

**NEW LAW MAY LIMIT SPONSORS' WILLINGNESS TO
PROVIDE SUBJECT INJURY LANGUAGE IN
CLINICAL TRIAL AGREEMENTS**

Clinical Trial Sponsor as Primary Plan under the Medicare Secondary Payer Rule

Although Medicare covers routine patient care costs in qualifying clinical trials, many private insurers do not. In order to alleviate patient concerns regarding potential costs associated with routine care in connection with the trial or the cost of care relating to complications from the trial, sponsors of clinical trials often agree to pay for costs associated with research-related injuries to clinical trial participants where such costs are not otherwise covered by third party payors.

In a letter dated April 13, 2004 from the Office of Financial Management of the Centers for Medicare and Medicaid Services (CMS), the Director of the Financial Services Group concluded that when a trial sponsor promises to pay for research-related injuries, the Medicare Secondary Payor (MSP) rules render Medicare benefits secondary to benefits payable by such sponsor, as such sponsor agreement constitutes a "plan or policy of insurance under which payment can reasonably be expected to be made" in the event such an injury occurs. The essence of the MSP rules is that Medicare will be responsible for patient care costs only to the extent certain other payors are not so responsible. The MSP precludes payment when "payment has been made or can reasonably be expected to be made under a liability insurance policy or plan (including a self-insured plan)."¹

While the 2004 CMS letter is not law, it is considered by the healthcare industry to be an articulation of Medicare policy. Under this policy, the sponsor's agreement to pay for a study subject's injuries constitutes a plan of liability insurance under MSP rules and, accordingly, the sponsor becomes the payor of first resort and Medicare will not pay for such injuries.

New Law May Create Additional Reporting Responsibility for Trial Sponsor

On December 29, 2007, the Medicare, Medicaid and SCHIP Extension Act of 2007 (the Act) became law. Prior to the Act, the MSP rules placed the obligation to report MSP-related circumstances on health care providers (e.g. clinical trial investigators and/or the clinical trial sites). As discussed above, the 2004 CMS letter found that an agreement by a sponsor who promised to pay for research-related injury constitutes a liability insurance plan. The Act amended the MSP statute to provide that "applicable plans," which include "liability insurance (including self-insured)" will be responsible for determining patient eligibility for Medicare benefits and for reporting that and other information to the Secretary. Sponsors are deemed "plans or policies of insurance" and are therefore subject to the Act's requirements. These new obligations will include the following:

- (i) determining whether a claimant is entitled to Medicare benefits,
- (ii) if the claimant is determined to be entitled to Medicare benefits, submitting information regarding such claimant's identity and other information that the Secretary specifies.

If a sponsor, as an applicable plan, fails to comply with these reporting requirements with respect to any claimant, it will be subject to a civil money penalty of \$1,000 for each day of non-compliance with respect to each claimant. Moreover, there may be potential liability under the Federal False Claims Act or "causing" the submission of an improper claim by the investigators or clinical trial sites.

Since the CMS letter includes agreements by sponsors of clinical trials to pay for research-related injuries as being a primary plan for purposes of the MSP rules, sponsors of clinical trials may be concerned with their CMS reporting obligations under the new Act and the possibility of civil money penalties if they do not so comply. As a result,

institutions should be aware that sponsors may reduce or eliminate their obligation to contractually pay for subject injuries. Institutions should explore alternative subject injury language provisions for both clinical trial agreements and informed consent forms to ensure that the institution and subjects will not bear liability of paying for injuries resulting from a subject's participation in sponsor-initiated trials. In addition, institutions should maintain detailed policies with respect to subject injury language in agreements and consents and how to manage requested deviations from this language.

1. 42 U.S.C. Section 1395(b)(2)(A)(ii).

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