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State/Territory Name: IN

State Plan Amendment (SPA) #: 21-0009

This file contains the following documents in the order listed:

1) Approval Letter
2) Additional Companion letter (delete if not if applicable)
3) Summary Form (with 179-like data)
4) Approved SPA Pages

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
601 E. 12th St., Room 355
Kansas City, Missouri 64106

CENTERS FOR MEDICARE & MEDICAID SERVICES
CENTER FOR MEDICAID & CHIP SERVICES

Medicaid and CHIP Operations Group

December 13, 2021

Allison Taylor
Medicaid Director
Indiana Family and Social Services Administration
402 W. Washington Street, Rm W374, MS 07
Indianapolis, IN 46204

Re: Indiana State Plan Amendment (SPA) 21-0009

Dear Ms. Taylor:

The Centers for Medicare & Medicaid Services (CMS) reviewed your Medicaid State Plan Amendment (SPA) submitted under transmittal number (TN) 21-0009. This amendment proposes to clarify what licensed practitioners may order diabetes self-management training.

We conducted our review of your submittal according to statutory requirements in Title XIX of the Social Security Act and implementing regulations at 42 CFR § 433 Subpart D. This letter is to inform you that Indiana Medicaid SPA 21-0009 was approved on December 13, 2021, with an effective date of December 1, 2021. Please note that a companion letter is attached to this approval.

If you have any questions, please contact Mai Le-Yuen at 312.353.2853 or via email at mai.le-yuen@cms.hhs.gov.

Sincerely

James G. Scott, Director
Division of Program Operations

Enclosures

cc: Madison May Gruthusen, FSSA

DEPARTMENT OF HEALTH & HUMAN SERVICES
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December 13, 2021

Allison Taylor
Medicaid Director
Indiana Family and Social Services Administration
402 W. Washington Street, Rm W374, MS 07
Indianapolis, IN 46204

Re: CMS Companion Letter -Transmittal Number (TN) 21-0009

Dear Ms. Taylor:

This letter is being sent as a companion to the Centers for Medicare & Medicaid Services (CMS) approval of State Plan Amendment (SPA) TN 21-0009 which clarifies what practitioners may order diabetes self-management training services. Consistent with our guidance contained in our State Medicaid Director (SMD) 10-020 letter and November 6, 2017 CMCS Information Bulletin, CMS conducted a "same page" review of all coverage language contained in TN-21-0009. In our review of the SPA submission, we identified the following same page review concerns on page 3 of the Addendum to the Attachment 3.1-A.

The submitted state plan page indicates that chiropractic treatment services are provided with a 50 visit annual limit on the number of therapeutic physical medicine treatments. The state plan also does not specify a distinct process for Early and Periodic Screening, Diagnostic and Treatment (EPSDT) beneficiaries to access additional services based on medical need.

Indiana has communicated that the state will review the ongoing need for the limit, and consider a process and policy to demonstrate compliance with federal requirements. To achieve this, the state plan language should be revised to indicate that limits are applied in a manner consistent with regulations 42 CFR 440.230 and all other applicable federal requirements. Indiana has the discretion to remove the limits from the state plan, clarify that the visit limit may be exceeded with prior authorization or demonstrate that the limit is sufficient to meet the purpose of the service. If the state elects to keep the limit in the plan page as is currently written, Indiana will need to:

(1) Specify in the state plan that EPSDT beneficiaries may receive services in excess of the limitations and through what process and
(2) Provide documentation to CMS to demonstrate sufficiency of the benefit, consistent with 42 CFR 440.230 and the attached 2014 Associate Regional Administrator (ARA) Sufficiency Memo.

The state has 90 days from the date of this letter to address the issues described above. During this time period, the state must either submit a state plan amendment with the additional

information or a corrective action plan describing in detail how the state will resolve the issues in a timely manner. Failure to respond may result in the initiation of a formal compliance process. During the 90-day compliance period, CMS will be available to provide technical assistance if needed.

If you have any questions, please contact Mai Le-Yuen at 312.353.2853 or via email at mai.le-yuen@cms.hhs.gov.

Sincerely,

James G. Scott, Director
Division of Program Operations

Enclosures

cc: Madison May Gruthusen, FSSA

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-26-12
Baltimore, Maryland 21244-1850

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES
CENTER FOR MEDICAID & CHIP SERVICES

DATE: December 16, 2014

TO: Associate Regional Administrators for Medicaid

FROM: Barbara Edwards, Director
Disabled and Elderly Health Programs Group

SUBJECT: Sufficiency of Mandatory and Optional Services

We are sharing the below policy with you and requesting that you distribute it to your states. This serves as a formalization of current State Plan Amendment review practice and is intended to provide further clarification to all states.

