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State/Territory Name: Puerto Rico

State Plan Amendment (SPA) #: 15-0001

This file contains the following documents in the order listed:

- 1) CMS Approval Letter
- 2) CMS Companion Letter
- 3) CMS 179 Form/Summary Form (with 179-like data)
- 4) Approved SPA Templates

Department of Health & Human Services
Centers for Medicare & Medicaid Services
New York Regional Office
26 Federal Plaza, Room 37-100
New York, NY 10278



DIVISION OF MEDICAID AND CHILDREN'S HEALTH OPERATION

September 9, 2015

Ricardo A. Colon Padilla, CPA
Medicaid Director
Puerto Rico Medicaid Program
Puerto Rico Department of Health
P.O. Box 70184
San Juan, Puerto Rico 70184


Dear Mr. Colon:

We have completed our review of the submission of Puerto Rico State Plan Amendment (SPA) 15-0001 which was received in our office on June 26, 2015 and find it acceptable for incorporation into Puerto Rico's Medicaid State Plan. This Family Planning SPA was submitted to include contraceptives prescription drugs effective April 1, 2015.

Please note that the approval date of this SPA is September 9, 2015 with an effective date of April 1, 2015. Copy of the approved State Plan pages and the signed CMS-179 are enclosed.

If you have any questions, please contact Ivelisse M. Salce at (212) 616-2411.

Sincerely,



Michael Melendez
Associate Regional Administrator
Division of Medicaid and Children's Health

Cc. Lindsey Wilde
Sheri Gaskins

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
New York State Department of Health
Bureau of Federal Relations & Provider Assessments
99 Washington Ave - One Commerce Plaza, Suite 1430
Albany, NY 12210



DIVISION OF MEDICAID & CHILDREN'S HEALTH OPERATIONS

September 9, 2015

Ricardo A. Colon Padilla, CPA
Medicaid Director
Puerto Rico Medicaid Program
Puerto Rico Department of Health
P.O. Box 70184
San Juan, Puerto Rico 70184

Dear Mr. Padilla:

This letter is being sent as a companion to our approval of your Puerto Rico State Plan Amendment (SPA 15-0001), approved on September 9, 2015. During our processing of PR SPA 15-0001, we also reviewed the services that appeared on the submitted pages and the associated coverage provisions corresponding to those same services. Based on that review, we determined that Attachment 3.1-A and 3.1-B page 8 are not in compliance with current CMS regulations, statute, or guidance.

Section 1902 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 containing all information necessary for CMS to determine whether the plan can be approved as a basis for Federal financial participation (FFP) in the state program.

To that end, CMS welcomes the opportunity to work with you and your staff to discuss options for resolving concerns as outlined below:

Dental Services:

Attachment 3.1-A & 3.1-B, Page 8, Item 10 (Dental Benefit):

1. Please provide responses to the sufficiency questions below:
 - a. **BACKGROUND.** What was the reason for these limitations? If the reason for the limitations 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?

- b. **PURPOSE.** What is the clinical purpose of the dental benefit and how has that purpose been achieved with these limitations?
- c. **DATA SUPPORT** 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:
- Aged, Blind and Disabled
 - Non-Dually Eligible Adults (for analyses of services for which Medicare would not be primary payer, otherwise the analysis would include dually eligible individuals)
 - Pregnant Women
 - Parents/Caretakers/Other Non-Disabled Adults
 - Adult expansion group
- d. **CLINICAL SUPPORT.** If the data requested above is not available, or is not relevant to demonstrate the sufficiency of the limited benefit, please indicate support for the 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 scope of services has meaningful clinical merit to achieve its intended purpose.
- e. **EXCEPTIONS.** Are there any exemptions to the proposed limitations? If so, how was this exemption determined to be appropriate? Does PR 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 limits 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 limitations?
- f. **BENEFICIARY IMPACT.** Please describe how beneficiaries were impacted by these limitations. If the limitations cannot be exceeded based on a determination of medical necessity:
- How have those affected by the limitations obtained the medical services they need beyond the stated limits?
 - Are beneficiary's billed and expected to pay for any care that may not be covered? Or, instead is the provider or practitioner expected to absorb the costs of the provided services?
- g. **DELIVERY SYSTEM.** Do the limitations 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 were adjusted to reflect the change.
- h. **TRACKING.** How are the limitations tracked? Are both providers and beneficiaries informed in advance so they know they have reached the limit? Please summarize the process.

