Legal Corner

Navigating the Clinical Trial Billing Maze

By James B. Pfadenhauer

If you have been involved in clinical research, you have likely been confronted with how one handles billing for items and services that study participants receive over the course of a clinical trial. Indeed, disparate payer requirements and, often, a lack of coordination among investigators, research sites, and sponsors, have made billing in the clinical trial context a challenge. Complex Medicare rules add to the difficulty of getting clinical trial billing right—a fact brought home by Rush University Medical Center's settlement with the federal government regarding clinical trial billing improprieties in late 2005. This article describes the Rush situation and its implications for clinical trial billing and offers some suggestions for making the billing process associated with your future research activities go smoothly.

The Rush Situation

In December 2005, Chicago's Rush University Medical Center and the federal government entered into a settlement regarding clinical trial billing that has received significant attention in the research and legal communities. The issue at Rush began in 2003 with an internal review of the medical center's Division of Hematology and Oncology. The assessment revealed that certain services performed in the course of cancer research studies that were not reimbursable by Medicare (due to its rules regarding clinical trials) had in fact been billed to the program. Rush took decisive action upon its discovery of the billing errors. It instituted a bill hold for all clinical trial services within the Division of Hematology and Oncology, broadened the scope of its investigation of clinical trial billing practices, and, most notably, disclosed the billing issues to the federal government.

The result of Rush's self-disclosure was an agreement to pay approximately \$1 million, with \$53,000 paid to the Illinois Medicaid program and the remainder paid to Medicare, to settle the overpayment issue. The settlement covered a 6-year period and included a 50% penalty. Rush was not required to enter into a typical corporate integrity agreement, which would have required an independent organization to review Rush's compliance with the agreement's terms, but instead entered into a less onerous certification of compliance agreement that imposes certain reporting obligations on Rush and requires the medical center to certify annually that it is continuing its compliance program.

Implications of the Rush Settlement

Rush's self-disclosure and the government's response have caused many to look to the medical center's situation for

lessons on how to approach clinical trial billing properly and effectively. Rush's billing issues were attributed in large part to a lack of coordination between its research and billing operations, and its corrective action focused on the centralization of clinical trial billing processes within the medical center. An outgrowth of that effort is Rush's Research & Clinical Trials Administration Office, which conducts coverage analyses of all clinical trials and also is a liaison between the medical center's research and billing arms. Rush's initial coverage analysis occurs when a study is proposed and assesses whether a trial is feasible from a financial perspective. Rush conducts a final coverage analysis that takes the informed consent documentation (which can affect what is billable and what is not), sponsorship budget, and study protocol into account to create tools that allow for proper billing to payers, including Medicare.

Suggestions Going Forward

There are steps you can take to increase the likelihood that proper billing will occur in connection with research in which you are involved.

First, if you are acting as the investigator for a study and are negotiating the sponsorship agreement with the research sponsor, you can avoid future billing snarls by involving hospital billing and research administration personnel early in the discussion—even if the hospital does not have a process in place for centralized sponsorship agreement negotiation. Second, keep an open dialogue with hospital billing personnel throughout the course of a trial so that questions from you or them can be addressed efficiently. Finally, if your hospital does not already have a central office responsible for clinical trial compliance, urge hospital administration to consider establishing an office to perform this function.

These steps will not guarantee that proper billing occurs, of course, but they should serve to help you access resources that will facilitate appropriate billing in the clinical trial context; that is, resources that can assist you in navigating the clinical trial billing maze.

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Editor's note: For more information on the clinical research billing issue, see page 265 for lessons learned from the two principals involved at Rush University.

The information contained in this article is general in nature. It is not intended to be, and should not be construed as, legal advice relating to any particular situation.