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State/Territory Name: South Carolina

State Plan Amendment (SPA) #: 14-017

This file contains the following documents in the order listed:

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
Atlanta Regional Office
61 Forsyth Street, Suite 4T20
Atlanta, Georgia 30303

DIVISION OF MEDICAID & CHILDREN'S HEALTH OPERATIONS

December 2, 2014

Mr. Christian L. Soura, Interim Director
SC Department of Health and Human Services
Post Office Box 8206
Columbia, South Carolina 29202-8206

Attention: Sheila Chavis

RE: Title XIX State Plan Amendment, SC 14-017

Dear Mr. Soura:

We have reviewed the proposed State Plan Amendment, SC 14-017, which was submitted to the Atlanta Regional Office on September 25, 2014. This state plan amendment updates the coverage criteria for Preventative Services.

Based on the information provided, the Medicaid State Plan Amendment SC 14-017 was approved on December 2, 2014. The effective date of this amendment is September 1, 2014. We are enclosing the approved HCFA-179 and the plan pages.

A companion letter is also being issued with this approval to address concerns related to the "Preventive Services for Primary Care Enhancement" (PSPCE) on page 6.1-A, Attachment 3.1-A, Limitation Supplement.

If you have any additional questions or need further assistance, please contact Maria Drake at (404) 562-3697 or Maria.Drake@cms.hhs.gov.

Sincerely,

//s//

Jackie Glaze
Associate Regional Administrator
Division of Medicaid & Children's Health Operations

Enclosures

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
Atlanta Regional Office
61 Forsyth Street, Suite 4T20
Atlanta, Georgia 30303

DIVISION OF MEDICAID & CHILDREN'S HEALTH OPERATIONS

December 2, 2014

Mr. Christian L. Soura, Interim Director
SC Department of Health and Human Services
Post Office Box 8206
Columbia, South Carolina 29202-8206

Attention: Sheila Chavis

RE: Title XIX State Plan Amendment (SPA), SC 14-017 Companion Letter

Dear Mr. Soura:

This letter is being sent as a companion to our approval of South Carolina State Plan Amendment (SPA) 14-017 that was submitted to update coverage criteria for Preventative Services.

The Centers for Medicare & Medicaid Services (CMS) has the following concerns related to our review of SC SPA 14-017 which included an analysis of "Preventive Services for Primary Care Enhancement" (PSPCE) on page 6.1-A, Attachment 3.1-A, Limitation Supplement. Based on our review, we determined that approval of this service was not integral to the approval of the SPA, but also that the PSPCE program is not in compliance with current regulations, statute, or CMS guidance.

Section 1902(a) of the Social Security Act (the Act) requires that states have a state plan for medical assistance that meets certain federal requirements that set out a framework for the state program. Implementing regulations at 42 CFR 430.10 require that the state plan be a comprehensive written statement describing the nature and scope of the state's Medicaid program and that it contain all information necessary for CMS to determine whether the plan can be approved to serve as the basis for Federal financial participation (FFP) in the state program. The PSPCE program appears to be a disease management program and as such, must comply with regulations at 42 CFR 440.130(c) and the related guidance in section 4385 of the State Medicaid Manual that govern the preventive services benefit; or the requirements of the other licensed practitioners benefit under 42 CFR 440.60(d). All services must also meet the state plan requirements for statewideness at section 1902(a)(1) of the Social Security Act (Act), free choice of providers at section 1902(a)(23) of the Act, and

comparability at section 1902(a)(10)(B) of the Act. If the State is unable to meet all the requirements for retaining the PSPCE program in the state plan, then the State should consider using the section 1915(b) waiver authority or the section 1932(a) state option for managed care. The State Medicaid Director Letter #04-002 contains guidance about Disease Management Programs and applicable authorities and can be found at this link:
http://www.medicaid.gov/Federal-Policy-Guidance/downloads/smd022504.pdf

Within 90 days of the date of this letter, the state is required to submit a State plan amendment that resolves the issues, or a corrective action plan to resolve the issues, whichever is most appropriate. During the 90-day period, CMS is available to provide technical assistance to the state. State plans that are not in compliance with the requirement referenced above are grounds for initiating a formal compliance process.

