Compliance Advisory:

CMS Issues Clinical Trials MSP Instruction

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Sponsors more heavily impacted than providers, but research organizations need to put more emphasis on identifying when complications occur

The Centers for Medicare & Medicaid Services (CMS) issued a one paragraph instruction on June 16, 2010 regarding Medicare Secondary Payer (MSP) rules and clinical research studies. The new instruction declares that the sponsor's payments will be considered "liability insurance" under the MSP rules "*when* payment is made by the sponsor for complications or injuries…" (emphasis added) The instruction will likely have more immediate impact on sponsors than health care providers because as a "liability plan" the sponsor will need to complete a special registration with CMS and provide on-going reports to CMS. The instruction could be the catalyst for significant changes in whether sponsors will continue to pay for "complications and injuries" since sponsors will need to function like health insurance plans if they pay for "complications and injuries."

A copy of the instruction is reprinted at the end of this Advisory.

> CMS: "When payments are made by sponsors of clinical trials for complications or injuries arising out of the trials, such payments are considered to be payments by liability insurance...."

The new instruction was dated May 26, 2010 and cited its authority as the MSP provisions of the Medicare, Medicaid, and SCHIP Extension Act of 2007, specifically Section 111 that sets up a host of MSP reporting obligations.[1] CMS has previously attempted to clarify its position on sponsors paying for clinical trial-related services on a conditional basis in both a notorious 2004 private letter and a 2008 educational document. Neither document used the appropriate regulatory process to establish a new rule or enact binding obligations. Some of the most controversial parts of the 2008 document were retracted in 2009. CMS appears to have found the right method this time to issue its instructions.

Section 111 of the statutory changes to the MSP rules in 2007 require an elaborate registration and reporting process for insurance plans that are considered by MSP rules to be primary to Medicare. Congress gave CMS wide berth to issue implementation rules for the registration and reporting process "by program instruction or otherwise" so that CMS would not need to go through the formal rule-making process of drafts and official publication in the Federal Register. While the instruction appears to be a weak attempt at creating a new rule, it arguably comports with the process set out in the statute.

Under the MSP rules, a Responsible Reporting Entity (RRE) must register with CMS and must provide a variety of reports about its ongoing responsibility to pay. RREs includes group health plans and non-group health plans, such as workers compensation and no-fault automobile insurance. RREs also include other types of liability insurance plans even when the liability insurance is not part of a policy but is considered "self-insurance." The new instruction characterizes a clinical trial sponsor as a "liability plan" under the MSP statute "when payments are made by sponsors of clinical trials for complications and injuries arising out of the trials." In those circumstances, the sponsor will be considered the primary payer and Medicare will serve as the secondary payer. The sponsor would, accordingly, be an RRE. When an RRE exists, the provider cannot bill Medicare for any services being paid by the RRE.

1 See 42 U.S.C. 1395y(b)(7) & (8)

The RRE registration is a federal process without respect to what a State may consider to be an insurance plan. Sponsors that qualify as an RRE under the new instruction may need to comply with State insurance laws if the sponsor identifies itself as a liability plan. States vary considerably in how their insurance codes are structured for defining insurance plans and setting out State registration requirements.

Has the conditional payment clause question been answered?

The research community has been waiting quite a while for clarification from CMS on how the MSP rules interact with clinical trials. The instruction is startlingly silent as to whether so-called "conditional payment clauses" in clinical trial agreements are triggered by the new instruction. A conditional payment clause is usually structured as, "if the subject's insurance denies coverage for X-procedure, then the sponsor will pay the institution for X-procedure." Research organizations have debated to no conclusion whether these conditional payment clauses make the sponsor the primary payer for Medicare beneficiaries thereby not allowing the provider to bill Medicare for anything that might be covered by the conditional payment clause.

The new instruction is completely silent on conditional payment clauses. The instruction merely states the circumstance of "when payments are made by sponsors…" The instruction does not reference situations when the sponsor pays services for certain enrollees and not others. The instruction appears to be limited to "when" a sponsor pays. A plain reading of this very short instruction implies that the "*when*" refers to a situation in which the sponsor has a legal obligation to pay. In conditional payment clauses, the sponsor has no legal obligation to pay for the service if the subject's insurance covers the service.

