What’s New in GCP?
Medicare Secondary Payer Rules Cause Problems
When Dealing With Research-Related Injury Payments


While there is much concerted effort to have the elderly participate in clinical trials, Medicare’s rules regarding payment, especially in the case of subject injury, can make sponsors and trial sites leery.

The Medicare Secondary Payer (MSP) Rule is in place to make sure CMS “only pays when it really should pay,” Eve Brunts, a Partner with Ropes & Gray LLP, said at the recent MAGI conference. “If someone is covered by a plan other than Medicare, Medicare is secondary” in paying medical bills, Michael Roach, with Aegis Compliance & Ethics, said at the conference in Boston.

“Sponsors and sites both want to allocate responsibility in advance,” he noted. “That’s natural and part of the contracting process.” Typically, subject injury language is in place in the clinical trial agreement and the informed consent form, but it also may appear in the protocol requirement services language or in the budget document, detailing what the sponsor will pay for. “You need to make sure these documents are in sync,” Roach urged.

A major problem is that CMS holds that if a sponsor pays for subject injury that is the result of an investigational product in a clinical trial, it becomes the primary insurer and has to meet the reporting requirements under the rule. CMS’s “position is that conditional payment language or an outright commitment to pay means that the sponsor is like a liability insurer for these situations and for these subjects,” Roach said.

Who’s in Denial?

The conditional language states that the sponsor will pay for medical services to treat subject injury if the subject’s insurer denies the claim. “It is beginning to change so that the conditional payment language is not there,” Roach said, however, “it is pretty common in subject injury language.”

The problem is that CMS holds that if the sponsor has agreed to pay, even with the conditional language, CMS cannot be billed and therefore the claim would not be denied, triggering sponsor payment.

“This is a dilemma,” Roach noted. “The sponsor says they will pay if you get a denial, but you can’t bill to get the denial.” In addition, there are operational concerns for the trial sites to make sure that they don’t bill Medicare for subject injury treatment. “It can be hard for institutions to operationalize this and make sure they don’t bill in the case of subject injury,” because if they do, they “run the risk of substantial penalties and fines.”

“Those substantive MSP rules have their primary burden on the clinical sites — the providers — because they have to determine whether and when they will actually have to submit claims to third-party payers, such as Medicare, for services provided to treat research-related injury,” Brunts added.
Roach suggested defining “what is and what is not an injury in your contract. It might be appropriate to say injury is not a manifestation of known adverse events.” Another approach is to “go silent” in the informed consent by saying “if you are injured, we will provide medical care and your insurance will be billed. If they don’t pay, you are responsible and you are not waiving your rights, which is code for if this happens — sue us,” he said.

There have been indications in the past that CMS may consider conditional payment language related to protocol-required services triggering the MSP statute. “If at some point they say that, and if they say that this has always been the law and you’ve got seven years’ worth of clinical trial agreements in place, you’ve got a heck of a problem and a big repayment due,” Roach said.

**Reporting Requirements Detailed**

Brunts noted that the Medicare, Medicaid and SCHIP Extension Act of 2007 (MMSEA) (P.L.110-173) established new reporting requirements for insurers who are the primary payer on health claims.

The law requires insurers — termed responsible reporting entities (RREs) — to determine whether an individual who has filed a claim for medical expenses is entitled to Medicare benefits and, if they are, the RRE must electronically report the individual’s name and information about the claim and injury to the Medicare program. The payments are recorded as either on-going responsibility for medical (ORM) or total payment obligation to claimant (TPOC). Most frequently, clinical trial injury claims are ORM, as the “individual entity assumes responsibility on an on-going basis to pay the medical bills,” Brunts said. ORMs require two reports — one when it starts and one when it ends. “That obviously requires communication with the site and with the subject to reach agreement on when it is terminated,” she added.

The reporting requirements have been phased in and, over time, “the threshold amount for reporting has gotten lower and lower” and is now $5,000.

According to CMS, the reporting requirements apply “to payments that are made by a clinical trial sponsor to cover health care expenses for research-related injuries,” Brunts said. “One nuance is that it applies to payment made by sponsor directly... If they purchased insurance that covers this type of payment for subject injury, the insurer makes the payment and is the one that is going to be on the hook for having to make the reports,” she said.

Brunts noted that if a sponsor is likely to have more than 500 reports in a given year, they are required to register a full quarter before making the first report to test their ability to exchange information electronically with CMS. “Keep in mind that this 500-claim threshold isn’t just clinical trial claims,” she added. “A large pharmaceutical or medical device manufacturer may also be reporting on product liability claims and things like that, so it is a lot easier to hit that 500-claim threshold.”

She added that she is “repeatedly surprised at the extent to which sponsors are not aware of these obligations, and I think that CMS would be surprised too.”

The law requires “a fair amount of information” to be reported and “all of this information is going to come to the sponsor from the clinical site,” she said. It includes information on the injured party; the injury, incident or illness; self-insurance information; plan information; information on the injured party’s attorney or representative (where applicable); and information on the settlement, judgment, award or other payment. Right now, the information includes sensitive information, such as the individual’s Social Security and Medicare numbers, which “typically would not be released to third-party sponsors.”
However, those requirements will be eliminated in June 2014 “because there was so much pushback on providing that information,” Brunts said.