If you have any questions regarding this amendment, please contact Maria Drake at (404) 562-3697.

Sincerely,

//s//

Jackie Glaze
Associate Regional Administrator
Division of Medicaid & Children's Health Operations

Enclosures

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

Center for Medicaid and State Operations

SMDL #04-002

February 25, 2004

Dear State Medicaid Director:

Disease management represents an exciting opportunity to significantly improve the care delivered to Medicaid beneficiaries with chronic conditions. It has emerged in both the public and private sector as a strategy to bring the benefits of care coordination techniques honed in managed care organizations (MCOs) to populations and regions that traditionally have not had access to those comprehensive capitated systems.

This letter provides guidance on how states can cover disease management in their Medicaid programs. This letter outlines some of the more common options; states interested in other strategies should contact us for assistance.

Background

Disease management is a set of interventions designed to improve the health of individuals, especially those with chronic diseases. Disease management programs usually include:

- identification of patients and matching the intervention with need;
- support for adherence to evidence-based medical practice guidelines, including providing medical treatment guidelines to physicians and other providers, and providing support services to assist the physician in monitoring the patient;
- services designed to enhance patient management, and adherence to an individualized treatment plan (e.g., patient education, monitoring and reminders, and behavior modification programs aimed at encouraging lifestyle changes);
- routine reporting and feedback loops (may include communication with patient, physician, health plan and ancillary providers, and practice profiling); and
- collection and analysis of process and outcome measures.

Traditionally, disease management was part of the comprehensive care furnished by MCOs. Today, we are seeing a multitude of strategies in order to bring disease management to fee-for-service (FFS) populations. States are building comprehensive systems in-house or contracting out the function to Disease Management Organizations (DMOs). This letter outlines some of the options available to states with regard to designing and operating disease management programs.

Disease Management as a Medical Service

Disease management programs that focus interventions on the beneficiary may qualify as medical services under Medicaid. In order to qualify as a medical service, disease management must include direct services. Direct services require the use of licensed practitioners such as nurses, pharmacists, or physicians who provide services directly to individual beneficiaries in order to improve or maintain their health. Examples include medical assessments, disease and dietary education, instruction in health self-management, and medical monitoring. These medical state plan services are eligible for Federal financial participation at the state's regular Federal Medical Assistance Percentage rate. Each proposal will be assessed to determine whether it qualifies as a medical service or administrative function, which in turn determines the Federal matching rate. There are a number of disease management models that may qualify as medical services under Medicaid, and we outline three major ones below.

Disease Management through Contracting With a Disease Management Organization (DMO)

One model is to contract with a DMO. The DMO manages the overall care of the beneficiary, but does not actually prior authorize or otherwise restrict access to other Medicaid services. In this model, the state often requires performance guarantees, including capitating the DMO for disease management services, as well as putting the DMO at risk for reducing overall expenditures. Capitated DMOs qualify as Prepaid Ambulatory Health Plans and are subject to a limited subset of the managed care regulations at 42 CFR Part 438.

Disease Management through an Enhanced Primary Care Case Management (PCCM) Program

A second model of beneficiary-focused disease management is to enhance a PCCM managed care program. In these programs, the state works with PCCM providers to enhance the care it delivers to its enrollees with certain chronic conditions. The state also may provide additional support in the form of case managers for complex cases and furnish ongoing monitoring reports on enrollee utilization. PCCM providers are often paid enhanced case management fees for providing disease management, in addition to the regular FFS reimbursement for other state plan services they provide.

Disease Management through Individual Providers

States can also offer disease management through individual FFS providers in the community (e.g., physicians, pharmacists, or dietitians). The providers often agree to undergo specified training, and bill on an FFS basis for disease management services provided. States may simply offer this option to interested providers, or build a more comprehensive system that provides additional support, training, and oversight.

