



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

1. Medicare Secondary Payer laws govern the coordination of benefits between Medicare and “Primary Plans.” 42 U.S.C. §1395y(b)(2)(A).
 - 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.