MEADE & ROACH LLP

Compliance Advisory: CMS "Clarifies" Medicare Coverage for Research Services

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Whether a Provider Pursues Collection Against Non-Medicare Research Patients Now Affects Ability to Bill Medicare Within Same Study

The Medicare Program released a "Special Edition Article"[1] on September 30, 2008 that addresses the implications of so-called "contingency payment clauses" in clinical trial agreements and moved into new territory by pinning payment of research services for Medicare beneficiaries on how non-Medicare enrollees are charged for study services.

The Centers for Medicare & Medicaid Services (CMS) positioned the Special Edition Article as a "clarification" of an existing rule in the Medicare Benefit Policy Manual[2] and linked the manual provision to the "free of charge" rule in the Medicare Clinical Trial Policy (CTP).[3] Much of the discussion up to September 30 was whether the Medicare Secondary Payer statute[4] applied to situations in which a sponsor agrees to pay for a study service only after the enrollee's insurance denies coverage. CMS ignored the Medicare Secondary Payer line of discussion and anchored their "clarification" in an obscure Medicare Benefit Policy Manual provision that is entitled "No Legal Obligation to Pay for or Provide Services."

CMS's discussion is as far reaching as it is complex. The "No Legal Obligation to Pay" provision of the Benefit Policy Manual sets out situations in which Medicare has no obligation to pay for items and services if a provider treats Medicare beneficiaries differently from non-Medicare patients or if other situations trigger Medicare exclusions. The provision sets out limited situations (such as patient indigency) when waiving charges for non-Medicare patients will not disturb Medicare coverage.

"If the provider does not pursue collections against the research subject after the patient's insurance denies coverage, CMS argues that the provider's actions disallow billing for the same service for Medicare patients enrolled in the study."

The "No Legal Obligation to Pay" provision addresses scenarios such as billing Medicare for a service while not billing non-Medicare patients for the same service. This provision of the manual operates to prohibit billing Medicare for the same service that is provided free to non-Medicare beneficiaries. In such a case, Medicare has no legal obligation to pay for the service and the provider also cannot charge the Medicare beneficiary.

Into this provision CMS inserted clinical research situations. The Special Edition Article advances the idea that if a provider does not charge a non-Medicare enrollee for a research study service, then the Medicare enrollee must also receive that same study service free. If the provider does not pursue collections against the research subject after the patient's insurance denies coverage, CMS argues that the provider's actions disallow billing for the same service for Medicare patients enrolled in the study.

1 MLN Matters SE0822 (September 30, 2008).

2 Medicare Benefit Policy Manual, Chapter 16, Section 40.

3 National Coverage Determination 310.1.

4 42 USC 1395y

The CTP "Free of Charge" Rule

CMS utilizes the CTP's "free of charge" rule which prohibits billing Medicare for "items and services customarily provided by the research sponsors *free of charge* for any enrollee in the trial." (emphasis added). This provision of the CTP has generally been understood to apply to situations in which the sponsor pays outright for a specific service. If the sponsor pays outright for the service, then Medicare cannot be billed for the service.

The Special Edition Article sets up the "clarification" through a question that reaches back to the CTP "free of charge" rule:

> "If a research sponsor says in writing that they will pay for routine costs if there is no reimbursement from any insurance company (including Medicare), does that fall into the "free of charge" category?"

Although CMS's answer is not a straight-forward yes or no, the implication of the answer appears to be a "yes," in that the sponsor's legal obligation to pay for the service after the patient's insurer denies coverage renders that service into the "free of charge" category under the CTP, causing that service to be non-billable to Medicare.

CMS does not stop with the sponsor's obligation in the clinical trial agreement to pay for services denied coverage, but applies the "free of charge" category to any instance in which the provider does not pursue collection against an enrollee. CMS states,

> "If private insurers deny the routine costs and the provider of services does not pursue the non-Medicare patients for payment after the denials (even though the non-Medicare patient has the ability to pay), Medicare payment cannot be made and the beneficiary cannot be charged for the routine costs."

Impact on Unfunded Studies

One of the most striking aspects of the September 30 "clarification" is that it did not confine itself to clinical trial agreements or sponsor obligations, but anchored its analysis in whether the provider pursues collection against the non-Medicare patients. The CMS "clarification" is not premised on whether any sponsor or other organization pays for the service. The CMS analysis is grounded in the provider's actions.

The "clarification" may have significant consequences for research studies without funding during which the scheduled services may be denied by an enrollee's commercial insurance. As an example, take a scheduled service (for instance, an X-ray scheduled at Week 2) for which a commercial insurer denies coverage. If the provider decides to not pursue payment from *Patient 1*, then the service must be provided free to *Patient 2*, if *Patient 2* is a Medicare beneficiary, even though Medicare would ordinarily cover the service. In many unfunded investigator-initiated studies, providers may use a patient-by-patient approach to billing insurers since no sponsor funding exists. The CMS "clarification" discussion is not premised on sponsor funding being the determinative factor in when Medicare cannot be billed; rather, the discussion focuses on whether the provider pursues collection against the non-Medicare patients enrolled in the study.