2. Item (K), on page 8, indicates a limitation for prophylaxis for adults is the same as for children. It is not clear why this limitation is included. Further, children in EPSDT must receive all medically necessary 1905(a) benefits. Inclusion in the state plan with a limitation appears, to run afoul of the EPSDT assurance. The comments in this item apply to the remaining questions below.
3. Item (L), on page 8, indicates a more robust fluoride benefit for individuals age 19 and under. It is not permissible to target a population based on age per comparability requirements at 1902(a) (10) (B). That being said if PR is serving all individuals under age 21 this could be viewed as EPSDT. However, children in EPSDT must receive all medically necessary 1905(a) benefits. Please clarify if this benefit is for all individuals under the age of 21?
4. Item (M), on page 8, indicates a limitation based on age for fissure sealants including deciduous molars. Once again, it is not permissible to target a population based on age per comparability requirements at 1902(a) (10) (B). If this benefit were provided to all individuals under the age of 21 it would not run afoul of comparability requirements because it would be provided via EPSDT. It may be that the services described are no longer effective once a child has reached a developmental milestone (this would be described in your medical necessity criteria and not in the state plan pages). If this is the case, please provide the medical rational for the limitation.
5. At the bottom of page 8, PR provides anesthesia for children with a 'special condition'.
 - a. Please describe the special condition
 - b. Please confirm that children is meant to include the entire EPSDT population
 - c. Please clarify whether or not the adult population receives anesthesia.

The State has 90 days from the date of this letter – until 12/09/2015 – to address the issues described above. Within this 90-days period, the State may submit a SPA to address these issues or may submit a corrective action plan describing in detail how the State will resolve the issues identified above in a timely manner. Failure to respond within the 90 days will result in the initiation of a formal compliance process. During the 90-days period, CMS will provide any required technical assistance to assist you in resolving these issues. If you have any additional questions or require any further assistance, please contact Ivelisse Salce at (212) 616-2411 or Ivelisse.Salce@cms.hhs.gov.

Sincerely,



Ricardo Holligan
Acting Associate Regional Administrator
Division of Medicaid & Children's Health Operations

cc: Jason Frandson
Sheri Gaskin

| | | |
|---|---|-------------------------|
| TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL FOR: CENTER FOR MEDICARE & MEDICAID SERVICES (CMS) | 1. TRANSMITTAL NUMBER PR-15-001 | 2. STATE Puerto Rico |
| | 3. PROGRAM IDENTIFICATION: Title XIX of the Social Security Act (Medicaid) | |
| TO: REGIONAL ADMINISTRATOR Centers for Medicare & Medicaid Services (CMS) Department of Health and Human Services (HHS) | 4. PROPOSED EFFECTIVE DATE April 1, 2015 | |

5. TYPE OF PLAN MATERIAL (Check One)

NEW STATE PLAN AMENDMENT TO CONSIDERED AS NEW PLAN AMENDMENT

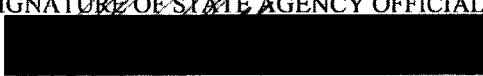
COMPLETE BLOCKS 6 THRU 10 IF THIS IS AN AMENDMENT (Separate transmittal for each amendment)

| | |
|---|---|
| 6. FEDERAL STATUTE/REGULATION CITATION Section 1905 (a)(4)(C) of the Social Security Act 42 CFR §440.40(c), §440.210(a)(2)(i), and §440.250(c) 42 CFR §441.10(i) and §441.20 | 7. FEDERAL BUDGET IMPACT a. FFY <u>2015 (2 quarter)</u> \$ <u>\$7,156,445.00</u> b. FFY <u>2016</u> \$ <u>\$13,818,877.00</u> |
| 8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT Description for Attachment 3.1-A, pages 6, 8, and 9 Description for Attachment 3.1-B, pages 6, 8, and 9 | 9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable) Description for Attachment 3.1-A, pages 6, 8, 9, and 9a Description for Attachment 3.1-B, pages 6, 8, 9, and 9a |

10. SUBJECT OF AMENDMENT
FAMILY PLANNING SERVICES TO INCLUDE CONTRACEPTIVES PRESCRIPTION DRUGS

11. GOVERNOR'S REVIEW (Check One)

GOVERNOR'S OFFICE REPORTED NO COMMENT OTHER, AS SPECIFIED
 COMMENTS OF GOVERNOR'S OFFICE ENCLOSED
 NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL

| | |
|---|---|
| 12. SIGNATURE OF STATE AGENCY OFFICIAL  | 16. RETURN TO PUERTO RICO MEDICAID PROGRAM PUERTO RICO DEPARTMENT OF HEALTH PO BOX 70184 SAN JUAN PR 00936-8184 |
| 13. TYPE NAME RICARDO A. COLÓN-PADILLA, CPA | |
| 14. TITLE EXECUTIVE DIRECTOR | |
| 15. DATE SUBMITTED June 30, 2015 | |

