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New Medicaid Coverage Requirement related to Clinical Trials State Plan Amendment effective January 1, 2022

On or before March 31, 2022, the Montana Department of Public Health and Human Services (DPHHS) is submitting a State Plan Amendment (SPA), effective January 1, 2022, to meet new requirements to cover routine patient costs related to Medicaid members' participation in qualifying clinical trials.

The Consolidated Appropriations Act (CAA) adds a new mandatory 1905(a)(30) benefit that covers services in connection to qualifying clinical trials, effective January 1, 2022. The aim of this policy is to allow Medicaid members to participate in these qualifying clinical trials. States will need to submit a new coverage SPA to effectuate this new coverage requirement, effective with respect to items and services furnished on or after January 1, 2022, unless the exception for state legislation described above applies. Additionally, states will need to submit a reimbursement SPA to describe payment methodologies that will be used to pay service providers.

States do not need to add any new services to their state plans or waivers. Routine patient costs do not include any investigational item or service that is the subject of the trial and not currently covered under a state plan or waiver.

Because Montana Medicaid already covers routine patient care for patients participating in a clinical trial, the amendment is not expected to have an impact on Montana Medicaid expenditures.

We invite your public comments and questions postmarked **through January 31, 2022**. You may direct comments to Mary Eve Kulawik, Medicaid State Plan Amendment and Waiver Coordinator, at (406) 444-2584 or mkulawik@mt.gov; or Director's Office, PO Box 4210, Helena MT 59604-4210.