Operating Authorities

All of the above models can be authorized through state plan amendments (SPAs) or waivers. Waiver authority can provide states with greater flexibility to design more focused programs. For instance, states that want to limit the number of disease management providers in order to achieve better cost and administrative efficiencies may request selective contracting authority under section 1915(b)(4) of the Social Security Act (the Act). Waiver authority also can be used to intentionally restrict geographic areas where disease management is available; restrict eligible beneficiaries (e.g., exclude Medicare beneficiaries); or mandate beneficiary enrollment.

Additionally, a SPA authorized under section 1932(a) of the Act provides much of the same flexibility available under waivers, and also does not require the periodic renewals associated with programs operating under waiver authority. This SPA authority to mandate enrollment was created by the Balanced Budget Act of 1997 and applies to PCCM or MCO-model disease management programs. As with waiver authority, section 1932(a) SPA authority provides flexibility with respect to limiting providers, eligible populations, and geographic areas that is not normally available under traditional SPAs. In particular, states offering disease management delivered as part of an enhanced PCCM program may want to consider this option.

A SPA may authorize disease management activities through expansions of the covered benefits for "other licensed practitioners" or "preventive services," as appropriate. A disease management SPA must meet the requirements of section 1902(a) of the Act, including statewideness, comparability, and freedom of choice. These requirements apply to both capitated and FFS disease management providers.

Disease Management as an Administrative Function

A disease management program that is limited to administrative activities by the state and its contractors would not constitute "medical assistance," but could be eligible for Federal matching funds for administration of the State plan at the standard administrative matching rate of 50 percent. For example, states or their contractors (e.g., a Quality Improvement Organization, Pharmacy Benefits Manager, or other outside vendor) may work with providers to: promote adherence to evidence-based guidelines; improve provider-patient communication skills; and provide routine feedback on beneficiary utilization of services. In this model, contact with beneficiaries is indirect: the change in provider practice patterns enhances beneficiary care. In addition, there may be targeted mailings to beneficiaries, but no face-to-face contact. The examples here are generally considered administrative functions, and may be eligible for Federal administrative match. State plan requirements such as statewideness and comparability do not apply to administrative functions.

Funding from Outside Sources

Pharmaceutical manufacturers may offer to fund disease management programs for Medicaid beneficiaries. Such funding would be considered a supplemental rebate under section 1927 of the Act, and, in accordance with the September 18, 2002, State Medicaid Director letter, the state needs to report an offset in the amount of Federal funds claimed based on the value of what the state received from the manufacturer.

Dual Eligibles

In general, disease management is not a Medicare-covered service. As a result, states may voluntarily or mandatorily enroll dual eligibles into a Medicaid disease management program. This is because in either case, enrollment does not affect their access to Medicare services. When enrolling dual eligibles, states must ensure that Medicare is the primary payer with respect to the limited Medicare coverage of diabetes self-management training sessions, and when disease management is available through a Medicare demonstration (please see the CMS Web site at http://cms.hhs.gov/healthplans/research).

For Further Information

We are available to provide technical assistance to states interested in establishing disease management programs for their populations. We encourage states to take advantage of the opportunities disease management programs offer to provide coordinated, cost-effective care that improves the health of Medicaid beneficiaries. If you have any questions about providing disease management, please call Ms. Jean Sheil, Director of the Family and Children's Health Programs Group at (410) 786-5647, or e-mail her at jsheil@cms.hhs.gov.

Sincerely,

/s/

Dennis G. Smith
Director

cc:
CMS Regional Administrators

CMS Associate Regional Administrators
for Medicaid and State Operations

Kathryn Kotula
Director, Health Policy Unit
American Public Human Services Association

Joy Wilson
Director, Health Committee
National Conference of State Legislatures

Matt Salo
Director of Health Legislation
National Governors Association

Brent Ewig
Senior Director, Access Policy
Association of State and Territorial Health Officials

Jim Frogue
Director, Health and Human Services Task Force
American Legislative Exchange Council

Trudi Matthews
Senior Health Policy Analyst
Council of State Governments

Dr. Michael Trujillo
Director
Indian Health Service

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: SC 14-017

2. STATE: South Carolina

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
September 1, 2014

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 440.130

7. FEDERAL BUDGET IMPACT:
a. FFY 2014 $167,000
b. FFY 2015 $2,000,000

8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT:

Attachment 3.1-A Limitation Supplement, Page 6, 6.1 & 6.1a (new page)

9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT *(If Applicable)*:

Attachment 3.1-A Limitation Supplement, Page 6 & 6.1

10. SUBJECT OF AMENDMENT:
Update coverage criteria for Preventative Services. This change will update and expand the services that are covered as a preventative benefit.

