

**Application for**

**Section 1915(b) (4) Waiver**

**Fee-for-Service**

**Selective Contracting Program**

June, 2012

v1.0

## Table of Contents

Facesheet	3
Section A - Waiver Program Description	4
Part I: Program Overview	
Tribal Consultation	4
Program Description	4
Waiver Services	7
A. Statutory Authority	8
B. Delivery Systems	8
C. Restriction of Freedom-of-Choice	8
D. Populations Affected by Waiver	9
Part II: Access, Provider Capacity and Utilization Standards	
A. Timely Access Standards	10
B. Provider Capacity Standards	10
C. Utilization Standards	14
Part III: Quality	
A. Quality Standards and Contract Monitoring	15
B. Coordination and Continuity-of-Care Standards	16
Part IV: Program Operations	
A. Beneficiary Information	17
B. Individuals with Special Needs	17
Section B - Waiver Cost-Effectiveness and Efficiency	18

**Application for Section 1915(b) (4) Waiver  
Fee-for-Service (FFS) Selective Contracting Program**

Facesheet

The **State** of Alabama requests a waiver/amendment under the authority of section 1915(b) of the Act. The Medicaid agency will directly operate the waiver.

The **name of the waiver program** is Synagis® (palivizumab) Management Program  
(List each program name if the waiver authorizes more than one program.).

**Type of request.** This is:

- an initial request for new waiver. All sections are filled.
- a request to amend an existing waiver, which modifies Section/Part \_\_\_\_\_
- a renewal request

Section A is:

- replaced in full
- carried over with no changes
- changes noted in **BOLD**.

Section B is:

- replaced in full
- changes noted in **BOLD**.

**Effective Dates:** This waiver/renewal/amendment is requested for a period of 2 years beginning 9/1/2013 and ending 8/31/2015.

**State Contact:** The State contact person for this waiver is Kelli Littlejohn, PharmD and can be reached by telephone at (334) 353-4525, or fax at (334) 353-5623, or e-mail at kelli.littlejohn@medicaid.alabama.gov. (List for each program)

# Section A - Waiver Program Description

## Part I: Program Overview

### Tribal Consultation:

Describe the efforts the State has made to ensure that Federally-recognized tribes in the State are aware of and have had the opportunity to comment on this waiver proposal (if additional space is needed, please supplement your answer with a Word attachment).

Alabama has one federally recognized tribe, the Poarch Band of Creek Indians with members primarily located in one county. It is estimated that there are approximately 220 federally recognized tribal members that are Medicaid eligible.

The Agency mailed a letter to the tribal chief to inform the tribe of the intent of the AMA intent to implement the Synagis Management Program waiver. The purpose of this notice was to seek input and answer any tribal concerns related to the waiver.

### Program Description:

Provide a brief description of the proposed selective contracting program or, if this is a request to amend an existing selective contracting waiver, the history of and changes requested to the existing program. Please include the estimated number of enrollees served throughout the waiver (if additional space is needed, please supplement your answer with a Word attachment).

The Agency's goal for the Synagis® Program is to maintain access to quality care for recipients who have a medical need for Synagis® (palivizumab) and to provide clinical support in the Fee-for-Service delivery system, while at the same time enhancing administrative efficiencies and cost-effectiveness. Medicaid plans to determine, through the competitive bidding process, a sole-source vendor to provide Synagis. Synagis® is a product that is not delivered directly to the patient; it is delivered to the physician's office for administration. Therefore, there will be no change to patient access by implementing this program.

The following chart details palivizumab claims billed during the 2011-2012 season. \*Recipients are counted only once in a season.