FOR REGIONAL OFFICE USE ONLY

| | |
|-------------------|---|
| 17. DATE RECEIVED | 18. DATE APPROVED September 09, 2015 |
|-------------------|---|

PLAN APPROVED - ONE COPY ATTACHED

| | |
|---|--|
| 19. EFFECTIVE DATE OF APPROVED MATERIAL APR 01 2015 | 20. SIGNATURE OF REGIONAL OFFICIAL  |
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| | |
|------------------------------------|--|
| 21. TYPED NAME Ricardo Holligan | 22. TITLE Division of Medicaid & Children's Health Operations |
|------------------------------------|--|

23. REMARKS

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
STATE / TERRITORY: COMMONWEALTH OF PUERTO RICO

AMOUNT, DURATION, AND SCOPE OF MEDICAL AND REMEDIAL CARE AND
SERVICES PROVIDED TO THE CATEGORICALLY NEEDY

3. Other laboratory and X-ray services.
Diagnostic blood tests and X-rays are covered, but the following special procedures and diagnostic tests are provided subject to benefits included under the plan's special coverage and medical necessity criteria:
- a. Computerized tomography.
 - b. Magnetic Resonance Tests Imaging
 - c. Cardiac catheterization
 - d. Holter Tests
 - e. Doppler Tests
 - f. Stress Tests
 - g. Lithotripsy
 - h. Electromyography
 - i. Single Photon Emission Computerized – Tomography Test (SPECT)
 - j. Ocular Plesthymography (OPG)
 - k. Impedance Plesthymography
 - l. Other invasive and non-invasive cardiovascular, cerebrovascular, and neurosurgical procedures
 - m. Nuclear Medicine tests
 - n. Endoscopies for diagnostic purposes
 - o. Genetic Studies.
- 4.c. Family Planning Services: The coverage benefits of the Puerto Rico Medicaid and CHIP Programs provide the following Family Planning Services: (i) education and counseling, (ii) pregnancy testing, (iii) infertility assessment, (iv) sterilization services in accordance with 42 CFR 441.200 subpart F, (v) laboratory services, (vi) at least one of every class and category of FDA (Food and Drug Administration) approved contraceptive medication, (vii) cost and insertion/removal of non-oral products, such as long acting reversible contraceptives (LARC), and (viii) other FDA approved contraceptive medications or methods when it is medically necessary and approved through a prior authorization or exception process.
- 5.a. Physician services in the patient's home are provided based on medical necessity.

Transmittal No.: 15-001

Effective Date: April 1, 2015

Supersedes TN No.: 03-001-A

Approval Date: SEP 09 2015

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
STATE / TERRITORY: COMMONWEALTH OF PUERTO RICO

AMOUNT, DURATION, AND SCOPE OF MEDICAL AND REMEDIAL CARE AND SERVICES
PROVIDED TO THE CATEGORICALLY NEEDY

9. Clinic services are provided according to and within to the State Plan coverage and complaint with 42 CFR 440.90, including preventive, diagnostic, therapeutic, rehabilitative, or palliative services that are furnished by a facility that is not part of a hospital but is organized and operated to provide medical care to outpatients. The term includes the following services furnished to outpatients: (a) services furnished at the clinic by or under the direction of a physician or dentist and (b) services furnished outside the clinic, by clinic personnel under the direction of a physician, to an eligible individual who does not reside in a permanent dwelling or does not have a fixed home or mailing address. These clinics include Department of Health Clinics, Preven Clinics, Urgent Care Clinics, and Physician operated clinics.
10. Dental Services
- a. One (1) Initial comprehensive oral examination
 - b. One (1) Periodic oral examination every six (6) months
 - c. Limited oral examination-defined problem
 - d. One (1) Intraoral complete series, including bitewings, every three (3) years
 - e. One (1) Intraoral periapical first film
 - f. Intraoral-periapical-each additional film, per year up to five (5) times
 - g. One (1) Bitewing, single film
 - h. One (1) Bitewings-two films, per year
 - i. One (1) Panoramic film, every three (3) years
 - j. One (1) Prophylaxis-adult, every six (6) months
 - k. One (1) Prophylaxis-child, every six (6) months
 - l. One (1) Topical application of fluoride, every six (6) months for beneficiaries under 19 years of age
 - m. Fissure sealants for beneficiaries up to 14 years of age inclusive, per lifetime, per tooth (01351). Deciduous molars are included for beneficiaries up to 8 years of age when clinically necessary.
 - n. Amalgam Restorations
 - o. Resin Restorations
 - p. Root Canal Therapy
 - q. Oral Surgery
 - r. Palliative Treatment
- General anesthesia for dental treatment in cases of children with special condition:
- a. General anesthesia for the first (30) minutes
 - b. General anesthesia for each (15) additional minutes

