

Public Notice Regarding Mandatory Medicaid Coverage of Routine Patient Costs Furnished in Connection with Participation in Qualifying Clinical Trials

December 28, 2021

Pursuant to Sections 1902(a)13(A) of the Social Security Act and 42 Code of Federal Regulations (CFR) 447.205, which mandate that proposed changes in statewide methods and standards for setting Medicaid payment rates be published and made available for review and comment, this is to advise that:

1. The Missouri Department of Social Services, MO HealthNet Division (DSS/MHD) provides notice of the following:

Effective for dates of service beginning January 1, 2022, DSS/MHD will amend its State Plan to allow for the provision of routine patient costs furnished in connection with participation in qualifying clinical trials. These services will be limited to any item or service provided to the individual under the qualifying clinical trial, including any item or service provided to prevent, diagnose, monitor, or treat complications resulting from participation in the qualifying clinical trial, to the extent that the provision of such items or services to the beneficiary would otherwise be covered outside the course of participation in the qualifying clinical trial under the state plan. Routine patient costs do not include any investigational item or service that is the subject of the qualifying clinical trial and is not otherwise covered outside of the clinical trial under the state plan.

2. There will be no annual estimated cost to MO HealthNet because MHD currently covers services furnished in connection with participation in qualifying clinical trials.
3. MO HealthNet will submit any necessary changes resulting from the provision of routine patient costs furnished in connection with participation in qualifying clinical trials requirements to the Centers for Medicare & Medicaid Services (CMS) for review and approval. Once completed, a copy of the proposed State Plan Amendment with supporting documentation will be available for public review by contacting the Department of Social Services, MO HealthNet Division at Ask.MHD@dss.mo.gov and a copy will be available on MHD's website.
4. DSS/MHD assures that individuals under twenty-one (21) years of age, pursuant to EPSDT federal regulations, Section 440.345 of Title 42 of the Code of Federal Regulations, may receive additional services if determined medically necessary.
5. The proposed amendment complies with the American Recovery and Reinvestment Act of 2009.

6. Comments may be sent by regular mail, express, or overnight mail, in person or by courier within 30 days after publication of this notice and must be sent or delivered to the following address:
MO HealthNet Division
P.O. Box 6500
Jefferson City, MO 65102-6500
Attention: Kim Johnson

Comments may also be emailed to Ask.MHD@dss.mo.gov. Please use "Public Comment for Mandatory Medicaid Coverage of Routine Patient Costs Furnished in Connection with Participation in Qualifying Clinical Trials" in the subject line.

7. No public hearing will be held.