We have developed a standard set of questions for evaluating the sufficiency of both mandatory and optional services for individuals 21 years and older. The purpose of these questions is to provide a consistent framework to determine compliance with Federal regulations at 42 CFR 440.230(b) with respect to the requirement that any service provided under the state plan is "sufficient in amount, duration and scope to reasonably achieve its purpose." This document is intended to clarify the circumstances under which these sufficiency questions are, and are not, required to be asked. We note that CMS and states should be familiar with the entirety of 42 CFR 440.230, which has implications beyond the sufficiency of benefits.

Previously, states that proposed an amount, duration or scope limitation on a mandatory service had to demonstrate that the limitation would meet the needs of at least 90% of the Medicaid population as a whole. This analysis does not depict the potential impact of the limitation on individuals with special health care needs such as pregnant women, elders, and individuals with disabilities. More recently we have modified that approach and this document reflects that modification. We are therefore clarifying that the sufficiency of mandatory services should be demonstrated by ensuring that the proposed limitation meets the needs of at least 90% of beneficiaries in each of the following eligibility groups, based on an analysis of claims data of individuals who have utilized the service (children are not listed here because EPSDT provisions ensure that across-the-board hard limits cannot be applied to children):

- Aged, blind and disabled
- Non-dually-eligible adults, unless the proposed limitation applies to a service in which Medicare is not the primary payer, when the analysis would include dually eligible adults
- Pregnant women
- Parents and caretakers
- Adult expansion group, if applicable

States have significant discretion in the provision of optional Medicaid services, including the ability to define the purpose the service is intended to achieve. However, we are clarifying here that

optional services also must be provided in an amount, duration and scope that are sufficient to meet the State's defined purpose. Without meeting this threshold, the service could be meaningless, not meeting the needs of beneficiaries, and not cost effective for state or Federal reimbursement. Therefore states need to ensure the sufficiency of proposed amount, duration or scope limitations on optional services by providing the same data analysis as required for mandatory services, but as applied within the context of the state's defined purpose of the service. Based on the state's defined purpose of the service, limitations on optional services must meet the needs of at least 90% of beneficiaries in each of the eligibility groups listed above who have previously utilized the service. For instance, States looking to provide a dental benefit that relieves pain and prevents infection would need to demonstrate that their proposed dental benefit meets those needs of 90% of beneficiaries within each eligibility group who used the dental benefit.

As a general matter, the sufficiency questions apply when a State plan contains hard limitations on the amount, duration or scope of a mandatory or optional service. The questions also recognize situations when a state may not have appropriate or robust data to demonstrate the sufficiency of the limitation. In those cases, states will be asked to submit alternative documentation to support the sufficiency of the proposed service limitation. This may include a description of the state's process that led to the proposed/existing parameters of the benefit. Funding constraints alone do not justify the imposition of a benefit limit. A limit may be prompted by budgetary constraints, but to be approvable it must meet sufficiency standards. Depending on the limitation and information contained elsewhere in the SPA submission, the questions may need to be tailored to recognize the specific provisions in the SPA and some questions may not be appropriate to every SPA.

The sufficiency questions will be asked in the following circumstances when the State plan contains limitations on the amount, duration and scope of a service that cannot be exceeded with prior authorization or based on a determination of medical necessity by the State:

<u>The sufficiency questions must be asked in the following circumstances:</u>

- State is reducing the amount, duration or scope of a service;
- State is adding a new, limited service to a State plan (e.g., adding a limited scope of adult dental services);
- State is increasing existing coverage but that coverage still contains limits.

<u>The sufficiency questions are not required in the following circumstances:</u>

- The state is completely eliminating a service (in which case questions relating to advance notice to beneficiaries and continuity of treatment must be asked in lieu of sufficiency questions);
- The state is amending a service with no limitations noted or with "soft" limits that can be exceeded through prior authorization or some other process. Although sufficiency questions are not asked, other questions may be needed to confirm the service, such as how providers are educated that prior authorization should be pursued in order to provide services above a soft limit, rather than generating a bill to beneficiaries for services provided above the limit.

> In addition, any prior authorization process utilized must not serve as a barrier to accessing needed services, and must be publicized to providers and stakeholders.

To ensure the sufficiency of each benefit provided to Medicaid beneficiaries, we are clarifying that hard limitations (i.e., service caps without a possible override based on medical necessity) encompassing more than one benefit category are not permitted. As CMS has communicated to states proposing aggregate limitations in their state plan, such an approach makes it virtually impossible to measure the sufficiency of each impacted benefit.

