

**ALABAMA MEDICAID AGENCY  
Synagis Management Program  
INVITATION TO BID (ITB)**

**Bid Number**

**13-X-2252452**

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## **Attachments**

- A. Sample Contract
- B. HIPAA Business Associate Addendum
- C. Relationship Disclosure Statement
- D. Evaluation Checklist

**ALABAMA MEDICAID AGENCY**  
**Medical and Quality Review Services**  
**INVITATION TO BID (ITB)**

**SECTION 1 INTRODUCTION TO PROCUREMENT**

**1.0 PURPOSE**

The Alabama Medicaid Agency, hereinafter called Medicaid, an Agency of the State of Alabama, hereby solicits bids for the procurement of services with a Contractor requesting proposals from vendors with expertise to implement a Synagis® Program for Alabama Medicaid recipients. Medicaid seeks to select one Contractor to assist in developing, implementing and operating a Synagis® Program and to serve as Medicaid's preferred provider of Synagis® pharmacy services. The Synagis® Program will address the needs of the Alabama Medicaid recipients being prescribed Synagis® and the specialized Prior Authorization required prior to approval. The projected implementation date of the program is August 1, 2013.

For the purposes of this RFP, "Synagis®" is defined as the following NDCs :

<b>NDC/Strength</b>
60574411401 50mg/0.5 ml
60574411301 100mg/ml

New NDC or HCPC Codes for Synagis® and/or palivizumab will automatically default into the program.

Synagis® currently requires Prior Authorization for reimbursement through Medicaid; the criteria follows the most recent AAP guidelines, and the criteria for the 2012-2013 season, as well as additional information, is can be found at the Agency website at the link [http://medicaid.alabama.gov/CONTENT/4.0\\_Programs/4.5.0\\_Pharmacy/4.5.14\\_Synagis.a.spx](http://medicaid.alabama.gov/CONTENT/4.0_Programs/4.5.0_Pharmacy/4.5.14_Synagis.a.spx).

The Agency's goal for the Synagis® Program is to maintain access to quality care for recipients who have a medical need for Synagis® and to provide clinical support in the Fee-for-Service delivery system while at the same time enhancing administrative efficiencies and cost-effectiveness.

Currently, Alabama Medicaid uses First DataBank (FDB) for the management of the drug file, to include pricing. Hewlett Packard (HP) is the current fiscal agent responsible for the MMIS system and claims processing. Health Information Designs, Inc (HID) is the Administrative Contractor responsible for Prior Authorization review/approval/denial.

More pharmacy specific information can be found on the Alabama Medicaid website [www.medicaid.alabama.gov](http://www.medicaid.alabama.gov). Historical data for Synagis® 2011-2012 season can be found in Appendix A.

All information contained in this ITB and any amendments reflect the best and most accurate information available to Medicaid at the time of ITB preparation. No inaccuracies in such data shall constitute a basis for change of the payments to the Contractor or a basis for legal recovery of damages, actual, consequential or punitive, except to the extent that such inaccuracies are the result of intentional misrepresentation by Medicaid.

The Contractor to whom the ITB is awarded shall be responsible for the performance of all duties contained within this ITB for the firm and fixed price quoted in Contractor's bid to this ITB. All bids must state a firm and fixed price for the services described.

## **1.1 GENERAL ITB REQUIREMENTS**

Medicaid will enter into a contract for 12 months, commencing August 1, 2013 through July 31, 2014. Medicaid shall have two one-year options for extending this contract at the original contract price. At the end of each contract year Medicaid may, at its discretion, exercise the extension option and allow the period of performance to be extended for an additional contract year. Such option shall be exercised by written notice to the Contractor within 90 days prior to the termination date of the contract or any extension. The bid response must present a complete and detailed description of the bidder's qualifications to perform, and its approach to carry out the requirements of this ITB.

All proposals must be received by the State of Alabama's Department of Finance, Division of Purchasing as specified in the Schedule of Activities.

## **1.2 PROJECT MANAGER**

The individual designated by this bid to coordinate activities, resolve questions, monitor Contractor performance, ensure that all contract requirements are met, approve payments and act as Medicaid contact for the Contractor is:

Kelli D. Littlejohn, Pharm.D.  
Alabama Medicaid Agency  
P.O. Box 5624  
501 Dexter Avenue  
Montgomery, Al 36103-5624  
Email: [kelli.littlejohn@medicaid.alabama.gov](mailto:kelli.littlejohn@medicaid.alabama.gov)  
(334) 353-4525  
(334) 353-5623 (fax)

## **1.3 SCHEDULE OF ACTIVITIES**

The schedule of activities for this bid process is listed below. All dates are estimated and are subject to change. All times are central time (CT).

