

New CMS Guidance Clarifies Medicare Coverage for Clinical Trial Services

The Centers for Medicare & Medicaid Services (CMS) issued guidance earlier this week clarifying Medicare coverage for services provided in clinical trials. Specifically, CMS is applying to clinical trials the general Medicare principle that Medicare will not pay for services for which neither the beneficiary nor any other party has any legal obligation to pay. The application of this principle calls into question Medicare coverage for clinical trial services when a sponsor has agreed to pay for the services to the extent the services are not covered by insurance (which language has previously raised concerns under Medicare secondary payer rules in the research injury context). CMS does, however, affirm Medicare coverage for clinical trial services when a provider waives charges or the collection of beneficiary cost-sharing amounts (such as co-pays) for such services for patients who are indigent. Finally, CMS reminds providers that payment by a research sponsor for beneficiary cost-sharing amounts in a clinical trial raises fraud and abuse concerns.

Providers involved in clinical trials and research sponsors should consider their clinical trial funding, budgeting and/or billing practices in light of the new [CMS guidance](#).

If you have any questions about this guidance, please contact [Eye Brunts](#), [Terry Coleman](#) or your usual Ropes & Gray attorney.

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