

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

December 28, 2021

Pursuant to Section 440.386 of Title 42 of the Code of Federal Regulations, which mandates the state provide public notice of its intent to submit a State Plan Amendment to amend the Alternative Benefit Plan authorized under Section 1937 of the Social Security Act for individuals 19 to 64 who are eligible for Medicaid pursuant to Section 1902 (a)(10)(A)(i)(VII) of the Social Security Act, 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 Alternative Benefit 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 amendment to the Alternative Benefit Plan 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](mailto: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](mailto: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.