In the ordinary course of an MSP situation (for example, a homeowner's liability plan), the MSP rules work intimately with the specific policy provisions of the liability plan. These policy provisions are unique to the insurance plan. If a Medicare beneficiary falls in a driveway, Medicare does not automatically become secondary merely because the owner of the driveway has homeowner's insurance. The critical question is whether the homeowner's insurance will cover the treatment for the fall. If for some reason the policy does not cover the fall, then the MSP rule is not triggered since the liability plan has no obligation to pay.

The new CMS instruction falls under the same MSP rules that apply to the homeowner's policy example above. If the sponsor has no obligation to pay (based on whatever circumstances those may be), then it does not trigger the MSP statute and Medicare should still cover the treatment of complications and injury just as if the sponsor had not agreed to pay for the treatment.

Could health care providers be a "Responsible Reporting Entity"?

For the most part, health care providers will not be an RRE under the instruction because a hospital or physician rarely serves as the sponsor. However, not all sponsors are pharmaceutical companies or device manufacturers. Schools of Medicine and other research organizations should carefully evaluate whether they are taking on the role of an RRE. If the School is serving as a sponsor or holding itself out as the guarantor of payment for treatment of complications or injury, then it may also be considered an RRE under the new instruction.

This risk of inadvertently becoming an RRE could also apply to a provider that may promise to pay for treatment of complications or injury through the research informed consent. A research informed consent for a research study that involves more than minimal risk must address subject-injury during the trial, though it need not promise payment for treatment in the event of injury.[2] If the provider makes a promise to pay for treatment in the event of injury, that could make the provider an RRE.

Intersection with the Clinical Trial Policy?

While it will be rare that a health care provider would become an RRE under the new instruction, there continues to be an unknown of how this instruction intersects with CMS's Clinical Trial Policy ("CTP")[3] and Medicare's "no legal obligation to pay" provisions.[4] The CTP states that there is no coverage for routine costs during a qualifying clinical trial when "items and services [are] customarily provided by the research sponsor free of charge for any enrollee in the trial." This has generally been interpreted that if X-service during a clinical trial is paid by the sponsor for one patient, then Medicare must not be billed for X-service for any patient enrolled in the same research study. In essence, Medicare must get the "best deal" that anyone else receives during the trial. This has also been referred to as the "most favored nation" status of Medicare during clinical trials.

Along these lines, arguments have been advanced that if

2 45 CFR 46.116(a)(6).

3 National Coverage Determination 310.1.

4 See, Medicare Benefit Policy Manual, Chapter 16, Section 40.

a sponsor pays for treatment of a complication during a clinical trial for one patient because the patient's insurance denies coverage for the service, then Medicare should not be billed when another enrollee who is a Medicare beneficiary experiences a complication in the same trial. There has been no consensus on how to handle these conditional payment circumstances, but in the context of "complications" this line of interpretation seems unfounded. It is difficult to see how the CTP's most favored nation rule is triggered for complications, unless there is an outright statement that the sponsor will pay for all complications. Complications are neither scheduled for all enrollees in a study nor are they rarely the same for each patient. When a complication occurs, the physician must respond based on the patient's unique clinical presentation.

As an example, assume that Patient Smith and Patient Jones are enrolled in a research study and both have complications arising from the study. Patient Smith has commercial insurance coverage and Patient Jones is a Medicare beneficiary. Patient Smith experiences a complication and needs a CT scan while Patient Jones has a different complication and needs a CBC and a blood chemistry panel. There could be a host of grounds for why Patient Smith's insurance will not cover the CT for reasons other than being a complication from a clinical trial (perhaps the CT machine being used is not covered by the policy). Because Patient Smith's commercial insurance does not cover the CT scan (and the sponsor agrees to pay on denial), it does not follow that Patient Jones' medically necessary CBC and chemistry panel is not covered by the Medicare Program. The blood tests are entirely different types of services than a CT scan and Patient Jones needs blood tests for different reasons than Patient Smith needs the CT scan.

What are "complications"?

