## Table of Contents

**State/Territory Name:** Pennsylvania  
**State Plan Amendment (SPA) #:** 22-0013  

This file contains the following documents in the order listed:

1. Approval Letter  
2. CMS 179 Form/Summary Form (with 179-like data)  
3. Approved SPA Pages
April 7, 2022

M. Snead
Acting Secretary
Pennsylvania Department of Human Services
P.O. Box 2675
Harrisburg, PA 17105

Re: Pennsylvania State Plan Amendment (SPA) 22-0013

Dear Acting Secretary Snead:

The Centers for Medicare & Medicaid Services (CMS) reviewed your Medicaid State Plan Amendment (SPA) submitted under transmittal number (TN) 22-0013. This amendment provides required assurances that the state is appropriately covering and paying for routine patient costs of items and services for beneficiaries enrolled in qualifying clinical trials.

We conducted our review of your submittal according to statutory requirements in Title XIX of the Social Security Act and implementing regulations. This letter is to inform you that Pennsylvania Medicaid SPA 22-0013 was approved on April 7, 2022, with an effective date of January 1, 2022.

If you have any questions, please contact Dan Belnap at 215-861-4273 or via email at Dan.Belnap@cms.hhs.gov.

Sincerely,

[Redacted]
James G. Scott, Director
Division of Program Operations

cc: Eve Lickers
    Pam Machamer-Peechatka
    Lacey Gates
**Coverage of the routine patient costs for beneficiaries in qualifying clinical trials.**

10. **GOVERNOR’S REVIEW (Check One)**
   - [ ] GOVERNOR’S OFFICE REPORTED NO COMMENT
   - [x] OTHER, AS SPECIFIED:
   - [ ] COMMENTS OF GOVERNOR’S OFFICE ENCLOSED
   - [ ] NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL

15. **RETURN TO**
   - Commonwealth of Pennsylvania
   - Department of Human Services
   - Office of Medical Assistance Programs
   - Bureau of Policy, Analysis and Planning
   - P.O. Box 2675
   - Harrisburg, Pennsylvania 17105-2675

**FOR CMS USE ONLY**

16. **DATE RECEIVED**
   - March 29, 2022

17. **DATE APPROVED**
   - April 7, 2022

18. **EFFECTIVE DATE OF APPROVED MATERIAL**
   - January 1, 2022

20. **TYPED NAME OF APPROVING OFFICIAL**
   - James G. Scott

21. **TITLE OF APPROVING OFFICIAL**
   - Director, Division of Program Operations

**22. REMARKS**

**Instructions on Back**
30. Coverage of Routine Patient Cost in Qualifying Clinical Trial

*The state needs to check each assurance below.

Provided: __X____

I. General Assurances:

Routine Patient Cost – Section 1905(gg)(1)

__X__ Coverage of routine patient cost for items and services as defined in section 1905(gg)(1) that are furnished in connection with participation in a qualified clinical trial.

Qualifying Clinical Trial – Section 1905(gg)(2)

__X__ A qualified clinical trial is a clinical trial that meets the definition at section 1905(gg)(2).

Coverage Determination – Section 1905(gg)(3)

__X__ A determination with respect to coverage for an individual participating in a qualified clinical trial will be made in accordance with section 1905(gg)(3).