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Effective Date: April 1, 2015

Supersedes TN No.: 03-001-A

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STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
STATE / TERRITORY: COMMONWEALTH OF PUERTO RICO

AMOUNT, DURATION, AND SCOPE OF MEDICAL AND REMEDIAL CARE AND
SERVICES PROVIDED TO THE CATEGORICALLY NEEDY

Description of Limitation

- 11.a. Physical therapy and or chiropractor services as determined medically necessary.
- a. Initial 15 sessions available without prior authorization.
 - b. Additional 15 sessions require prior authorization.
 - c. The treatment limit is combined with the limit for chiropractic care.
 - d. An individual may receive a total of 30 physical therapy and/or chiropractic sessions combined.
 - e. Additional session beyond 30 is allowed with medical necessity and requires a prior authorization process.
- 12.a. Prescribed drugs
- a. The PRHIA maintains a drug Formulary as the official formulary of drugs provided by the Health Reform Plan coverage, which contains most of the vast majority of therapeutic alternative categories available.
 - b. A preferred drug list (PDL) is also maintained as a cost-effective utilization tool in rendering prescription benefits under the Health Reform Plan.
 - c. The MCOs, MBHOs, and Direct Providers, that are contracted, agree to conduct the pharmacy billing and claims through the PRHIA's contracted Pharmacy Benefits Manager (PBM).
 - d. Under exceptional circumstances, a drug not included in the Formulary could be covered only through exceptional circumstances and procedure set forth below.

Transmittal No.: 15-001

Effective Date: April 1, 2015

Supersedes TN No.: 14-008

Approval Date: _____

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
STATE / TERRITORY: COMMONWEALTH OF PUERTO RICO

AMOUNT, DURATION, AND SCOPE OF MEDICAL AND REMEDIAL CARE AND
SERVICES PROVIDED TO THE CATEGORICALLY NEEDY

Description of Limitation

Limitations and Conditions of the Prescription Services

- a. Contraceptives drugs are covered under the Health Reform Plan for the treatment of menstrual dysfunction and for birth control purposes, as follows:
 - (i) At least one of every class and category of FDA (Food and Drug Administration) approved contraceptive medication,
 - (ii) At least one of every class and category of FDA approved contraceptive method, and
 - (iii) Other FDA approved contraceptive medications or methods when it is medically necessary and approved through a prior authorization or exception process.
- b. Drugs required for the ambulatory or hospitalized treatment of diagnosed beneficiaries with AIDS or with an HIV positive factor are covered under the special coverage to include only antiretrovirals but excluding Protease inhibitors. The Protease inhibitors are not covered benefits financed under the Health Reform Plan, they are provided to Medicaid beneficiaries through coordination with the Regional Immunological Clinics of the Commonwealth Health Department's PASET Division.
- c. Immunosuppressant drugs for all transplant patients are covered only to the extent of maintenance treatment post-surgery to ensure the continuity of health stability of the beneficiary, as well as emergencies that may result after surgery (as transplants are not covered).
- d. New drugs for future inclusion are evaluated through an active process for revising on a continuous basis and evaluate the future inclusion of new medicines or the removal of medicines from the formulary. Considering the dynamic nature of this process, the PRHIA requires the inclusion or exclusion of medicines as changes and advances affect the standard practice for the treatment of conditions or developments of standard practices for the treatment of a condition or particular treatments.

Transmittal No.: 15-001

Effective Date: April 1, 2015

Supersedes TN No.: NEW

Approval Date: SEP 09 2015

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
STATE / TERRITORY: COMMONWEALTH OF PUERTO RICO

AMOUNT, DURATION, AND SCOPE OF MEDICAL AND REMEDIAL CARE AND
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 - d. Under exceptional circumstances, a drug not included in the Formulary could be covered only through exceptional circumstances and procedure set forth below.

Transmittal No.: 15-001

Effective Date: April 1, 2015

Supersedes TN No.: 14-008

Approval Date: _____

SEP 09 2015

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
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