Bid Released	6/12/13
Pre-Bid Questions Due	6/21/13 by 5:00 p.m.
Posting of Responses to Final Questions	6/28/13
Bids Due	7/17/13 by 5:00 p.m.
Bids Opened	7/18/13 10:00 a.m.
Contract Award	7/25/13
Program Start Date	8/01/13

## 1.4 BIDDER QUALIFICATIONS

### General

This document outlines the qualifications which must be met in order for an entity to serve as Contractor. It is imperative that potential Contractors describe **in detail** how they intend to approach each section of the Scope of Work specified in Section 4 of the ITB. The ability to perform these services must be carefully documented, even if the bidder has been or is currently participating in a Medicaid Program. Bids will be evaluated based on the written information that is presented in the bid, which underscores the importance and the necessity of providing in-depth information in the bid with all supporting documentation necessary.

The bidder must demonstrate in the bid a thorough working knowledge of program policy requirements as described in these ITB specifications, including but not limited to the applicable Operational Manuals, State Plan for Medical Assistance, Administrative Code requirements and Code of Federal Regulations (CFR) requirements.

Entities that are currently excluded under federal and/or state laws from participation in Medicare/Medicaid or any State's health care programs are prohibited from submitting bids.

### Entities submitting bids must:

- a. Have all necessary business licenses, registrations and professional certifications at the time of the contracting to be able to do business in Alabama. Alabama law provides that a foreign corporation (an out-of-state company/firm) may not transact business in the state of Alabama until it obtains a Certificate of Authority from the Secretary of State, Section 10-2B-15.01, et seq., Code of Alabama 1975. To obtain forms for a Certificate of Authority, contact the Secretary of State, Corporations Division, (334) 242-5324, [www.sos.state.al.us](http://www.sos.state.al.us). The Certificate of Authority or a letter/form showing application has been made for a Certificate of Authority must be submitted with the bid.

- b. Have operated within the last three years and have provided Synagis® during the 2012-2013 RSV season.
- c. Be fiscally sound and possess adequate financial reserves.
- d. Furnish a minimum of three references to include contact name, title, telephone number, and address.
- e. Submit corporate experience information to include the number of any related contracts currently held and company longevity.
- f. Be an enrolled Alabama Medicaid provider (pharmacy or physician) and have a physical location within the State of Alabama (ie follow current policy to be able to dispense Synagis® for Alabama Medicaid recipients).

## 1.5 PRE-BID QUESTIONS

Pre-bid questions are intended to be an informal, interactive exchange of information. It is the opportunity to ask questions to clarify any uncertainties that exist.

Questions related to this solicitation must be directed in writing to the Project Manager. Bidders cannot contact or ask questions of other Medicaid staff. Contact with or questioning of Medicaid staff to obtain information about this ITB other than written inquiries to the Project Manager shall result in the rejection of the bid.

Questions must be received by the dates specified in the Schedule of Activities. **Questions received after this date cannot be considered.** Questions may be submitted hard copy via regular mail, fax, or by email. Questions pertaining to this solicitation should specifically reference the page and paragraph numbers in the ITB to which the question refers. Vague or non-specific questions may be returned to bidders for clarification. Medicaid must receive all clarifications by the deadline dates.

## 1.6 AMENDMENTS TO BID

Amendments may be issued subsequent to the issue date of this ITB. Receipt of ITB amendments must be acknowledged by the potential bidder by signing and returning the signature page of the amendment to Medicaid. **A copy of acknowledgements must also be returned as a part of the bidder's proposal.**

## 1.7 BID REJECTION

Notwithstanding any other provision of this solicitation, Medicaid expressly reserves the right to:

- a. Reject any or all bids, or portions thereof;
- b. Reissue the ITB and/or;
- c. Cancel all or part of this procurement.