With respect to "same page" and "corresponding page" review, we will continue to follow the guidance contained in our letter to State Medicaid Directors dated 10/1/2010 as it applies to our coverage; however, we will make determinations about whether to apply the new set of sufficiency questions to those SPAs on a case-by-case basis.

http://downloads.cms.gov/cmsgov/archived-downloads/SMDL/downloads/SMD10020.pdf

If you have any questions about the information contained in this memo, you may contact Melissa Harris at Melissa.harris@cms.hhs.gov. Thank you.

Attachment

1) **BACKGROUND.** What is the reason for this limitation? If the reason for the limitation is duplication of services, abuse or inappropriate utilization, please provide the evidence that supports this reasoning. What other approaches/initiatives/processes have you tried or considered to address this matter?

2) **PURPOSE.** (specific to optional services). What is the clinical purpose of this benefit and will that purpose be achieved even with this limit?

3) **DATA SUPPORT- New.** Using claims data within the last 12 months, what percentage of Medicaid beneficiaries who need services included under the benefit would be fully served (i.e., receive all the services they require) under the new limit? For optional services, the question becomes for what percentage of those served would the intended purpose described above be achieved? Please provide this information for the following eligibility groups:
   a. Aged, Blind and Disabled
   b. Non-Dually Eligible Adults (for analyses of services for which Medicare would not be primary payer, otherwise the analysis would include dually-eligible individuals)
   c. Pregnant Women
   d. Parents/Caretakers /Other Non-Disabled Adults
   e. Adult expansion group, if applicable; limitations may not circumvent the floor of coverage for Essential Health Benefits (EHBs) as articulated in the commercial plan defining EHBs.

4) **DATA SUPPORT- Existing**. With respect to existing limitations and using data within the last 12 months, what percentage of Medicaid beneficiaries utilized the maximum amount of the service? Please provide this information for the following eligibility groups:
   a. Aged, Blind and Disabled
   b. Non-Dually Eligible Adults (for analyses of services for which Medicare would not be primary payer, otherwise the analysis would include dually eligible individuals)
   c. Pregnant Women
   d. Parents/Caretakers /Other Non-Disabled Adults
   e. Adult expansion group, if applicable

5) **CLINICAL SUPPORT.** If the data requested above is not available, or is not relevant to demonstrating the sufficiency of the limited benefit, please indicate support for this proposed scope of services through clinical literature or evidence-based practice guidelines, or describe your consultation with your provider community or others that resulted in an assurance that this proposed scope of services has meaningful clinical merit to achieve its intended purpose.

6) **EXCEPTIONS.** Are there any exemptions to the proposed limitations? If so, how was this exemption determined to be appropriate? Does the state have a process for granting other exemptions if similar circumstances warrant? (e.g., if there is an exemption for individuals with one condition because their needs are greater, is there a process for other individuals with conditions that result in greater needs to request an exemption?) Can additional services beyond the proposed limit be provided based on a determination of medical necessity? That is, will there be an exception or prior authorization process for beneficiaries that require services beyond the limitation?

7) **BENEFICIARY IMPACT.** Please describe what will or is likely to occur to beneficiaries who will be impacted by this limitation. If the limit cannot be exceeded based on a determination of medical necessity:
   a. How will those affected by the limitation obtain the medical services they need beyond the stated limits?
   b. Will beneficiaries be billed and expected to pay for any care that may not be covered? Or, instead will the provider or practitioner be expected to absorb the costs of the provided services?
   c. Will beneficiaries be reassessed to determine need for the service prior to the plan amendment's effective date?
   d. If the beneficiary's covered services are being reduced, will the beneficiary be notified of their appeals rights per 42 CFR 431.206?

8) **DELIVERY SYSTEM.** Will the proposed limitation apply to services performed through managed care contracts, fee-for-service (FFS) or both? If applied in managed care, indicate whether or not the capitation rates will be adjusted to reflect the change.

9) **IMPLEMENTATION.** How will the State be implementing the limit? For example, how will the State be publicizing this limit to beneficiaries and providers in a timely manner that allows decisions on the provision of care to be made in acknowledgement of the limit?

