

## Part B Insider (Multispecialty) Coding Alert

### Physician Notes: Clinical Studies May Be at Risk for Kickback Attacks

#### Watch your copayment collection to avoid getting whacked

The intersection of clinical research and the anti-kickback statute is treacherous terrain now that Medicare covers more expenses related to clinical trials.

A Feb. 9 advisory opinion from the HHS Office of Inspector General (No. 04-01) makes the point. In it, the OIG addresses whether or not a medical supply manufacturer's waiver of Part B cost-sharing obligations for equipment used by Medicare beneficiaries in a clinical trial sponsored by the National Institutes of Health would constitute a violation of anti-kickback laws.

The OIG affirms that though the arrangement does wave kickback red flags, the parties in question wouldn't be subject to sanctions. Here's why:

The funding and overall organization, direction and treatment of the study are under the discretion of non-profit organizations.

The clinical study is not intended to benefit a specific product.

The study is undertaken for the public good, and the outcome would likely have "significant consequences" for Medicare beneficiaries.

**Warning:** Routine copay waivers remain a big risk area. Despite the OIG's conclusion in its first advisory opinion of 2004, the agency forewarns healthcare organizations that its reading of the arrangement under scrutiny is a narrow one. "Since commercial or private studies pose significantly different risks under the [national coverage decision covering clinical trial costs] and the Medicare fraud and abuse authorities," the opinion says, "routine waivers of cost-sharing obligations to enrollees in such studies would not necessarily be sheltered from ... sanction under the anti-kickback statute."

To see the opinion, go online to <http://oig.hhs.gov/fraud/docs/advisoryopinions/2004/ao0401G.pdf>.

**A group called Doctors for Medical Liability Reform is launching** a multimillion-dollar campaign for legal limits on medical malpractice awards. The campaign will include half-hour infomercials in Washington and North Carolina, two states with open Senate seats, the Charlotte Observer reports.

**The Medicare reform law passed last December may hit** organ transplant patients especially hard. It cuts most drugs from 95 percent of average wholesale price to 85 percent of AWP. This includes immunosuppressive drugs, says a new article from the Associated Press. As a result, many patients with transplanted kidneys or other organs can't receive the drugs they need to keep their bodies from rejecting the transplants.

Echo Transplant Pharmacy in Flushing, N.Y., stopped taking new Medicare patients late last month, and others say that the cut of \$1,000 or \$2,000 per year may push them out of Medicare. So far, the Centers for Medicare & Medicaid Services has exempted best-selling immunosuppressant CellCept from the cut, and Madison, N.J.-based Wyeth is seeking

an exemption for its drug Rapamune.