Claims	Total Reimbursement Amount	Total Patients
4541	\$10,173,894	1088

### Waiver Services:

Please list all existing State Plan services the State will provide through this selective contracting

## A. Statutory Authority

1. **Waiver Authority.** The State is seeking authority under the following subsection of 1915(b):

**1915(b) (4) - FFS Selective Contracting program**

2. **Sections Waived.** The State requests a waiver of these sections of 1902 of the Social Security Act:

- a.  **Section 1902(a) (1) - Statewideness**
- b.  **Section 1902(a) (10) (B) - Comparability of Services**
- c.  **Section 1902(a) (23) - Freedom of Choice**
- d.  **Other Sections of 1902 - (please specify)**

## B. Delivery Systems

1. **Reimbursement.** Payment for the selective contracting program is:

- the same as stipulated in the State Plan  
 is different than stipulated in the State Plan (please describe)

The rate procured through the competitive bidding process will be the final rate paid to the provider per milliliter of drug; there will be no additive administrative/delivery/dispensing fees.

2. **Procurement.** The State will select the contractor in the following manner:

- Competitive** procurement  
 **Open** cooperative procurement  
 **Sole source** procurement  
 **Other** (please describe)

## C. Restriction of Freedom of Choice

1. **Provider Limitations.**

Beneficiaries will be limited to a single provider in their service area.

Beneficiaries will be given a choice of providers in their service area.

(NOTE: Please indicate the area(s) of the State where the waiver program will be implemented)

2. **State Standards.**

Detail any difference between the state standards that will be applied under this waiver and those detailed in the State Plan coverage or reimbursement documents (if additional space is needed, please supplement your answer with a Word attachment). N/A

**D. Populations Affected by Waiver**

(May be modified as needed to fit the State’s specific circumstances)

1. **Included Populations.** The following populations are included in the waiver:

- Section 1931 Children and Related Populations
- Section 1931 Adults and Related Populations
- Blind/Disabled Adults and Related Populations
- Blind/Disabled Children and Related Populations
- Aged and Related Populations
- Foster Care Children
- Title XXI CHIP Children

2. **Excluded Populations.** Indicate if any of the following populations are excluded from participating in the waiver: N/A Only children under the age of 2 are approved for Synagis.

- Dual Eligibles
- Poverty Level Pregnant Women
- Individuals with other insurance
- Individuals residing in a nursing facility or ICF/MR
- Individuals enrolled in a managed care program
- Individuals participating in a HCBS Waiver program
- American Indians/Alaskan Natives
- Special Needs Children (State Defined). Please provide this definition.
- Individuals receiving retroactive eligibility
- Other (Please define):

**Part II: Access, Provider Capacity and Utilization Standards**

**A. Timely Access Standards**

Describe the standard that the State will adopt (or if this is a renewal or amendment of an

existing selective contracting waiver, provide evidence that the State has adopted) defining timely Medicaid beneficiary access to the contracted services, *i.e.*, what constitutes timely access to the service?

1. How does the State measure (or propose to measure) the timeliness of Medicaid beneficiary access to the services covered under the selective contracting program (if additional space is needed, please supplement your answer with a Word attachment)?

Synagis® is a product that is not delivered directly to the patient; it is delivered to the physician's office for administration. Therefore, there will be no change to patient access by implementing this program. Within the scope of work of the competitive bid document, prospective vendors must show experience, keep adequate stock of product on hand, and operate an efficient, accurate and responsive distribution and delivery system. The selected contractor will be mandated to supply Synagis within 2 business days of obtaining a "clean" prescription.

2. Describe the remedies the State has or will put in place in the event that Medicaid beneficiaries are unable to access the contracted service in a timely fashion (if additional space is needed, please supplement your answer with a Word attachment).

Medicaid will inform a selected Contractor when the Contractor's performance does not comply with the Contract requirements. The selected Contractor must prepare and submit for Medicaid approval a corrective action plan for each identified problem within the timeframe determined by Medicaid. The corrective action plan must include, but is not limited to:

1. Brief description of Medicaid's findings.
2. Specific steps the selected Contractor will take to correct the situation or reasons why the selected Contractor believes corrective action is not necessary.
3. Name(s) and title(s) of responsible staff person(s).
4. Timetable for performance of each corrective action step.
5. Monitoring the selected Contractor will perform to ensure that it takes the specified corrective action steps.
6. Signature of a senior executive.