10) **TRACKING.** How will the limitation be tracked? Will both providers and beneficiaries be informed in advance so they know they have reached the limit? Please summarize the process.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH CARE FINANCING ADMINISTRATION

FORM APPROVED
OMB NO. 0938-0193

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL

FOR: HEALTH CARE FINANCING ADMINISTRATION

1. TRANSMITTAL NUMBER: 21-0009

2. STATE: Indiana

3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID)

TO: REGIONAL ADMINISTRATOR
HEALTH CARE FINANCING ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

4. PROPOSED EFFECTIVE DATE: December 1, 2021

5. TYPE OF PLAN MATERIAL *(Check One)*:

☐ NEW STATE PLAN ☐ AMENDMENT TO BE CONSIDERED AS NEW PLAN ☒ AMENDMENT

COMPLETE BLOCKS 6 THRU 10 IF THIS IS AN AMENDMENT *(Separate Transmittal for each amendment)*

6. FEDERAL STATUTE/REGULATION CITATION:
42 CFR § 440.60

7. FEDERAL BUDGET IMPACT (*thousands*):
a. FFY 2021 $0
b. FFY 2022 $0

8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT:
Attachment 3.1-A Addendum Page 3

9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT *(If Applicable)*:
Attachment 3.1-A Addendum Page 3

10. SUBJECT OF AMENDMENT:
This State Plan Amendment makes conforming changes to the Medicaid State Plan to clarify Indiana Medicaid in regards to what practitioners may order diabetes self-management training (DSMT). These changes will add nurse practitioners, clinical nurse specialists, certified nurse midwives and physician assistants to the list of providers who may order DSMT services.

11. GOVERNOR'S REVIEW *(Check One)*:
☐ GOVERNOR'S OFFICE REPORTED NO COMMENT
☐ COMMENTS OF GOVERNOR'S OFFICE ENCLOSED
☐ NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL
☒ OTHER, AS SPECIFIED:
Indiana's Medicaid State Plan does not require the Governor's review. See Section 7.4 of the State Plan

12. SIGNATURE OF STATE AGENCY OFFICIAL:

13. TYPED NAME: Allison Taylor

14. TITLE: Medicaid Director

15. DATE SUBMITTED: September 15, 2021

16. RETURN TO:
Allison Taylor
Medicaid Director
Indiana Office of Medicaid Policy and Planning
402 West Washington Street, Room W374
Indianapolis, IN 46204
ATTN: Amy Owens, Government Relations Manager

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED: 9/15/21

18. DATE APPROVED: 12/13/21

PLAN APPROVED – ONE COPY ATTACHED

19. EFFECTIVE DATE OF APPROVED MATERIAL: 12/1/21

20. SIGNATURE OF REGIONAL OFFICIAL:
Digitally signed by James G. Scott -S
Date: 2021.12.13 19:25:52 -06'00'

21. TYPED NAME: James G. Scott

22. TITLE: Director, Division of Program Operations

23. REMARKS:

FORM HCFA-179 (07-92)

6.b. Optometrists' services

Optometrists' services are provided in accordance with 42 CFR 440.060.

Reimbursement is available for medically necessary services provided by an optometrist within the scope of practice as define by Indiana law and subject to procedure code limitations.

6.c. Chiropractors' services

Chiropractors' services include only services that—

(1) Are provided by chiropractor who is licensed by the State and meets standards issued by the Secretary of Health and Human Services under 42 CFR 420.21(a); and
(2) Consists of treatment by means of manual manipulation of the spine that the chiropractor is legally authorized by the State to perform
(3) Provided with limitations
Reimbursement is limited to 5 office visits and up to 50 therapeutic physical medicine treatments per recipient per year; however, the 5 office visits are included in the 50 visit/treatment maximum. DME and electromyography services are not covered. Reimbursement is subject to the scope of service limitations set out in 405 IAC 5. Reimbursement is not available for any chiropractic service provided outside the scope of IC 25-10-1-1, et seq., and 846 IAC 1-3-1, et seq., or for any chiropractic service for which federal financial participation is not available.

Subject to prior authorization requirements and 405 IAC 5-15-4 these limits do not apply to treatments found necessary for children under the age 21, after a diagnosis as a result an EPSDT service.

6.d. Other Practitioners' services

Nurse Practitioners' services

Provided with limitations.
Reimbursement is available for medically necessary, reasonable and preventive health care services provided by a licensed, certified nurse practitioner within the scope of the applicable license and certification.

Diabetes Self-Management
And Training Services

Reimbursement is limited to a total of sixteen units (15 minutes each) per recipient, per rolling calendar year. Additional units may be prior authorized. Services must be medically necessary; provided by health care professionals who are licensed, registered or certified under applicable Indiana law and who have specialized training in the management of diabetes; and ordered in writing by a physician, podiatrist, nurse practitioner, clinical nurse specialist, certified nurse midwife and physician assistant.