Sponsors “are very concerned with making sure they get access to the information,” Brunts added, “because they are under very strict penalties if they are not compliant — a fine of $1,000 a day plus legal penalties and repayment of any payments that were mistakenly made.” However, the same legislation that removed reporting of sensitive information also provided for “some flexibility” on the fines, although CMS has “not yet issued any safe harbors to allow that flexibility to be implemented,” she noted.

**Issues Cited for Sponsors and Sites**

The reporting requirements can cause data integrity concerns for sponsors. Much of the information requested by CMS is blinded from the sponsor during the clinical trial. “If they access that information, it could raise questions about the integrity of the trial and the data generated,” Brunts said.

Sponsors are taking two approaches to this problem: providing a firewall for their employees who have to access the information for reporting or contracting the reporting to third-party vendors.

Another concern is building system capability with the sites to provide the information. Brunts recommended a systematic approach spelled out in the Clinical Trial Agreement for handling the requests for information that are needed for the reporting.

“The most important thing for both sides is to be very clear about what the obligations are,” Brunts said. “The Clinical Trial Agreement should be very clear about the obligation to report, so no unexpected requests occur during the clinical trial.”

Some sponsors are asking to review all research-related injuries before claims are submitted to Medicare, just to determine whether the sponsor has a payment obligation. “That is a huge operational issue for clinical sites,” Brunts said, in considering whether they can comply with the sponsor request and still meet their timing requirements for submitting claims.

Sponsors also are requiring trial sites to comply with the information requirements or administrative processes as a condition of payment for research-related injuries. Sponsors “need to know the clinical site is going to be collecting the information needed to make the determination on [the sponsor’s] obligations,” she said.

There are also HIPAA and privacy concerns that may be lessened in June 2014, but some of the information will still be considered protected health information. “There is an emerging consensus that providing this information is related to determining who has the payment responsibility, and so it falls within payment for covered entities,” she said. “Any doubts about whether or not you can provide the information can be eliminated proactively by [detailing] the issue in the clinical trial agreement and the informed consent form. We are definitely seeing sponsors and sites put that in those documents.”

Although the MSP reporting obligations fall primarily on sponsors, sites have to report if they pay for research-related injuries. “The patient is screaming that they have medical bills, and the family is calling and we know what happens — the site says ‘we’ll deal with it. We haven’t worked things out with the sponsor yet, [so] we’ll just pay.’ At that point, you have assumed responsibility for payment for a research-related injury and you have potentially put yourself in the position of being a responsible reporting entity,” Brunts said.
Guidance Unclear and Lacking

Brunts noted the guidelines and alerts posted on the MSP reporting website “are massive and very detailed, but they focus on very operational issues and not the conceptual issues that sponsors and sites struggle with.”

Among the questions:

• What triggers a reporting obligation? Is it when a payment is made, or when the clinical trial agreement or informed consent form that contains information on paying for research-related injury is signed? Or is it when the injury occurs? “It gets very complicated because if...there is a subject injury, is the sponsor responsible, under the contract or in the informed consent form, assuming that they are consistent? Did the injury relate to the study product or the administration or implantation of the study product? If not, the sponsor may not have an obligation. If it did, you have to go through the contract [looking for carve outs] the sponsor built into the contract. Was this caused by the negligence of the investigator or the clinical site? Did the subject fail to follow instructions? Was there a material breach of the agreement? It is not until all of that has really been considered” that the determination of responsibility for payment can be made, “once they know that back to the day of the incident,” Brunts said.

• What types of payments would a sponsor not have to report? “CMS has suggested that if certain tests are done for diagnostic purposes, but diagnostic in a sense of trying to figure out not how to treat the patient but whether the sponsor is responsible — did their drug really cause this injury — they see that as kind of a defense test or defense-related procedure, and it would not fall under the MSP reporting requirements.”

• Is it a complication or an injury? “This is a big question that obviously comes up in the MSP reporting context and is unresolved.”

Subjects Need To Know

Brunts noted that “it is very important to let the individual subject know this information will be collected by the sponsor or someone acting on the sponsor’s behalf and identify specifically what information will be collected. Let them know that it will potentially include a Medicare or Social Security number, tell them why the information is being collected, and let them know that the information is going to be shared with third parties, such as the government. And if your informed consent form is separate from your HIPAA authorization, then you need to make sure that that document is also consistent and provides the same disclosure to the subject.

She suggested informed consent language that says:

When the sponsor is going to pay for treatment for your injury, the sponsor or its representatives may need to collect certain personal information about you, such as your name, date of birth, gender, social security number, and Medicare identification number (if you have one). The sponsor needs this information to comply with a Medicare reporting obligation. This information may be collected directly from you, or from researchers, physicians or other healthcare providers who treated your problem or injury. This information and also information about your injury or other health problems may be shared with others, including sponsor representatives, the sponsor’s insurance company, and the Centers for Medicare & Medicaid Services.
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