OFFICE OF THE SECRETARY OF FAMILY AND SOCIAL SERVICES Office of Medicaid Policy and Planning

Public Notice of Alternative Benefit Plan Qualifying Clinical Trials

In accordance with public notice requirements established at 42 CFR 440.386, the Indiana Family and Social Services Administration (FSSA), Office of Medicaid Policy and Planning (OMPP) publishes this notice of proposed changes to modify the benefits cost avoidance policies related to certain types of care and payment of an existing Alternative Benefit Plan (ABP). This public notice will run from 09/14/2022 until 09/28/2022.

FSSA – OMPP proposes to modify coverage requirements for routine patient costs associated with participation in qualifying clinical trials.

OMPP is making these changes to comply with Division CC, Title II, Section 210 of the Consolidated Appropriations Act, 2021 (Public Law 116-260) (section 210) amended section 1905(a) of the Social Security Act, by adding to the definition of "medical assistance" a new benefit at section 1905(a)(30) for routine patient costs for items and services furnished in connection with participation by Medicaid beneficiaries in qualifying clinical trials. Previously, only clinical trials for cancer were covered under the ABPs.

Given that the federal requirements provide only for coverage and payment for otherwise covered services, this State Plan Amendment will specify that the services covered and the payment methodology will remain the same as the underlying services. Since there is no anticipation of substantive changes to coverage or payment, it is estimated that there will be no fiscal impact resulting from these changes. This change takes effect October 1, 2022.

A copy of this notice is now on file at the Indiana Government Center South, 402 West Washington Street, Room W451, Indianapolis, Indiana and is open for public inspection. Also, a copy of this notice is now available and may be inspected by contacting the local county Division of Family Resources office, except in Marion County, where public inspection may be made at 402 West Washington Street, Room W374, Indianapolis, Indiana.

There will be no public hearing. Written comments may be directed to FSSA, Office of Medicaid Policy and Planning, Attention: Madison May-Gruthusen, 402 West Washington Street, Room W382, P.O. Box 7083, Indianapolis, IN 46207-7083 or by email to spacomment@fssa.in.gov. Correspondence should be identified in the following manner: COMMENT RE: QUALIFYING CLINICAL TRIALS. Written comments will be made available for public inspection at the address herein of the OMPP.

Daniel Rusyniak, MD Secretary Office of the Secretary of Family and Social Services

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