

# JOINTS STUDY



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October 17, 2005

Mark B. McClellan, MD PhD  
Administrator  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
Baltimore MD 21244-1850

**RE: Request for a limited waiver of application of the 75% Rule to patients and facilities participating in a national study on post-acute rehabilitation for patients with lower extremity joint replacement**

Dear Dr. McClellan:

I am writing to request a very limited and temporary waiver from select CMS policies in order to assure the research integrity of a large national study on the rehabilitation of patients with lower extremity joint replacements in skilled nursing facilities (SNFs) and inpatient rehabilitation facilities (IRFs). A detailed description of a limited waiver of the 75% Rule for patients and facilities that participate in the study, along with supporting documentation and data, is provided in Attachment 1.

The goal of this study is to provide an in-depth characterization of care received in SNFs and IRFs, to identify the specific interventions that shape patient outcomes, and to aid decision makers in determining which setting of care may be more effective and cost-effective for which types of joint replacement patients. The 2-year study entails the participation of approximately 20 facilities selected from across the nation and will include 2,800 patients when completed. An abstract of the study is provided in Attachment 2.

Known as the JOINTS Study [Joint Replacement Outcomes in IRFs and Nursing Treatment Sites], this study responds to CMS's call for government, academic, and "industry rehabilitation groups to conduct general and targeted research that would inform all interested parties regarding the types of patients that would benefit most from intensive inpatient rehabilitation" (70 Fed. Reg. (June 24, 2005)). This industry-sponsored study is a full and open inquiry to help determine what is best for joint replacement patients.

The JOINTS Study is being led by a team of researchers from the National Rehabilitation Hospital (NRH) in Washington, DC and the Institute for Clinical Outcomes Research (ICOR) in Salt Lake City. Both organizations come with a long-standing record in clinical and health services research in primary care, acute care, post-acute care, and long-term care. The NRH-ICOR team has collaborated on several projects—most recently on a large international multi-site stroke rehabilitation study that serves as a template for the current study. More information about the NRH-ICOR study team can be found in Attachment 3.

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Letter to Mark B. McClellan, MD PhD  
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A Policy Advisory Panel consisting of payer, provider, government, and consumer stakeholders has been assembled to advise NRH-ICOR study team in the design and implementation of the study. (A list of Panel members is provided in Attachment 4.) The Panel held its first meeting on September 27, 2005. Dr. James Bowman of the CMS Chronic Care Policy Group attended the meeting as an observer. The Panel made several key recommendations, one of which was to request CMS to approve a limited waiver of the 75% Rule for IRFs participating in the study.

We are requesting your earliest possible response in order to help maintain the research integrity of the study, provide greater certainty for participating facilities, and to help insure the generalizability of study findings. I am available for to answer any questions you or your staff may have.

Thank you for your consideration.

Sincerely,

Gerben DeJong, PhD  
Senior Fellow, National Rehabilitation Hospital  
& Principal Investigator, JOINTS Study

cc: Herb Kuhn, Director  
CMS Center for Medicare Management

Laurence Wilson, Director  
CMS Chronic Care Policy Group

Bob Kuhl, Director  
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James Bowman, MD, MBA, Medical Officer  
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Attachments:

Attachment 1: Waiver Request

Attachment 2: JOINTS Study Abstract

Attachment 3: The NRH-ICOR Team

Attachment 4: Policy Advisory Panel Members