SPONSOR PAYMENTS IN CLINICAL TRIALS

Maine Medical Center Policy:

1. Clinical trial sponsors shall not condition payments related to subject injury upon the denial of patient insurance coverage.

Reasoning

   a. “Primary Plans” are:
      i. Group health plans,
      ii. Workers compensation plans,
      iii. Automobile plans,
      iv. No-fault liability plans, and
   v. Liability insurance policies or plans (including self-insured plans)
      1. Defined as “insurance (including a self-insurance plan) that provides payment based on the policyholder’s alleged legal liability for injury or illness or damage to property.” MSP Manual, Ch. 1, §10.6.

2. Clinical Trial Sponsors become a “Primary Plan” when they agree to make payments for subject injury:
   a. “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).” Medicare Guidance, MMSEA §111 (emphasis added).
   b. Prior guidance from a Director within CMS (the “Lutz Letter”) is further evidence of CMS’s stance on this issue.

3. Medicare is secondary to any liability insurance. MSP Manual §10.6

Conclusion

Payments made by a clinical trial sponsor are considered payments by a liability insurance plan/policy (and therefore subject to Medicare Secondary Payer laws) when they are for research-related injuries. As such, the sponsor has primary payment responsibility for research-related injuries.