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Hazards Of Billing For Health Care In Clinical Trials

Law360, New York (September 19, 2013, 6:27 PM ET) -- On Aug. 28, 2013, the United States attorney for the Northern District of Georgia and the Georgia attorney general announced that Emory University will pay $1.5 million to settle charges arising from an action brought by a whistleblower (Emory's former clinical research finance manager) alleging that Emory's Winship Cancer Institute had illegally billed Medicare, Medicaid and Tricare (formerly known as CHAMPUS) for clinical services that were, or should have been, paid for by the sponsors of the clinical trials.

This is just the latest reminder of the complexity and hazards inherent in billing for clinical care that is provided to patients enrolled in research trials. In its own statement, Emory correctly cited the "extremely complex" nature of billing for cancer patients enrolled in clinical trials.

In its November 2011 civil complaint, the government had accused Emory and several related institutions of utilizing "dysfunctional, substandard clinical study accounting and control systems which defendants knew or were reckless in not knowing would result in submission of false claims."[1]

The billing rules in question focus on the often blurry distinction between so-called "conventional care" (i.e., items or services typically provided absent a clinical trial) not covered by a sponsor's contract and items or services in the study beyond conventional care, which should be covered by the sponsor's contract.

In addition to conventional care, the Centers for Medicare & Medicaid Services rules allow for certain other items and services to be covered, such as items or services required solely for the provision of complications. But any item or service is by definition not covered if the sponsor customarily provides such items or services without charge to any enrollee in the trial.

These rules are so complicated, and the review process necessary to adhere to them is so elaborate that Emory included in its own statement an announcement that it will establish an entirely new billing department dedicated solely to research-related care.

What is more, the government's allegations of overbilling and double-billing were not limited to claims on behalf of federal and state governmental programs. The complaint also alleged that in some cases, the trial subjects — that is, the patients — had been billed for co-pay amounts, or their insurance companies had been billed, or both, when, in fact, the sponsor of the trial should have been responsible for those charges.

It bears emphasizing that in cases such as this, the issue is not simply whether the sponsor, in fact, paid for the services. The issue is not even simply whether the sponsor was billed. Rather, the issue is whether under the contract, the sponsor should have paid for the services.

So, to resolve the issue, the inquiry is not so much what the institution and the sponsor thought as what the contract said. Thus, the language of the sponsor contract is critical, irrespective of what the parties actually do or even what they believe.

One reason compliance is so difficult in these cases is that the situation often — even typically — involves numerous parties with varying, often inconsistent, interests. The Emory case provides an instructive illustration of this factor.

Defendants in the case included, in addition to Emory, the Woodruff Health Sciences Center, Emory Healthcare, the Emory School of Medicine, Grady Memorial Hospital and the Emory Clinic. The complaint recited that every clinical study at the medical school involved services at one or more of 11 Emory-related facilities. And, of course, the number of health care professionals involved in each study would dwarf that figure.

Somewhat chillingly, the government apparently regarded the inconsistency of financial interests among the defendants with some suspicion. Thus, the complaint recited that

the relationship between Emory and ESM [i.e., Emory School of Medicine], on one side, and Research Affiliates [i.e., the Emory-related provider institutions], on the other, is both symbiotic and zero-sum in that each side enables the other's success, yet the two sides must divide between the limited pool of cash provided by research grants and third-party insurers including Federal Health Care Programs.

Neither Emory nor its Medical School was necessarily the contracting party — that is, the party that negotiated and entered into the contract with the sponsor. The complaint noted that contracts in question were not negotiated with Emory or its medical school or even with any of the 11 health care facilities.

Rather, the contracts were negotiated by principal investigators and clinical research coordinators. Indeed, according to the complaint, contracts executed before June 2007 were entered into by individual academic departments without material assistance or supervision from the university or the medical school.

One especially noteworthy aspect of the case is the obvious years-long efforts on the part of the defendants to address the persistent problem of billing errors.

Indeed, the government cited, as evidence of the defendants' knowledge of noncompliance, the voluminous correspondence within and among the defendant institutions about the need to address the clinical billing problem. The government even cited the institutions' educational sessions on clinical trial billing compliance as evidence of that knowledge.

In this respect, an institution is in something of a Catch-22. As noted above, the government may cite correspondence and educational training on the subject as evidence that the institution knows what the rules are and understands them. But an institution certainly cannot safely avoid educational training sessions on the subject and probably cannot avoid correspondence, including email traffic, among employees.

The reason is that compliance with the rules takes more than knowledge of them at a high level within the organization. It requires constant, real-time monitoring by the many employees typically involved in registration, charting, coding and billing in connection with clinical trials. And often, these employees, who are vital to a compliant process, are neither highly educated nor highly paid.

Another lesson of the case is the shockingly high price that an institution may face for billing errors in clinical trial situations. Although the government filed a civil, rather than a criminal, case, nevertheless, the stakes were by no means limited to recovery of the overbilled amount.

In this case, the government invoked the False Claims Act. That automatically triples the potential liability of a defendant and at least raises the specter of criminal liability. In addition, such violations can carry a penalty of $11,000 per incorrect bill, and that is over and above the triple damage amount.

Finally, because the case arose as a qui tam action and involved allegations of retaliation against the employee whistleblower, the employer faced the prospect of responsibility for the attorneys' fees incurred by the whistleblower in bringing and pursuing the action. In sum, when it comes to billing errors in clinical trials, the potential liability can be enormous.

This case provides several practical lessons for academic medical centers and other institutions that have entered, or may contemplate entering, into clinical research trials that could involve patient care charges that may be borne by anyone other than the clinical trial sponsor.

Some of the lessons are reflected in the following guidelines:

- Make sure that everyone involved in the contract negotiations knows the billing rules and knows them cold.

- Keep the rules foremost in mind when negotiating the contract with the sponsor.

- Establish a contract negotiation process that provides for review and check-off by all appropriate parties — not simply the contracting party.

- Make sure that everyone involved in registration, charting, coding and billing knows the rules applicable to that particular part of the process and knows them cold.

- Establish a billing review process that provides for review and check-off by all appropriate parties.

- Before billing anyone other than the sponsor (and "anyone" includes patients who make co-payments and commercial insurers), make sure that it's not the sponsor's responsibility.

- Be alert to the evidentiary trail left by communications about the billing process; for example, try to assure that questions or comments about the process — especially those in writing — don't appear to be allegations of wrongdoing.

- Remember that anyone involved in, or knowledgeable about, the billing process could be a potential whistleblower.

- In formulating and adopting policies, remember that the institution may be held to the standard set by those policies, even if that standard is higher that the law requires.

Everyone acknowledges that the rules for billing for health care services in clinical trials are complicated and difficult in the extreme. Cases like the one reflected in the Emory announcement remind us that the government nevertheless stands ready to enforce them vigorously.

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[1] First amended complaint, United States v. Emory University, Civ. No. 1:09-cv-3569-AT (N.D. Ga. 2009) available at http://www.pacer.gov/psco/cgi-bin/links.pl (individual U.S. District court site Georgia Northern-ECF).