## 1.8 BID SUBMISSION REQUIREMENTS

### General

- a. All bids must be submitted in accordance with the requirements of the Division of Purchasing of the State of Alabama.
- b. Each bid must include an individual bid guarantee in the amount of \$5000 payable to the State of Alabama. This bid guarantee ensures a firm bid for contracting purposes for 90 calendar days after the bid due date. Bid guarantees provided by unsuccessful bidders will be returned after 90 calendar days. The form of the bid guarantee shall be one of the following:
  - (1) Cashier's check (personal or company checks are not acceptable)
  - (2) Other type of bank or certified check
  - (3) Money Order
  - (4) Surety guarantee issued by a company authorized to do business in the State of Alabama.
  - (5) An irrevocable letter of credit
- c. Bids must be submitted with the following:
  - (1) One original and two original-quality copies under sealed cover
  - (2) Two electronic (Word 6.0 or later version format) copies of the Bid response on CD, jump drive, or disc clearly labeled with the Bidder's name. One electronic copy MUST be a complete version of the bid and the second electronic copy MUST have any confidential/proprietary information removed. Attachments may be submitted in PDF or similar formats.
- d. Sealed bid packages may be mailed or hand delivered and must be received by the date in the Schedule of Activities to:
 

State of Alabama  
 Division of Purchasing  
 RSA Union Building  
 100 N. Union Street  
 Suite 192  
 Montgomery, AL 36130-2401  
 Attention: Bernie Arant
- e. The outside cover of the package containing the bid shall be marked as follows:
 

Alabama Medicaid Synagis Management Program	
ITB #:	13-X-2252452
Bid Opening Date:	July 18, 2013
Proposed Contract Award:	July 25, 2013
Contract Start Date:	August 1, 2013
- f. Bids submitted in whole or part by email or fax will be rejected.
- g. Bids submitted after the deadline listed in the Schedule of Activities will be rejected. It

is the responsibility of the bidder to ensure the bid is delivered by the time specified.

- h. Each bid must specify a firm and fixed fee for each NDC/JCode listed in Appendix C for each unit prescribed. The Firm and Fixed Price of the first year of the proposed contract (Synagis® Season 2013-2014) and subsequent years (2014-15, 2015-16) must be separately stated in the RFP Cover Sheet on the first page of this document. The firm and fixed price will include any and all dispensing and/or administrative fees for all Synagis® dispensed. The bid price must appear on the Division of Purchasing Pricing page.

If the bid does not contain a firm and fixed price then the bid will not be considered to meet bid submission requirements.

- k. Numbers and estimates provided in this ITB are informational only and do not represent a binding agreement or guarantee by Medicaid.

## **1.9 BID SUBMISSION FORMAT**

Bids must demonstrate the ability to meet all program requirements. Failure to address any of the required bid specifications will result in the bid not meeting the responsiveness requirement. Bids not deemed responsive will not be considered.

Bids submitted without all forms and attachments required by the Division of Purchasing will be rejected.

a. Contents:

Each bid (including all copies thereof) shall be; 1) clearly sequentially numbered on the bottom (center) of each page; 2) submitted in three-ring binders; and 3) use 8.5 x 11-inch paper, two-sided copies, and a type font size of 11 points or larger.

b. Presentation:

Program specifics and descriptive information must be inserted as appropriate. All attachments including flowcharts, provider subcontracts, and copies of other program information should be properly identified. Brochures or other presentations, beyond that sufficient to present a complete and effective bid, are not desired. Audio and/or videotapes are not allowed. Elaborate artwork or expensive paper is not necessary nor desired.

c. Page Length:

Economy in preparation is encouraged. Additional credit is not given for extra description beyond that which is necessary. Bids must be within a 25 (front and back for a total of 50) page limit, with up to an additional 25 (front and back for a total of 50) pages as necessary for attachments. NOTE: The transmittal letter and its attachments are not considered in the page limits.

d. Bid Organization:

- (1) The bid must contain an Executive Summary of no more than three pages and should provide a brief overview of the history of the organization submitting the bid, experience of the entity, and proposed administration.
- (2) The bid must contain a cover sheet which identifies a contact person for the bid including full name, title, address, telephone number, e-mail address and fax number. All correspondence regarding the bid will be directed to this individual.
- (3) Bids must be organized following the outline specified in Section 1.12. Medicaid will use the outline as a checklist to perform its first overall evaluation of the bid submitted, prior to a more in-depth evaluation. It is permissible to copy Medicaid forms if required.
- (4) Medicaid discourages submission of bids that contain erasures, modifications or interlineations. Bids should be in final format at the time of submission. An authorized representative must initial erasures, interlineations or other modifications of the bid in original ink.