Using a patient-by-patient approach for billing during an unfunded study could disallow Medicare billing if the provider does not pursue collections against one non-Medicare enrollee where insurance will not cover a scheduled service. According to the Special Edition Article's "clarification," not pursuing collections against non-Medicare patients enrolled in a research study operates to prohibit the provider from billing for the same service to a Medicare patient enrolled in the research study, unless the provider did not pursue collections against the non-Medicare patient pursuant to the provider's "indigency policy" as discussed below

Negotiating Future Clinical Trial Agreements

Clinical trial agreements have numerous permutations of these contingency payment clauses, including situations which make contingency payments focused on specific services (such as imaging services), apply to all services required by the protocol, or apply only to "standard of care" services that are denied by the patient's insurer. The classic formulation of this clause is "If the subject's insurer denies coverage for ABC service, then the institution may invoice sponsor for ABC service."

The Special Edition Article appears to render these "contingency payment clauses" ill advised for now, unless the sponsor clearly is willing to accept and pay invoices for all the Medicare beneficiaries enrolled in the research study.

Exception for Indigent Patients

CMS allows an exception to the "free of charge" application when the patient meets the provider's indigency policy (or what might be called a charity care policy). A provider may waive the charges for a service (i.e., not pursue collections) and the waiver does not disturb billing Medicare for the same scheduled service if the patient qualifies as indigent. The patient may also be considered "medically indigent" in that the patient may be under-insured and the lack of coverage for the research service qualifies the patient under the provider's indigency policy.

CMS defers to each provider's local indigency policy and does not prescribe specific rules as to when or how the patient qualifies for indigency. It is important to note that many States have weighed in on how hospitals should construct their charity care policy. Provider charity care rules may vary from State to State.

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CMS's discussion suggests that if a clinical trial agreement contains a clause that the sponsor will pay for services for indigent enrollees, then that will not disturb Medicare billing for Medicare beneficiaries. However, CMS is careful to focus on indigency and not the uninsured as a broad class. Clauses in contracts in which the sponsor's obligation to pay is conditioned on the enrollee being uninsured and not conditioned on the patient's ability to pay will also operate to trigger the disallowance for Medicare beneficiaries.

While CMS did not discuss the implications of informed consents that promise services free to enrollees if they lack insurance or their insurer denies coverage, the September 30 "clarification" presumably applies equally to those situations since through the informed consent the institution is promising not to pursue collections against the patient if there is no insurance coverage for a scheduled protocol service.

Existing Clinical Trial Agreements

The September 30 "clarification" contains no future implementation date nor does it grandfather existing clinical trial agreements. CMS positioned the Special Edition Article not as a rule change but as a "clarification" of existing law – going so far as to state that CMS "reminds providers" of the Medicare Benefit Policy Manual provisions.

While there is considerable question whether this "clarification" is actually rule-making and not a "clarification" of existing law, for now CMS considers this policy to apply immediately to all clinical trial agreements. Providers should examine their current clinical trial agreements to understand the effects and adjust any Medicare Coverage Analyses accordingly. Additionally, since CMS considers this to be a clarification and CMS can be expected to apply this interpretation of the "no obligation to pay" rule retrospectively, providers need to review past clinical trial agreements and billing practices.

Suggested Steps for Providers to Comply with the Clarification

The following are suggestions that providers can consider in how to deal with the September 30 "clarification" and bring their research billing practices into line with CMS's position:

1. Consider not including "contingency payment clauses" in clinical trial agreements. Institutions should consider asking sponsors to pay for any service that may previously have been subject to a contingency payment clause (such as an expensive service in which conventional frequency is debatable).

2. If a sponsor is unwilling to pay for a service for all enrollees, consider utilizing a contingency payment clause only for enrollees who meet the provider's indigency policies.

3. Examine current clinical trial agreements to determine which have conditional payment clauses in them. Consider whether the language of the conditional payment clauses is triggered by oper-

ation of law under the CMS "clarification" so that the institution may be able to invoice the sponsor for services provided to Medicare enrollees.

4. Revise any Medicare Coverage Analyses that may be associated with clinical trial agreements that have contingency payment clauses. The services that are subject to the contingency payment clauses would need to be identified as not billable to Medicare on the Medicare Coverage Analysis.

5. Review the provider's indigency policy (or charity care policy) as to how research patients fit into the policy. If the provider's indigency policy does not sufficiently accommodate research situations, then consider revising the policy so that it does.

6. Reconsider any institutional approach for not pursuing payment for research services that are denied by a patient's insurer or merely because the patient does not have health insurance.

7. Examine the provider's bad debt policy as to how the provider pursues collections and determines that an unpaid bill is written off as bad debt and whether such situations constitute providing services "free of charge" or not. Categorizing a service as bad debt by following Medicare rules raises the possibility that it does not trigger the September 30 "clarification."

8. Review prospective budgets carefully, particularly unfunded investigator-initiated studies, to ensure that the organization understands the financial risks if it does not want to pursue collection against enrollees who are denied coverage by their insurer.

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