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Compliance Today - March 2023

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Understanding the new Medicaid research coverage regulation

by David A. Mata, Catherine Cruz-Montes, and Sarah M. Couture

On January 1, 2022, the new Medicaid clinical research coverage law became effective. State legislatures must amend their state plans to provide this new mandatory benefit. Clinical research sites should proactively take steps to address coverage issues, understand the regulation, and anticipate state coverage decisions.

Medicaid programs had no requirement to cover the costs of a clinical research trial until the passage of H.R. 133 – The Consolidated Appropriations Act of 2021, Sec. 210 of the Act, required states to add clinical research coverage as a mandatory benefit for Medicaid enrollees.[1] While this law aims to increase Medicaid enrollee participation in clinical research trials, the regulation may do the opposite. In fact, the law, as written, could decrease coverage and potentially harm participation and access.

To better understand how Medicaid coverage will impact research sites, it is important to understand Medicare coverage; this article will contrast Medicare coverage policies with those found in the new Medicaid research rule. Most payers follow the Medicare billing rules, as Medicare is the driver of reimbursement for the American healthcare system. Accordingly, clinical research billing operations follow the Medicare rules for determining which items may be billed to insurance and which must be covered by research funds. Billing Medicare has also carried the most risk, as false claims for payment can open the institution to federal penalties. The Medicaid rule contains similar language to Medicare language with which research sites are familiar, such as "routine cost" and "qualifying clinical trial."

However, the terms are defined differently and may result in varying degrees of coverage.

Medicare has been paying for "routine costs" in "qualifying clinical trials" since 2000 when Centers for Medicare & Medicaid Services (CMS) issued the Medical Clinical Trial Policy in national coverage determination (NCD) 310.1.[2] Under this policy, routine costs are defined as:

1. Items or services typically provided absent a clinical trial (i.e., conventional care).

2. Items or services required solely for the provision of the investigational item or service (e.g., administration of a noncovered chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications.

3. Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service, in particular, the diagnosis or treatment of complications.