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Clinical Trial SPA and Policy Changes

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3/14/2022

*Helping people. It's who we are and what we do.*



# Agenda

- Overview
- SPA and Policy Changes – Next Steps
- Key Terms



# Overview

- The proposed change is to ensure State Plan covers Medicaid recipients for items and services furnished in connection with participation in a Qualifying Clinical Trials (QCT).
- As a result of an amendment to the 2021 “Consolidated Appropriation Act” (CAA), section 1905 (a) of the Social Security Act (SSA) (42 U.S.C. 1396d) and 1902 (a)(10)(A) and 1937 (b)(5) of the Act to make this coverage mandatory.





# Policy Changes

- State Plan Amendment
  - Templates provided by Centers for Medicare and Medicaid Services (CMS): 3.1-A and 3.1-B
  - Attachment 3.1-A: Amount, Duration and Scope of Services provided, Categorically Needy Group(s)
  - Attachment 3.1-B: Amount, Duration and Scope of Services provided, Medically Needy Group(s)
- Medicaid Services Manual updates:
  - Medicaid Services Manual (MSM) 1500, Attachment A Policy#15-1 Early and Periodic Screening, Diagnostic and Treatment (EPSDT) programs
  - MSM 600 – Physician Services





# Next steps

- Tribal Consultation: Present proposal of policy language and changes and seek feedback.
- Public Workshop:
  - Present policy proposal of removal of clinical trial limitations set in MSM 1500, Attachment A Policy#15-1;
  - Introduce new proposed language draft in MSM 600 – Physicians; and
  - State Plan amendment
- Public Hearing: SPA, MSM 1500 and MSM 600





# Next steps cont.

- DHCFP is working with CMS and with our fiscal agent to understand implications this policy may or may not have to the Medicaid Management Information (MMIS) System and whether these clinical trial related services must be tracked.



# Questions?





# Acronyms

- EPSDT: Early and Periodic Screening, Diagnostic and Treatment
- CAA: Consolidated Appropriation Act
- CMS: Centers for Medicare and Medicaid Services
- MSM: Medicaid Services Manual
- AAP: American Academy of Pediatrics
- SSA: Social Security Act
- MMIS: Medicaid Management Information System





# Contact Information

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