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What's New in GCP?

CMS Officials Want To Reconsider Trial Policy

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The Centers for Medicare and Medicaid Services (CMS) would like another crack at revamping the agency's Clinical Trial Policy, but the official overseeing the policy acknowledges that it may take awhile.

"We attempted to do some changes of the Clinical Trial Policy over the last couple of years, but were unsuccessful," Steve Phurrough, the director of CMS's coverage and analysis group, told a November Food and Drug Law Institute (FDLI) conference on the relationship between CMS and FDA. "I would like to readdress that, but we will have to wait and see what the new department leadership feels about that. New administrative people aren't real interested in wanting change right up front, particularly of things that were not part of the discussion during the campaign. So I don't expect that this kind of issue is going to be looked at for three to six months after the change in administration."

CMS started working on revising the 2000 policy in 2006. In July 2007 the agency made a few changes in the policy and said it would reopen consideration of a more extensive revision. But then later in 2007 CMS decided not to revise the policy, noting it needed time to review the Food and Drug Administration Amendments Act of 2007 "to avoid imposing duplicative or inconsistent obligations."

"We do think that there needs to be a broader oversight of the kinds of trials that Medicare beneficiaries participate in and that we provide reimbursement for clinical services than we have under our Clinical Trials Policy," Phurrough said.

Medicare Advantage Causes Confusion

He noted there is "always confusion about Medicare Advantage plans." The policy holds that clinical services provided in clinical trials to Medicare Advantage enrollees are paid for under the fee-for-service system and not under the Clinical Trial Policy. The problem is that under that system, "beneficiaries may end up having co-pays that they do not have" under the Clinical Trial Policy. "There has been some discussion about whether that should change in the future," Phurrough said.

This can also cause blinding and masking problems for trials. He cited one study that was comparing two treatments for macular degeneration. One medication cost $50 a dose and the other $2,000. "There is a challenge as to how you blind those beneficiaries and providers when you have those bills," Phurrough said.

He noted the Medicare Improvements for Patients and Providers Act, signed this summer, does provide for "alternate payment decisions to ensure that clinical trials are conducted appropriately and that blinding and randomization can occur." Although "Congress gave us some flexibility to do alternate payments, unfortunately, they didn't define that very well," Phurrough said. "We're still having some discussion about how we implement that and what it really means." However, the agency does consider the legislation to be "a positive step in that we want more beneficiaries in clinical trials, but we don't want payment issues to prevent their participation," he said.

Secondary Payer Rules Are an Issue

Medicare secondary payer rules and regulations continue to be an issue, Phurrough said. The problem is in having sponsors agreeing to pay for services that are not reimbursed by insurers.

"If the provider has an arrangement with the beneficiary that says if Medicare doesn't pay for this, if your insurance doesn't pay for this, the trial sponsor will pay for it," the sponsor has assumed a legal obligation to pay and "Medicare is not going to pay anything," he said.

A trial sponsor agreement with providers and beneficiaries cannot remove the requirement that the trial subject is "ultimately responsible for the bill if everybody else doesn't pay for it," he said. "A provider cannot absolve a patient from what they are supposed to pay."

Phurrough noted the agency issued a "clarification" on the issue in early November, but "based on some of the e-mails I'm not sure it was clarified a lot." The clarification also covers payments for indigent non-Medicare subjects and sponsor payment of Medicare co-pays.

The clarification says that if routine trial costs are not billed to indigent non-Medicare subjects because of their inability to pay but are being billed to all other subjects, "a legal obligation to pay exists. Therefore, Medicare payment may be made and the beneficiary (who is not indigent) will be responsible for the applicable Medicare deductible and coinsurance amounts."

The clarification adds that "the provider of services should bill the beneficiary for co-payments and deductible but may waive that payment for beneficiaries who have a valid financial hardship."

On the question of whether sponsors can pay Medicare co-pays for trial subjects, the clarification noted that "this could be a fraud and abuse problem. In addition to CMS's policy, the Office of Inspector General (OIG) advises that nothing in OIG rules or regulations under the federal anti-kickback statute prohibits hospitals from waiving collection of charges to uninsured patients of limited means, so long as the waiver is not linked in any manner to the generation of business payable by a federal health care program."

OIG Watches for Anti-kickback Violations

Andrew Ruskin, a partner with Morgan, Lewis and Bochias, added at the FDLI conference that co-payments are not the only anti-kickback concern for trial sponsors. "OIG is absolutely aware of all of the money and consideration going back and forth between clinical trial sponsors, clinical trial sites, and beneficiaries and it has expressed concerns regarding possible violations of the anti-kickback statute, which basically says you cannot pay for a referral or arrange for services to be furnished by a particular practitioner and reimbursed by a federal health care program," Ruskin said.

He also said there are concerns about payment in cases of adverse events and procedures needed solely for the trial, rather than subject care. "If a clinical trial sponsor says that they will pay for an adverse event if no one else pays, then by virtue of the fact that they have said that they are going to be the payer of record, they have become a self-insured plan on par with Aetna and as a result CMS says 'we are not primary – you cannot bill us for those services.'" The trial sponsor must be billed first and CMS will pay whatever the remaining co-insurance is. "Of course there is no coinsurance; the sponsor is not a plan," he said. "It is illogical, and there is a lot of debate about this and it is an area where we absolutely need more guidance."

The other issue, which Ruskin said "is more clear cut in the statute," is that there is no Medicare coverage for items or services in which the beneficiary or any other payer has an obligation to pay. For example, the standard of care treatment for a particular illness or condition is two Computerized Axial Tomography (CAT) scans, but the protocol requires a third CAT scan and the sponsor indicates they will pay for the additional scan. "CMS has been nice enough to say 'we'll pay for the extra testing,' and the sponsor says 'we're going to pay for that third test' but won't pay for commercial insurers. You have just removed coverage for the Medicare population as well. It is one of those

lovely pitfalls where you have to watch out on the front end, and that is the 'legal obligation to pay' requirement," Ruskin said.

To Find Out More

The CMS Clarification of Medicare Payment for Routine Costs in a Clinical Trial is available at http://www.cms.hhs.gov/MLNMattersArticles/downloads/SE0822.pdf.

Other Recent GCP Developments in the Guide to Good Clinical Practice

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