The selected Contractor must implement the corrective action plan within the timeframe specified by Medicaid. Failure by the selected Contractor to implement corrective action plans, as required by Medicaid, may result in further action by Medicaid including, but not limited to, recoupment, penalties, and/or discontinuance of contract.

## **B. Provider Capacity Standards**

Describe how the State will ensure (or if this is a renewal or amendment of an existing selective contracting waiver, provide evidence that the State has ensured) that its selective contracting program provides a sufficient supply of contracted providers to meet Medicaid beneficiaries' needs.

1. Provide a detailed capacity analysis of the number of providers (e.g., by type, or

number of beds for facility-based programs), or vehicles (by type, per contractor for non-emergency transportation programs), needed per location or region to assure sufficient capacity under the selective contracting program (if additional space is needed, please supplement your answer with a Word attachment).

Synagis® is a product that is not delivered directly to the patient; it is delivered to the physician's office for administration. Therefore, there will be no change to patient access by implementing this program. Within the scope of work of the competitive bid document, prospective vendors must show experience, keep adequate stock of product on hand, and operate an efficient, accurate and responsive distribution and delivery system. Once vendor with appropriate experience and stock will be able to produce Synagis through all areas of the state. Please see attached bidding document for reference.

2. Describe how the State will evaluate and ensure on an ongoing basis that providers are appropriately distributed throughout the geographic regions covered by the selective contracting program so that Medicaid beneficiaries have sufficient and timely access throughout the regions affected by the program (if additional space is needed, please supplement your answer with a Word attachment).

The contract agreement mandates timely dispensing/delivery of Synagis, and requires clinical support. Otherwise, penalties will be applied.

## **B. Utilization Standards**

Describe the State's utilization standards specific to the selective contracting program.

1. How will the State (or if this is a renewal or amendment of an existing selective contracting waiver, provide evidence that the State) regularly monitor(s) the selective contracting program to determine appropriate Medicaid beneficiary utilization, as defined by the utilization standard described above (if additional space is needed, please supplement your answer with a Word attachment)?

Medicaid will randomly audit claims of the selected contractor to ensure compliance. If found non-compliant, the selected Contractor must implement the corrective action plan within the timeframe specified by Medicaid. Failure by the selected Contractor to implement corrective action plans, as required by Medicaid, may result in further action by Medicaid including, but not limited to, recoupment and/or discontinuance of contract.

2. Describe the remedies the State has or will put in place in the event that Medicaid beneficiary utilization falls below the utilization standards described above (if additional space is needed, please supplement your answer with a Word attachment).

If the vendor does not meet one or more of the standards/criteria listed in the scope of work, the Alabama Medicaid Agency shall provide a written notice of that determination, with an explanation therefore, to the provider. The provider will not be reimbursed for Synagis or palivizumab until the provider meets the standards as approved by the Agency. Other actions may include, but are not limited to, recoupment, penalties, and/or discontinuance of contract.

## **Part III: Quality**

### **A. Quality Standards and Contract Monitoring**

1. Describe the State's quality measurement standards specific to the selective contracting program (if additional space is needed, please supplement your answer with a Word attachment).
  - a. Describe how the State will (or if this is a renewal or amendment of an existing selective contracting waiver, provide evidence that the State):
    - i. Regularly monitor(s) the contracted providers to determine compliance with the State's quality standards for the selective contracting program.

Medicaid will randomly audit claims of the selected contractor to ensure compliance. If found non-compliant, the selected Contractor must implement the corrective action plan within the timeframe specified by Medicaid. Failure by the selected Contractor to implement corrective action plans, as required by Medicaid, may result in further action by Medicaid including, but not limited to, recoupment and/or discontinuance of contract.

