Rehabilitation Compliance Criteria*, 70 Fed. Reg. (June 24, 2005) where CMS states: “...we are actively encouraging government clinical research organizations, academic institutions, and industry rehabilitation groups to conduct both general and targeted research that would inform all interested parties regarding the types of patients that would most benefit from intensive inpatient rehabilitation.”

reporting to eRehabdata and 611 IRFs reporting to UDS over the entire period under review (from the 1st quarter of 2002 to the 2nd quarter of 2005).

In examining the data, there are four points in time to consider:

- **January 1, 2002.** CMS implements the Medicare prospective payment system (PPS) for IRFs.
- **4th Quarter, 2003.** The quarter in which the overall number of joint replacement admissions to IRFs peak out prior to the reinforcement of the 75% Rule.
- **July 1, 2004.** CMS begins 3-year transition period toward full implementation of 75% Rule: 50% of patients admitted to IRFs must come from one of 13 conditions starting July 1, 2004; 60% starting July 1, 2005; 65% starting July 1, 2006; and 75% starting July 1, 2007.

Both databases report a similar steady decline in the numbers Medicare beneficiaries with LE joint replacement being admitted to IRFs. This decline is occurring while the industry is still in the beginning stages of the 3-year phase-in toward full implementation of the 75% Rule. We cannot determine with certainty whether current trends will continue but a straight-line projection would suggest an ever diminishing pool of joint replacement patients in IRFs that will become available to the study. Moreover, the mix of joint replacement patients is changing with relatively small numbers of patients in some CMGs (e.g., CMG 801, 802, 805). This may limit the numbers of certain kinds of joint replacement patients entering the study and reduce the generalizability of the study's findings to those types of patients.

We estimate that 8-12 IRFs (target of 10 IRFs) will be participating in the study and request that patients admitted into the study within these facilities be exempt from the 75% rule and from LCD coverage restrictions on admission of lower extremity joint replacement patients.

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Table 1
Joint Replacement Patients in IRFs Reporting to eRehabdata.com
(N=144 IRFs;² Medicare only)³

	2002				2003				2004				2005		Change from Q4 '03 to Q2 '05	
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Number	Percent
All RIC 08 CMGs	4725	5425	5427	5704	5282	5901	5899	6289	5786	6215	5979	6027	5254	4473	-1816	-28.9%
Case mix index	0.67	0.68	0.69	0.70	0.69	0.70	0.70	0.70	0.70	0.70	0.71	0.72	0.71	0.73	+0.03	+4.3%
CMG 801⁴	379	362	341	380	344	310	337	335	328	323	300	272	234	166	-169	-50.4%
CMG 802	379	410	374	352	325	351	334	345	329	352	346	316	269	225	-120	-34.8%
CMG 803	1672	1966	1846	1937	1878	2046	2063	2151	2000	2221	2074	2072	1820	1402	-749	-34.8%
CMG 804	1296	1535	1561	1606	1452	1727	1609	1857	1680	1629	1606	1642	1454	1311	-546	-29.4%
CMG 805	426	510	570	615	565	695	728	806	673	821	772	843	727	625	-181	-22.5%
CMG 806	573	642	735	814	718	772	828	795	776	869	881	882	750	744	-51	-6.4%

Source: eRehabdata.com

²All 144 IRFs reported data for the entire period reported here, from the 1st quarter of 2002 through the 2nd quarter of 2005—the most recent quarter with complete data for the entire quarter.

³Boldface numbers indicate high-water mark in number of admissions of joint replacement patients to IRF facilities reporting to eRehabdata.

⁴ CMGs are listed from least severe (CMG 801) to most severe (CMG 806).

Table 2
Joint Replacement Patients in IRFs Reporting to eRehabdata.com
(N=144 IRFs;⁵ All Payers)⁶

	2002				2003				2004				2005		Change from Q4 '03 to Q2 '05	
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Number	Percent
All RIC 08 CMGs	8041	9127	9543	10138	8993	10175	10316	10819	9747	10375	9657	9672	8845	7367	-3452	-31.9%
Case Mix Index	0.65	0.66	0.67	0.67	0.67	0.68	0.68	0.68	0.67	0.68	0.69	0.70	0.70	0.71	0.03	4.4%
CMG 801⁷	760	762	752	816	738	679	712	720	688	659	557	518	445	385	-335	-46.5%
CMG 802	696	778	727	773	656	723	675	724	685	678	615	577	490	452	-272	-37.6%
CMG 803	2911	3423	3496	3754	3282	3696	3788	3932	3536	3945	3577	3484	3052	2449	-1483	-37.7%
CMG 804	2183	2475	2659	2653	2434	2863	2805	3029	2716	2665	2551	2653	2374	2142	-887	-29.3%
Source: eRehabdata.com CMG 805	688	786	851	982	894	1093	1155	1223	1069	1235	1158	1202	1052	911	-312	-25.5%
CMG 806	803	903	1058	1160	989	1121	1181	1191	1053	1193	1199	1238	1032	1028	-163	-13.7%

Source: eRehabdata.com

⁵All 144 IRFs reported data for the entire period reported here, from the 1st quarter of 2002 through the 2nd quarter of 2005—the most recent quarter with complete data for the entire quarter.

⁶Boldface numbers indicate high-water mark in number of admissions of joint replacement patients to IRF facilities reporting to eRehabdata.

⁷ CMGs are listed from least severe (CMG 801) to most severe (CMG 806).