Portfolio Media. Inc. | 860 Broadway, 6th Floor | New York, NY 10003 | www.law360.com
Phone: +1 646 783 7100 | Fax: +1 646 783 7161 | customerservice@law360.com

Medicare Change Heralds Easier Device Trial Reimbursements

By **Jeff Overley**

Law360, New York (July 26, 2013, 8:01 PM ET) -- Medicare's decisions about whether to cover certain costs in clinical trials for medical devices could become much more consistent under a proposal to centralize review instead of using numerous contractors, though concerns linger about how reviewers will apply potentially subjective standards, experts say.

In a proposed rule issued earlier this month, the Centers for Medicare and Medicaid Services floated the centralization plan and outlined more than a dozen standards to which trials must adhere if taxpayers are going to foot part of the bill.

"Appropriate study design is critical to ensure that not only are participants in research studies exposed to the least risk possible, but also to ensure that the results from the study would be useful in improving health care delivery," regulators wrote.

While the amount of money at stake varies depending on the nature of the device and the size of the trial, significant sums will be in play, said Gabrielle B. Goldstein, a member of the health services practice at Nixon Peabody LLP.

"Certainly there would be trials with many hundreds or thousands of people, and that can add up," Goldstein said.

Medicare helps defray study costs both to facilitate research and to help seniors get earlier access to promising treatments that could be years from approval. It has relied on contractors across the country to determine whether clinical trials should be subsidized, and variance in decisions about which studies qualify has fed frustration in the device industry.

"Most of the stakeholders told us that obtaining coverage of the device and the costs of routine items and services was inefficient, [and] that each Medicare contractor has different processes to review ... devices and studies," the proposed rule says.

To rectify matters, CMS plans to assign oversight to a single entity, which should eliminate some inconsistency, said Timothy P. Blanchard, a Medicare billing expert at Blanchard Manning LLP.

"It's a good idea in part because it allows folks to get a better idea in advance of who they're going to be dealing with," Blanchard said.

“The device is obviously the same device, whether it’s being used north, south, east or west in the country,” and so “there’s no scientific reason” for different conclusions about reimbursement, Blanchard said.

Medicare is also setting what are meant to be clear criteria for how a study must be structured to get help with costs. Experimental devices can get coverage for the cost of routine care, while proven devices being researched for additional uses can also get funding for the cost of the equipment itself.

Some of the criteria are straightforward, such as the requirement to register trials on a government website, but others seem open to interpretation.

Andrew Ruskin, a Medicare reimbursement expert at Morgan Lewis & Bockius LLP, called attention to a proposed requirement that “the rationale for the study is well supported by available scientific and medical information” — likely a judgment call, he said.

“What does it mean to be ‘well supported’ by existing scientific and medical information?” Ruskin asked.

Another proposed standard stipulates that study results must not be expected to “unjustifiably duplicate existing knowledge." Ruskin says it would be hard to apply a narrow and consistent definition to that criterion.

“How do you put bookends around what is ‘unjustifiably’ duplicative?” he asked.

But Goldstein said that because studies are vetted first by institutional review boards and the U.S. Food and Drug Administration, most will be well-positioned by the time they make it to CMS.

While the intensity of CMS’ analysis will hinge on the prerogatives of the centralized review entity, the agency is unlikely to demand huge revisions to a study's design, according to Goldstein.

“Who’s making the determination may drive how searching a review they really give this,” she said. “But I wouldn’t expect them to reinvent the wheel.”

Although subjectivity and inconsistent conclusions might still occur, at least device makers will be working with one entity, Blanchard said. Over time, they’ll get a greater understanding of expectations, and there should ultimately be fewer wrinkles.

“At a minimum, we’ll be reducing it to one contractor’s subjective view of it,” Blanchard said. “But [even] that will ultimately get reduced down to what they mean by ‘well supported’ and what their rules of thumb are.”

--Editing by Kat Laskowski and Melissa Tinklepaugh.