

## Public Notice

### State Plan Amendments IA-22-0005 and IA-22-0006

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

**Posted:** December 30, 2021

Notice is hereby given, in accordance with 42 CFR §440.386, that the Iowa Department of Human Services (DHS) has posted for public comment Medicaid State Plan Amendments (SPA) IA-22-0005 and IA-22-0006, regarding mandatory coverage of routine patient costs associated with clinical trials. These changes are being made to comply with [State Medicaid Director \(SMD\) Letter 21-0005](#) issued on December 7, 2021.

Effective on or after January 1, 2022, these SPAs will cover routine Medicaid services for members who are participating in a clinical trial. The new SPAs are needed to ensure that Iowa Medicaid appropriately covers and pays for routine patient costs of items and services for beneficiaries enrolled in qualifying clinical trials, as newly required under amendments made by section 210 of the Consolidated Appropriations Act (CAA). Pursuant to section 1905(a)(30) and 1905(gg)(1) of the Act, the routine patient costs that must be covered for a beneficiary participating in a qualifying clinical trial are 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 or waiver, including a demonstration project under section 1115 of the Act. The State assures that the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) services will be provided to individuals under 21 years of age through the Alternative Benefit Plan, pursuant to 42 CFR 440.345.

We intend to submit any necessary changes resulting from the CAA clinical trial requirements to CMS for review and approval. Currently, we estimate the changes and impact to payment methods and standards to be minimal. To the extent that the expected changes are modified as a result of the SPA submissions and resulting negotiations with CMS or additional guidance from CMS, the state will update the notice accordingly.

#### **Public Review and Comments:**

This notice is posted on the DHS website at the following link: [https://dhs.iowa.gov/public-notice/Clinical\\_Trials](https://dhs.iowa.gov/public-notice/Clinical_Trials). To reach all stakeholders, non-electronic copies will be available for review at each local DHS office. The updated SPA pages will be available in the near future.

Written comments may be sent to Belinda Silvernail, Program Manager-Policy, Iowa Medicaid Enterprise, 1305 East Walnut, Des Moines, IA 50319 or may be emailed to

[bsilver@dhs.state.ia.us](mailto:bsilver@dhs.state.ia.us). Please indicate SPA IA-22-0005 and IA-22-0006 in the subject line of the email. Written and emailed comments must be received no later than Monday January 31, 2022 at 4:30 p.m.

Submitted by:  
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Medicaid Director