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:
Mr. Keck was designated by the Governor to review and approve all State Plans

12. SIGNATURE OF STATE AGENCY OFFICIAL:
//s//

13. TYPED NAME:
Anthony E. Keck

14. TITLE:
Director

15. DATE SUBMITTED:
September 24, 2014

16. RETURN TO:

South Carolina Department of Health and Human Services
Post Office Box 8206
Columbia, South Carolina 29202-8206

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED: 09-25-14

18. DATE APPROVED: 12-02-14

PLAN APPROVED – ONE COPY ATTACHED

19. EFFECTIVE DATE OF APPROVED MATERIAL:
09-01-14

20. SIGNATURE OF REGIONAL OFFICIAL:
//s//

21. TYPED NAME:
Jackie Glaze

22. TITLE: Associate Regional Administrator Division of Medicaid & Children's Health Opns

23. REMARKS:

GENERAL EXCLUSIONS: As provided by Section 1927(d) of the Social Security Act, certain outpatient drugs may be excluded from coverage. Those excluded are:

A. Medications used for weight control (except lipase inhibitors).
B. Pharmaceuticals deemed less than effective by the Drug Efficacy Study Implementation (DESI) Program.
C. Over-the-counter (OTC) pharmaceuticals that are not in the Medicaid drug rebate program and those products that are otherwise excluded from Medicaid coverage in this section.
D. Topical forms of minoxidil when used for hair loss.
E. Agents when used to promote fertility. (Effective March 1, 1991)

As provided by Section 1927(k) (2) of the Social Security Act, certain other exclusions are:

F. Investigational/experimental pharmaceuticals or products without FDA approval under the Federal Food, Drug, and Cosmetic Act.

As provided by Section 1927(k) (3) of the Social Security Act, certain other exclusions are:

G. Injectable table pharmaceuticals administered by the physician in his office, in a clinic or in a mental health center.

Drug Prior Authorizations can be requested by the prescribing physician or pharmacist with needed documentation for items excluded from coverage and those drugs requiring special authorization as outlined in the Pharmaceutical Services Medicaid Manual, except those drugs ruled ineffective (DESI) by the Federal Government.

12c. PROSTHETIC OR ORTHOTIC APPLIANCES. Approval from the State Office is required prior to the provision of the prosthetic or orthotic appliance. Supplies, equipment, and appliance limitations are specified in the Durable Medical Equipment Provider Manual, and follow Medicare limitations.

12d. EYEGLASSES Coverage for eyeglasses will be limited to recipients under 21 years of age when medical necessity has been established. One pair of eyeglasses is available during a 365 day period to beneficiaries eligible under the EPSDT program. Additional lenses can be approved if the prescription changes at least one half diopter (0.50) during the 365 day period.

13c. Preventive Services are defined as routine services for adults or children when the procedures are performed in the absence of an illness or complaint(s). Preventative services are subject to certain limitations depending on age, risk factors, and frequency.. These best practice recommendations are subject to change as regulations and future clarifications are released by the USPSTF.

