

Legal Implications of Clinical Trial Sponsor Financial Support for Subject Healthcare Costs in Clinical Trials

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Introduction

When third party payer reimbursement is available for standard-of-care services during a clinical trial, sponsors generally ask subjects to request reimbursement. For example, Medicare covers the routine costs of certain clinical trials, certain trials of investigational devices, and items and services used to diagnose and treat complications arising from trial participation. However, if the third-party "primary payer" declines to reimburse the cost, the research site and subject generally expect the study sponsor to cover the cost as the "secondary payer," on the theory that the cost would not have been incurred absent the trial. Research subjects and sites will be less interested in participating in clinical trials if they have to pay these costs out of their own pockets. Many research subjects are Medicare beneficiaries, and Medicare, historically, has freely reimbursed many such costs. However, recently, Medicare has tightened its purse strings by applying statutory provisions that limit its designation as primary payer in clinical trials. Many clinical research sites and sponsors have not complied with CMS's interpretation of the Medicare statute, either out of ignorance or in the hope that it would change, but it has not changed. CMS's interpretation has now been in the public domain long enough for any "grace period" to have expired.

If a study subject is injured during the course of a clinical trial, ethical principles – and practical issues of enrollment – suggest that the subject should not bear the burden of out-of-pocket medical costs, including any deductibles or copayments. Unfortunately, various federal laws limit the sponsor's and site's ability to cover the subject's Medicare deductible and copayments. Various state laws, not discussed further in this article, impose similar limitations for private insurance. Although the federal government does not (or cannot) scrupulously police compliance with the relevant regulations, violations invite the possibility of severe penalties.

Medicare Coordination of Benefits

Coordination of benefits (COB) refers to the determination of which of two or more payment sources will pay for a particular service, either as a primary or secondary (or tertiary) payment source. The intentions are twofold: to prevent healthcare providers from receiving an aggregate of more than 100 percent of the total charges and to determine each payment source's share of the share of the payment obligation.¹ For private health insurance sources of payment (i.e., excluding Medicare and other government programs), COB rules are based in almost all cases on state laws or regulations. For Medicare, the rules are based on the "Medicare Secondary Payer" (MSP) provisions of the Medicare statute. (42 U.S.C. § 1395y(b)).

When Medicare began on July 1, 1966, it was the primary payer for all beneficiaries, except for those who received benefits from Workers' Compensation (WC), Veterans Health Administration (VHA) health programs, and the Federal Black Lung Program. Beginning in 1980, Congress enacted a series of changes to the MSP provisions. These changes designated a variety of coverage and benefit programs as primary to Medicare, including public and private group health plans and automobile, liability and no-fault insurance.²

Under the MSP provisions, if a Medicare beneficiary has these other payment sources (termed a "primary payer" or "primary plan"), then that insurance – not Medicare – is responsible for paying the bills. In the context of clinical research, the key clause is that primary payers include a "liability insurance policy or plan (including a self-insured plan)." ³ Any insurer that fails to pay the medical costs of a Medicare beneficiary when required can be subject to a suit for double damages by the federal government or a private whistleblower. Although a single case may not attract much attention, a pattern of non-compliance may generate substantial liabilities over time.

Until passage of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), drug and device manufacturers and clinical trial sponsors had minimal MSP liability exposure. However, the MMA amended the MSP provisions, in part, to "clarify" that an "entity that engages in a business, trade, or profession shall be deemed to have a self-insured plan if it carries its own risk (whether by failure to obtain insurance, or otherwise) in whole or in part." ⁴ Congress enacted this change "to remedy the effects of '[r]ecent court decisions' that would allow 'firms that self-insure to avoid paying Medicare for past medical payments related to the claim.'" ⁵ The MMA's MSP amendments also provide that liability to Medicare can be demonstrated by "a judgment, a payment conditioned upon the recipient's compromise, waiver, or release (whether or not there is a determination or admission of liability) of payment for items or services included in a claim against the primary plan or the primary plan's insured, or by other means." ⁶