The vaguest term used by the new instruction is the word "complications." The new instruction names "complications" in the same vein as "injuries" but in reality they are not the same. There is no definition of "complication" and this poses a serious problem for providers trying to determine what is a "complication" as distinguished from a research-related injury. Complications during research studies may be expected or unexpected. There are often a host of known potential complications during drug studies that are based on evidence and data from early phase or pre-clinical studies. These complications are usually side effects of the study drug and are disclosed to the patient in the research informed consent. These could be distinguished from unexpected complications (going by the more formal name of unanticipated adverse events) in which a situation occurs that was not contemplated or factored into the potential risk. Injury, implying liability, would be a subset of unexpected complications but complications is a much broader concept than injury.

Although it is disappointing that the CMS instruction does not contain a definition of complication, the impact of a complication on the MSP rules only applies when the sponsor pays for complications and injuries. This arguably defers to the clinical trial agreement to define when – and presumably under what myriad of circumstances – the sponsor will pay for complications and injury related to the clinical trial. In essence, it becomes a matter of contract law as to when the MSP rule is triggered and what the sponsor will consider to be complications. Whether the sponsor takes a very limited view of "complications" to include only unexpected complications or takes a broad view of "complications" to be any unscheduled event that may be to detect or treat a potential side effect, is a matter for the clinical trial agreement to sort out.

Registration for the sponsor

The weight of this instruction will fall most heavily on sponsors who must register with CMS if they agree to pay for complications and injuries (however complications and injuries may be defined in the clinical trial agreement). Sponsors will likely think twice now about whether they will pay for treatment of complications and injuries even on a conditional basis. Since Medicare covers complications under the CTP, many sponsors may choose not to cover complications and injuries under any circumstances rather than register as a liability plan with Medicare and potentially need to deal with various State insurance codes.

Penalties

The penalty for violating the instruction is tied to the MSP statute which sets out two enforcement measures. First, it sets out a $1000 per day fine for each day of non-compliance. This penalty would likely be bourn by the sponsor for failure to register with CMS as an RRE and failure to submit the various other reports required by the MSP rules. Secondly, it links non-compliance to the Civil Monetary Penalties Act which is enforced by the Office of Inspector General.

While penalties for the provider are not set out for non-compliance with the technicalities of the MSP instruction, providers do have risk if the sponsor is supposed to pay for an item or service but the item or service is billed to the Medicare Program. Both the U.S. False Claims Act and the CMP Act could be trigger by a provider's erroneous billing.

Practical Points

Although the instruction arguably does not change the law with respect to how providers deal with sponsors paying for treatment of complications and injuries, it does point out that CMS is carefully watching clinical trials billing compliance. The following are five practical points to consider:

1. Identify contracts in which the sponsor agrees to pay for complications and injury. Develop a log of which studies have these conditions and what the sponsor is covering.

2. Develop a system to identify when a patient enrolled in a research study is being treated for a complication or injury so that the sponsor can be billed if the contractual conditions are met. Most identification systems need to rely on medical record flags, emergency department notices, or clinical research coordinator notification to providers that a complication or injury has occurred.

3. If the sponsor is not paying for complications or injury during a research study, do not write such promises into the research informed consent. These same promises made by a health care provider or other institution, could trigger the same MSP rules discussed in the new instruction.

4. Define carefully in the clinical trial agreement what is meant by "complication" and "injury." Be cognizant that the terms of the clinical trial agreement could trigger Medicare obligations.

5. Consider not accepting clinical trial agreements that contain conditional payment clauses whether for scheduled services or for unscheduled events. While CMS has not technically prohibited these clauses, organizations must live with clinical trial agreements for many years and if the rules are clarified there will be no way to grandfather existing contracts. It is a better practice to budget appropriately from the beginning of the study than to accept conditional terms.

Dated May 26, 2010 by CMS

ALERT: Clinical Trials & Liability Insurance (Including Self-Insurance), No-Fault Insurance, and Workers' Compensation

When payments are made by sponsors of clinical trials for complications or injuries arising out of the trials, such payments are considered to be payments by liability insurance (including self-insurance) and must be reported. The appropriate Responsible Reporting Entity (RRE) should report the date that the injury/complication first arose as the Date of Incident (DOI). The situation should also be reported as one involving Ongoing Responsibility for Medicals (ORM).

If you have any questions about clinical research compliance, please contact:

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