- ii. Take(s) corrective action if there is a failure to comply.

If the vendor does not meet one or more of the standards/criteria listed in the scope of work, the Alabama Medicaid Agency shall provide a written notice of that determination, with an explanation therefore, to the provider. The provider will not be reimbursed for Synagis or palivizumab until the provider meets the standards as approved by the Agency. Other actions may include, but are not limited to, recoupment, penalties, and/or discontinuance of contract.

2. Describe the State's contract monitoring process specific to the selective contracting program (if additional space is needed, please supplement your answer with a Word attachment).
  - a. Describe how the State will (or if this is a renewal or amendment of an existing selective contracting waiver, provide evidence that the State):
    - i. Regularly monitor(s) the contracted providers to determine compliance with the contractual requirements of the selective contracting program.

Medicaid will randomly audit claims of the selected contractor to ensure compliance. If found non-compliant, the selected Contractor must implement the corrective action plan within the timeframe specified by Medicaid. Failure by the selected Contractor to implement corrective action plans, as required by Medicaid, may result in further action by Medicaid including, but not limited to, recoupment and/or discontinuance of contract.

- ii. Take(s) corrective action if there is a failure to comply.

If the vendor does not meet one or more of the standards/criteria listed in the scope of work, the Alabama Medicaid Agency shall provide a written notice of that determination, with an explanation therefore, to the provider. The provider will not be reimbursed for Synagis or palivizumab until the provider meets the standards as approved by the Agency. Other actions may include, but are not limited to, recoupment, penalties, and/or discontinuance of contract.

## **B. Coordination and Continuity of Care Standards**

Describe how the State assures that coordination and continuity of care is not negatively impacted by the selective contracting program (if additional space is needed, please supplement your answer with a Word attachment).

Upon discontinuation of services by the Contractor, the provider shall, at a minimum, coordinate for another designated health care provider to provide services to covered persons, prior to withdrawal of any Synagis-related services. The provider shall continue to provide services and supplies to a covered individual until the individual obtains an alternate source of services and supplies. Every effort shall be made by the provider (including notification to the Medicaid Director of Clinical Services/Pharmacy) to find an alternative provider to ensure that the coordination of care/transition follows the minimum standards as set forth in this document.

## **Part IV: Program Operations**

### **A. Beneficiary Information**

Describe how beneficiaries will get information about the selective contracting program (if additional space is needed, please supplement your answer with a Word attachment).

Synagis® is a product that is not delivered directly to the patient; it is delivered to the physician's office for administration. Therefore, there will be no change to patient access by implementing this program.

### **B. Individuals with Special Needs.**

## Section B - Waiver Cost-Effectiveness & Efficiency

### Efficient and economic provision of covered care and services:

1. Provide a description of the State's efficient and economic provision of covered care and services (if additional space is needed, please supplement your answer with a Word attachment).

In an effort to implement a consistent clinical standard for this very specific class of drugs, the Agency is implementing a Synagis Program in which the pharmacy provider will be held accountable to receive reimbursement for Synagis. Synagis® is a product that is not delivered directly to the patient; it is delivered to the physician's office for administration. Therefore, there will be no change to patient access by implementing this program.

Cost savings was derived by utilizing historical PBM costs (given to the Agency by an outside consultant) on Synagis, and applying Medicaid historical utilization data, compared to what Medicaid would have paid.

2. Project the waiver expenditures for the upcoming waiver period.

Year 1 from: 9/1/13 to 8/31/14

Trend rate from current expenditures (or historical figures): 17.91 %

Projected pre-waiver cost \$14,144,528

Projected Waiver cost \$ 13,250,863

Difference: \$893,665

Year 2 from: 9/1/14 to 8/31/15

Trend rate from current expenditures (or historical figures): 17.91 %

Projected pre-waiver cost      \$16,677,814

Projected Waiver cost      \$15,630,812

Difference:      \$1,047,002