Clinical trial sponsors must therefore now consider Medicare MSP when offering to pay for the medical care of injured study subjects. Informed consent forms and clinical trial agreements often include language to the effect that the sponsor will pay for "medically necessary services related to injuries received" as a result of study participation, "unless these services are not otherwise covered by another payer." Such language now carries the risk of substantial financial liability. On April 13, 2004, the Centers for Medicare & Medicaid Services (CMS) sent a letter confirming this position to an unnamed research institution in response to an inquiry regarding this practice.⁷ CMS interpreted the above-quoted consent form language as creating a self-insured liability plan that would be primary to Medicare. It reasoned that the attempt to limit sponsor responsibility for payments to items "not otherwise covered" by Medicare would thus be ineffective, and the trial sponsor would be required to reimburse CMS for any Medicare payments resulting from injuries resulting from the study. Although CMS's interpretation of MSP as it applies to clinical studies has not been tested in the courts, it is arguably consistent with the language of the MSP and would likely receive deference from a court. Research institutions are, of course, welcome to test this policy in the courts for themselves.

Pharmaceutical, biotechnology and medical device companies are not private insurers hoping to avoid their obligations to their policyholders and members. Nevertheless, this interpretation of the law by CMS appears to block the simple, good-faith intentions of study sponsors to cover out-of-pocket medical costs for injured subjects.

Potential compliance strategies for sponsors to address these clinical trial MSP issues include:

- Do not offer to pay any treatment costs that Medicare may cover. For some trials, it may be possible to identify specific costs that Medicare does not cover, and offer to pay only those, but Medicare does cover most costs of medical treatment. This approach will not appeal to research sites and subjects.
- Decide whether to pay for treating subject injuries only on a limited and post hoc basis, without writing this approach into the consent form or clinical site agreement. Although MSP law is unclear on this point, this approach may not create a "plan" and thus not trigger MSP obligations. Any post hoc payment is

less likely to implicate MSP issues if receipt of the payment is not conditioned on a Medicare beneficiary waiving any legal claims against the sponsor.⁸ This approach will not appeal to research sites and subjects.

- Pay all costs of medical treatment for injured subjects who are Medicare beneficiaries. Coverage may be available as a rider on the sponsor's clinical trial insurance. This approach is potentially expensive, but will appeal to research sites and subjects.
- Do not enroll Medicare beneficiaries in clinical trials. This approach will not appeal to research sites and subjects excluded from the trial, and may slow subject recruitment.

Regardless of the sponsor's response to this dilemma, the sponsor should resist the temptation of compensating the beneficiary for (and/or the provider of) injury-related services when a Medicare claim has been filed. If CMS were to take legal action to recover its payments, damages against the sponsor could equal twice the amount Medicare paid for the services, regardless of whether the sponsor had already paid the beneficiary (or provider) for the services.

Copayment Waivers

Research sites sometime waive subject copayments or deductibles. If the subject's medical insurance is through Medicare, the Veterans Administration, or other federal healthcare programs, two federal laws are potentially violated: the anti-kickback statute and the beneficiary inducements statute (unless the waiver is "unadvertised" and based on an individualized determination of financial need or exhaustion of reasonable collection efforts).

The federal anti-kickback statute prohibits any provider from knowingly and willfully paying remuneration to any person to induce that person to purchase, prescribe, recommend or refer a person for the furnishing of items and services payable under a federal healthcare program, e.g., Medicare or the Veterans Administration.⁹ Offering to cover a subject's copayment carries at least the appearance of a financial inducement to utilize healthcare services. The anti-kickback statute is complicated and covers a wide variety of conduct, including offering in-kind remuneration (such as free services) to induce someone to order an item reimbursed by Medicare. Conduct that may violate the anti-kickback statute does not do so if it falls within a statutory or regulatory safe harbor provision, but protection within a safe harbor requires full compliance with all of the safe harbor's requirements. On the other hand, conduct that does not comply with all of a safe harbor's requirements does not necessarily violate the anti-kickback statute.

The beneficiary inducement statute imposes civil monetary penalties against individuals or entities that offer "remuneration" to a beneficiary of Medicare or Medicaid when they know, or should know, that the remuneration is "likely to influence" the beneficiary's decision to order or receive items or services that are reimbursable under these programs from "a particular provider, practitioner, or supplier."¹⁰

This statute is narrower in some respects than the anti-kickback statute, in that it only covers remuneration to beneficiaries and has a narrower definition of remuneration than the anti-kickback statute. However, it is broader in other respects, in that the intent standard – knowledge or constructive knowledge that the remuneration is "likely to influence" the beneficiary – does not require an actual intent to induce. Under the beneficiary inducement statute, "remuneration" specifically includes the waiver of coinsurance or deductibles and "transfers of items or services for free or for other than market value."¹¹

The federal government normally does not take enforcement action against practices that technically violate the anti-kickback statute but do not create the risk of fraud and abuse

against federal healthcare programs. However, this policy may change (retroactively) for healthcare (and thus clinical research) because the HHS Office of Inspector General (OIG), which jointly enforces the anti-kickback statute along with the Justice Department, has frequently expressed concern that waiving copayments for non-indigent patients can create fraud and abuse risks, partly because it could promote overutilization and thereby increase costs to federal healthcare programs.