	Description
Abdominal aortic aneurysm screening: men	The USPSTF recommends one-time screening for abdominal aortic aneurysm by ultrasonography in men ages 65 to 75 years who have ever smoked.
Alcohol misuse: screening and counseling	The USPSTF recommends that clinicians screen adults age 18 years or older for alcohol misuse and provide persons engaged in risky or hazardous drinking with brief behavioral counseling interventions to reduce alcohol misuse.
Blood pressure screening in adults	The USPSTF recommends screening for high blood pressure in adults age 18 years and older.
Breast cancer screening	The USPSTF recommends screening mammography for women, with or without clinical breast examination, every 1 to 2 years for women age 40 years and older.
Cervical cancer screening	The USPSTF recommends screening for cervical cancer in women ages 21 to 65 years with cytology (Pap smear) every 3 years or, for women ages 30 to 65 years who want to lengthen the screening interval, screening with a combination of cytology and human papillomavirus (HPV) testing every 5 years.
Cholesterol abnormalities screening: men 35 and older	The USPSTF strongly recommends screening men age 35 years and older for lipid disorders.
Cholesterol abnormalities screening: men younger than 35	The USPSTF recommends screening men ages 20 to 35 years for lipid disorders if they are at increased risk for coronary heart disease.
Cholesterol abnormalities screening: women 45 and older	The USPSTF strongly recommends screening women age 45 years and older for lipid disorders if they are at increased risk for coronary heart disease.
Colorectal cancer screening	The USPSTF recommends screening for colorectal cancer using fecal occult blood testing, sigmoidoscopy, or colonoscopy in adults beginning at age 50 years and continuing until age 75 years. The risks and benefits of these screening methods vary.
Depression screening: adolescents	The USPSTF recommends screening adolescents (ages 12-18 years) for major depressive disorder when systems are in place to ensure accurate diagnosis, psychotherapy (cognitive-behavioral or interpersonal), and follow-up.
Depression screening: adults	The USPSTF recommends screening adults for depression when staff-assisted depression care supports are in place to assure accurate diagnosis, effective treatment, and follow-up.
Diabetes screening	The USPSTF recommends screening for type 2 diabetes in asymptomatic adults with sustained blood pressure (either treated or untreated) greater than 135/80 mm Hg.
Hepatitis C virus infection screening: adults	The USPSTF recommends screening for hepatitis C virus (HCV) infection in persons at high risk for infection. The USPSTF also recommends offering one-time screening for HCV infection to adults born between 1945 and 1965.

HIV screening: nonpregnant adolescents and adults	The USPSTF recommends that clinicians screen for HIV infection in adolescents and adults ages 15 to 65 years. Younger adolescents and older adults who are at increased risk should also be screened.
HIV screening: pregnant women	The USPSTF recommends that clinicians screen all pregnant women for HIV, including those who present in labor who are untested and whose HIV status is unknown.
Intimate partner violence screening: women of childbearing age	The USPSTF recommends that clinicians screen women of childbearing age for intimate partner violence, such as domestic violence, and provide or refer women who screen positive to intervention services. This recommendation applies to women who do not have signs or symptoms of abuse.
Lung cancer screening	The USPSTF recommends annual screening for lung cancer with low-dose computed tomography in adults ages 55 to 80 years who have a 30 pack-year smoking history and currently smoke or have quit within the past 15 years. Screening should be discontinued once a person has not smoked for 15 years or develops a health problem that substantially limits life expectancy or the ability or willingness to have curative lung surgery.
Skin cancer behavioral counseling	The USPSTF recommends counseling children, adolescents, and young adults ages 10 to 24 years who have fair skin about minimizing their exposure to ultraviolet radiation to reduce risk for skin cancer.
Tobacco use counseling and interventions: nonpregnant adults	The USPSTF recommends that clinicians ask all adults about tobacco use and provide tobacco cessation interventions for those who use tobacco products.
Tobacco use counseling: pregnant women	The USPSTF recommends that clinicians ask all pregnant women about tobacco use and provide augmented, pregnancy-tailored counseling to those who smoke.
Tobacco use interventions: children and adolescents	The USPSTF recommends that clinicians provide interventions, including education or brief counseling, to prevent initiation of tobacco use in school-aged children and adolescents.

13c. PREVENTIVE SERVICE FOR PRIMARY CARE ENHANCEMENT

A. Definition of Service - Preventive Services for Primary Care Enhancement (PSPCE) are services, including assessment and evaluation, furnished by physicians or other licensed practitioners of the healing arts acting within the scope of practice under State law which are furnished in order to:

- Prevent disease, disability, and other health conditions or their progression;
- Prolong life; and
- Promote physical and mental health and efficiency.