December 2005 Rush University Medical Center Settlement: Improper Medicare Billing in Clinical Trials under September 2000 NCD

On December 8, 2005, the United States Attorney's Office for the Northern District of Illinois reached a settlement with Rush University Medical Center in Chicago, under which Rush agreed to repay approximately $1 million to the federal and state governments for inappropriate clinical trials charges submitted to Medicare and Medicaid. According to a press release issued by Rush, these charges relate to services and items provided by Rush and its staff to patients enrolled in oncology clinical trials at that hospital. About a quarter of the $1 million payment represents a fine for the improper billing of these federally-funded health care programs; this fine was part of the settlement, even though, according to the Rush press release, the settlement was the direct result of a voluntary disclosure by Rush to federal authorities.

This recent settlement indicates that federal enforcement of Medicare and Medicaid clinical trials billing restrictions by U.S. Attorneys and by the HHS Office of the Inspector General (OIG) may be looming over hospitals, medical centers, and physician and faculty group practices. This area of billing is complicated by confusing and ambiguous billing rules, the unclear medical necessity of many services rendered to patients enrolled in clinical trials, and the presence of industry funding for many of these trials -- funding representing external payment for medical services that therefore may not be billed to any third party payor. Institutionally, most hospitals and physician practices are handicapped in implementing compliance efforts in this area because the process of negotiating clinical trials budgets with industry or government is largely insulated from the process of Part A and Part B billing. The predictable result is that too often, bills for either facility or physician services are generated, submitted and paid, even though the underlying services may not be medically necessary (and thus should not have been billed) or may already have been paid for in the study budget, thus offending the rule that Medicare is always a secondary payor and/or the principle that services should not be "double-billed" or "double-paid."

Alarmingly, although some medical centers have begun to implement embryonic forms of compliance to control Part A billing in this area, few faculty practice plans or physician practices appear to have implemented such systems. The risk of significant (even treble) fines under the False Claims Act therefore must be considered by compliance officers, attorneys, and billing and finance officers.

There are actually three sets of Medicare principles that apply to the billing of services rendered in clinical trials: first, the "old" Medicare law that only medically necessary services may be billed and that services related to non-covered services (such as experimental agents and therapies) also may not be billed; second, the Category A and Category B medical device regulations governing trials of medical devices; and third, the National Coverage Decision issued in September 2000 that somewhat expands coverage for selected trials, including those funded by federal agencies like the NIH. In order for billing practices to be assessed in any one trial, a preliminary analysis must be done to determine which set of rules applies; then additional analysis must be done to determine which services and items in a trial qualify as billable; and at that point, funding from industry or government sponsors must be evaluated to determine which services have already

been paid for and are thus rendered not billable. Ideally, this analysis should be done before a clinical trial budget is negotiated, so that medical centers and physician practices can build into those budgets reimbursement for non-billable services.

For the past 10 years, Ropes & Gray attorneys have counseled clients throughout the country on these clinical trials billing issues. We also have aggressively defended clients in federal and state investigations of clinical trials billing. These clients have included medical centers, physician practices, faculty practices, and industry research sponsors. We have worked with provider clients to design both clinical trial study budget processes and billing systems that capture appropriate reimbursement but prevent inappropriate billing of third party payors.

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