For example, an OIG Special Fraud Alert expressed concern about waiver of copayments encouraging overutilization of healthcare services and stated that, while providers can waive copayments in cases of financial hardship, "This hardship exception... must not be used routinely; it should be used occasionally to address the special financial needs of a particular patient. Except in such special cases, a good faith effort to collect deductibles and copayments must be made."¹² A safe harbor to the anti-kickback statute (42 CFR 1001.952(k)) also protects the waiver of copayments for inpatient hospital services paid under Medicare's prospective payment system in limited circumstances. Among other requirements, the hospital must offer to reduce or waive copayments "without regard to the reason for admission, the length of stay of the beneficiary, or the [DRG] for which the claim for Medicare reimbursement is filed."

In the context of clinical trials, the OIG has issued advisory opinions approving the waiver of copayments for non-indigent patients enrolled in government-sponsored clinical trials, but suggested (with little explanation) that waiving copayments in commercially sponsored trials creates greater "fraud and abuse" risks. The OIG's most recent advisory opinion stated that "trial sponsors waive cost-sharing obligations for enrollees in clinical trials to encourage them to participate in studies," but that "many clinical trials... will study items... for which there are effective, well established treatments already available" and consequently "enrollees could well be induced to forgo equally effective or more appropriate care."¹³ While the OIG declined to impose anti-kickback or beneficiary inducements sanctions in that particular case, it stated that:

In contrast to [the government-sponsored trial in question], many clinical trials are... sponsored by pharmaceutical companies or other private interests with no, or only limited, government involvement. Since commercial or private studies pose significantly different risks under... the Medicare fraud and abuse authorities, routine waivers of cost-sharing obligations to enrollees in such studies would not necessarily be sheltered from civil monetary penalties under [the beneficiary inducements statute] or sanction under the anti-kickback statute, absent an applicable exception.

Given the potential anti-kickback and beneficiary inducement risks associated with copayment waivers, clinical trial sponsors should consider whether requiring trial sites to waive copayments for all enrollees is necessary to ensure that a sufficient number of patients enroll in the trial. An alternative approach would be to allow waiver of copayments only in those circumstances where the OIG clearly considers this practice acceptable, i.e., (1) in cases of financial hardship, (2) where reasonable collection efforts have failed, or (3) where the waiver satisfies the standards in the anti-kickback safe harbor on waiver of beneficiary coinsurance and deductible amounts.

Conclusion

Clinical trial sponsors can employ various approaches to achieving the goal of conducting an efficient and cost-effective clinical trial. In many cases, relieving clinical trial subjects of the costs associated with care provided in the trial will be necessary. However, promises to pay for healthcare only if Medicare denies coverage or broad copayment waivers have significant liability risks and therefore should be avoided.

References

1. Barnes, M. and Korn, J., 38 J. Health L. 609, 625.
2. 42 U.S.C. § 1395y(b).
3. 42 U.S.C. § 1395y(b)(2)(B).
4. MMA § 301; 42 U.S.C. § 1395y(b)(2)(B).
5. H.R. Rep. No. 108-178(II)(2003).
6. 42 U.S.C. § 1395y(b)(2)(B).
7. Letter from Gerald Walters, Director, Financial Services Group, Office of Financial Management, CMS (Apr. 13, 2004).
8. Under CMS regulations, a plan can become responsible for paying for care if, for instance, the payment is "conditioned upon the recipient's compromise, waiver, or release (whether or not there is a determination or admission of liability)." 42 C.F.R. § 411.22(b)(2)
9. 42 U.S.C. § 1320a-7b(b).
10. 42 U.S.C. § 1320a-7a(a)(5)
11. 42 U.S.C. § 1320a-7a(i)(6).
12. 59 Fed. Reg. 65372, 65375 (Dec. 19, 1994).
13. OIG Advisory Opinion No. 04-01 (Jan. 21, 2004).

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