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Rush Settlement with Government May Help Clarify Billing Requirements for Medicare Patients in Research Studies

Sets Model for Provider Compliance with National Coverage Decision on Clinical Trials

CHICAGO - A settlement agreement between Rush University Medical Center and the federal government may serve to clarify federal rules that academic medical centers must follow in billing the government for services provided to a Medicare patient in a clinical research study.

This is one of the first settlements of overpayments related solely to the National Coverage Decision (NCD) on Clinical Trials that in September 2000 defined how Medicare would reimburse providers for services to patients in a clinical trial, or research study.

Rush voluntarily disclosed the existence of billing errors to the federal government in 2003 and cooperated with the U.S. Attorney's Office for the Northern District of Illinois and the Office of Inspector General (OIG) for the Department of Health & Human Services in their review of the matter. At a recent national conference on health care compliance matters, a representative of the OIG discussed Rush's voluntary disclosure and corrective action as a model resolution to a compliance issue.

Medicare published the NCD on Clinical Trials in 2000 with the goal of encouraging more of its beneficiaries to participate in clinical trials. However, complexities and ambiguities in the NCD on Clinical Trials have presented significant compliance challenges for providers and suppliers. For example, each clinical trial must be uniquely analyzed to determine which items and services are billable to Medicare. In complex clinical trials, this means the provider

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must establish a process to analyze potentially hundreds of services and items over the course of a patient's treatment.

In 2003 Rush discovered that it had inadvertently billed Medicare for services provided during cancer therapy research studies that were not reimbursable under the NCD on Clinical Trials. Rush officials self-disclosed the matter to the U.S. Attorney's Office within 30 days of identifying the issue and implemented comprehensive measures to minimize the chances of further overpayments for cancer clinical trials. This included implementing a bill hold on cancer research charges within 10 days of discovering the issue, voluntarily expanding its internal investigation and subsequent corrective action to cover all clinical trials at Rush and developing a new billing process flow with a strong commitment to audit the new billing approach.

Rush will pay the United States and the State of Illinois approximately $1 million to settle the matter on the cancer clinical trials overpayments that covers a six year period. This includes approximately $278,000 of the payment representing a 50 percent penalty**.** The government could have imposed a penalty of up to three times the amount owed but did not because of Rush's cooperation, voluntary disclosure and establishment of a clinical trials process office at the medical center.

Approximately $53,000 of the amount will be paid to the Illinois Medicaid Program with the remainder to Medicare. The actual overpayment Rush received during this time period was approximately $669,000. This represents approximately 1.5% of the annual Medicare revenue to Rush for cancer therapy during the six year time period.

In recognition of Rush's model response and corrective actions, and the fact that there was no evidence of purposeful wrongdoing, the OIG did not require Rush to enter into a Corporate Integrity Agreement. Instead, the OIG requested Rush agree to certify its compliance

program annually for a period of three years. Rush's compliance program has been in existence since 1997 and has been credited with being an industry leader.

In the course of resolving this matter, Rush officials not only provided a formal presentation to the OIG in Washington, D.C. but Rush also met with representatives of the Centers for Medicare and Medicaid Services (CMS) in Baltimore, Maryland to provide feedback on the operational challenges in implementing the NCD on Clinical Trials. At Rush's meeting with CMS in October, Rush officials presented and discussed several structural ambiguities in the NCD on Clinical Trials.

"Our goal was to provide CMS with ideas about how they might clarify the wording of the Clinical Trials NCD so that it is consistent with the government's stated policy goal of encouraging Medicare patients to enroll in clinical trials," said Dr. Cynthia Boyd, Rush associate vice president and chief compliance officer.

"In the course of working through this issue, we realized that the academic medical community needs to take a new approach to how they manage compliance with the clinical trials billing rules. This involves a synchronization of the Medicare rules, the compensation arrangements with the sponsors and the financial discussion in the patient's informed consent. Research institutions need to have in place a financial analysis process and compliance process that determines whether a research-related procedure qualifies as billable to Medicare and then properly communicate these determinations to the billing information systems," she said.

As part of its corrective action, Rush established a new office, the Research & Clinical Trials Administration Office, to coordinate these operational efforts.

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Rush University Medical Center is an academic medical center that encompasses the 600 staffed-bed hospital (including Rush Children's Hospital), the Johnston R. Bowman Health Center and Rush University. Rush University, with more than 1,270 students, is home to one of the first medical schools in the Midwest, and one of the nation's top-ranked nursing colleges. Rush University also offers graduate programs in allied health and the basic sciences. Rush is noted for bringing together clinical care and research to address major health problems, including arthritis and orthopedic disorders, cancer, heart disease, mental illness, neurological disorders and diseases associated with aging.