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Authority: Pub. L. 67-13, 42 Stat. 20 (June 10, 1921).

James R. Dalkin,
Director, Financial Management and Assurance, U.S. Government Accountability Office.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Notice of Hearing: Reconsideration of Disapproval Minnesota Medicaid State Plan Amendment (SPA) 12-0014-B

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Notice of hearing: Reconsideration of disapproval.

SUMMARY: This notice announces an administrative hearing to be held on August 21, 2018, at the Department of Health and Human Services, Centers for Medicare & Medicaid Services, Division of Medicaid & Children's Health Insurance Program Services, Chicago Regional Office, 233 N. Michigan Avenue, Suite 600, Chicago, Illinois 60601-5519, to reconsider CMS's decision to disapprove Minnesota's Medicaid SPA 12-0014-B.

DATES: Requests to participate in the hearing as a party must be received by the presiding officer by August 7, 2018.

FOR FURTHER INFORMATION CONTACT: Benjamin R. Cohen, Presiding Officer, CMS, 2520 Lord Baltimore Drive, Suite L, Baltimore, Maryland 21244, Telephone: (410) 786-3169.

SUPPLEMENTARY INFORMATION: This notice announces an administrative hearing to reconsider CMS's decision to disapprove Minnesota's Medicaid state plan amendment (SPA) 12-0014-B, which was submitted to the Centers for Medicare & Medicaid Services (CMS) on April 1, 2012 and disapproved on April 27, 2018. This SPA requested CMS approval to limit application of a resource disregard, in determining eligibility for several optional eligibility groups covered under its state plan, to individuals who were previously enrolled in the eligibility group described in section 1902(a)(10)(A)(ii)(XIII) (sometimes referred to as the "working disability" group) for at least 24 consecutive

months and who have an ineligible spouse.

The issues to be considered at the hearing are whether Minnesota SPA 12-0014-B is inconsistent with the requirements of:

- Section 1902(a)(17) of the Act and 42 CFR 435.601(d)(4), which require that states apply comparable eligibility standards and methodologies within eligibility groups.

Section 1116 of the Act and federal regulations at 42 CFR part 430 establish Department procedures that provide an administrative hearing for reconsideration of a disapproval of a state plan or plan amendment. CMS is required to publish in the **Federal Register** a copy of the notice to a state Medicaid agency that informs the agency of the time and place of the hearing, and the issues to be considered. If we subsequently notify the state Medicaid agency of additional issues that will be considered at the hearing, we will also publish that notice in the **Federal Register**.

Any individual or group that wants to participate in the hearing as a party must petition the presiding officer within 15 days after publication of this notice, in accordance with the requirements contained at 42 CFR 430.76(b)(2). Any interested person or organization that wants to participate as *amicus curiae* must petition the presiding officer before the hearing begins in accordance with the requirements contained at 42 CFR 430.76(c). If the hearing is later rescheduled, the presiding officer will notify all participants.

The notice to Minnesota announcing an administrative hearing to reconsider the disapproval of its SPA reads as follows:

Ms. Marie Zimmerman
Medicaid Director
State of Minnesota, Department of Human Services
540 Cedar Street, P.O. Box 64983
St. Paul, MN 55167
Dear Ms. Zimmerman

I am responding to your request for reconsideration of the decision to disapprove Minnesota's State Plan amendment (SPA) 12-0014-B, which was submitted to the Centers for Medicare & Medicaid Services (CMS) on April 1, 2012, and disapproved on April 27, 2018. I am scheduling a hearing on your request for reconsideration to be held on August 21, 2018, at the Department of Health and Human Services, Centers for Medicare & Medicaid Services, Division of Medicaid & Children's Health Insurance Program Services, Chicago Regional Office, 233 N. Michigan Avenue, Suite 600 Chicago, Illinois 60601-5519.

I am designating Mr. Benjamin R. Cohen as the presiding officer. If these arrangements

present any problems, please contact Mr. Cohen at (410) 786-3169. In order to facilitate any communication that may be necessary between the parties prior to the hearing, please notify the presiding officer to indicate acceptability of the hearing date that has been scheduled and provide names of the individuals who will represent the State at the hearing. If the hearing date is not acceptable, Mr. Cohen can set another date mutually agreeable to the parties. The hearing will be governed by the procedures prescribed by federal regulations at 42 CFR part 430.

SPA 12-0014-B proposed to limit application of a resource disregard, in determining eligibility for several optional eligibility groups covered under its state plan, to individuals who were previously enrolled in the eligibility group described in section 1902(a)(10)(A)(ii)(XIII) (sometimes referred to as the "working disability" group) for at least 24 consecutive months and who have an ineligible spouse.

The issues to be considered at the hearing are whether Minnesota SPA 12-0014-B is inconsistent with the requirements of:

- Section 1902(a)(17) of the Act and 42 CFR § 435.601(d)(4), which require that states apply comparable eligibility standards and methodologies within eligibility groups.

In the event that CMS and the state come to agreement on resolution of the issues which formed the basis for disapproval, this SPA may be moved to approval prior to the scheduled hearing.

Sincerely,
Seema Verma,
Administrator,
cc: Benjamin R. Cohen

Section 1116 of the Social Security Act (42 U.S.C. 1316; 42 CFR 430.18).

(Catalog of Federal Domestic Assistance program No. 13.714. Medicaid Assistance Program)

Dated: July 17, 2018.

Seema Verma,
Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2007-D-0369]

Product-Specific Guidances; Draft and Revised Draft Guidances for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of additional draft and revised draft product-specific guidances. The