## **1.10 BID OPENING**

Bid openings will be conducted at the office of the Purchasing Director, Suite 192, RSA Union Building, 100 N. Union Street, Montgomery, Alabama based upon the date in the Schedule of Activities. Bid openings will be conducted by Purchasing in accordance with its policies and procedures.

## **1.11 WITHDRAWAL OF BID**

A bid may be withdrawn at any time prior to the bid opening by submitting a withdrawal in writing signed by a person with appropriate authority. The withdrawal should be sent to the person at the address listed in 1.8 d.

## **1.12 TECHNICAL SPECIFICATIONS FORMAT**

The bid must include five separate sections with named tabs presented in the following order:

- a. Transmittal Letter
- b. Table of Contents
- c. Executive Summary
- d. Financial Statements
- e. Work plan for all required components
- f. Approach to customer service and administrative functions
- g. Corporate Capabilities
- h. Bidders Understanding of Alabama requirements
- i. References
- j. Submission of Pricing Schedule for firm and fixed bid price including Total Evaluated Bid Price

## 1.13 TRANSMITTAL LETTER

The Transmittal Letter is a cover letter addressed to Medicaid and the Division of Purchasing. It must include the following information:

- a. Identification of all materials and enclosures being submitted collectively as the bid in response to this ITB.
- b. A statement identifying each amendment or addendum to this ITB that has been received; if no amendments or addenda have been received, a statement to that effect must be included. The bidder must list each ITB amendment or addendum acknowledged and received, by amendment or addendum number.
- c. Identification of the bidder that will be the Contractor and the name of the corporation or other legal entity submitting the bid. The bidder must assume sole and exclusive responsibility for all of the contract responsibilities and work indicated in the ITB (including any and all addenda). Any effort to limit or qualify this responsibility, or assign any responsibility to a subcontractor will result in the bid being rejected as non-responsive to the bid requirements. Bidder must use this section to state whether it is a: partnership, non-profit corporation, Alabama corporation, non-Alabama corporation or some other structure.
- d. A statement of compliance with Affirmative Action and Equal Employment Opportunity regulations that confirms that the bidder does not discriminate in its employment practices with regard to race, color, religion, age (except as provided by law), sex, marital status, developmental disability, political affiliation, national origin, or handicap, and complies with all applicable provisions of Public Law 101-336, Americans with Disabilities Act of 1990.
- e. A statement acknowledging and agreeing to all of the rights of Medicaid contained in the provisions of this ITB.
- f. A statement that the bidder understands and will comply with all of the provisions of the ITB.
- g. A statement that the prices proposed have been arrived at independently without consultation, communication, or agreement with any other bidder or competitor involved in the procurement for this contract.
- h. A statement that the bidder, through its duly authorized representatives, has in no way entered into any arrangement or agreement with any other bidder or competitor which could lessen or destroy free competition in awarding the contract sought by the attached bid.
- i. A statement that, unless otherwise required by law, the prices quoted must not be knowingly disclosed by the bidder, directly or indirectly, prior to award of the contract, to any other bidder, competitor or any other person or entity.

- j. A statement that the bidder has not and will not make any attempt to induce any other person or firm to withhold or submit a bid for the purposes of restricting competition.
- k. A statement that the person signing this bid is authorized to make decisions on behalf of the bidder's organization as to the prices quoted.
- l. A statement that no person or agency has been employed or retained to solicit or secure the proposed contract based on an agreement or understanding for a commission, percentage, brokerage, or contingent fee.
- m. A statement that the bidder and its subcontractors will maintain a drug-free workplace.
- n. A statement that the successful bidder will be required to complete a financial disclosure statement and Health Insurance Portability and Accountability Act (HIPAA) business associate agreement with the executed contract. See Attachments A, B, and C.

## **1.14 SUBCONTRACTS**

The contract shall not be assigned without written consent of Medicaid. Contractor may subcontract for the professional services necessary for the completion and maintenance of this contract and for the performance of its duties under this contract with advance written approval of both the subcontracted function and the subcontractor by Medicaid. Subcontractors shall demonstrate the capability to perform the function to be subcontracted at a level equal or superior to the requirements of the contract relevant to the service to be performed. All subcontracts shall be in writing, with the subcontractor functions and duties clearly identified, and shall require the subcontractor to comply with all applicable provisions of this ITB. Contractor shall at all times remain responsible for the performance by subcontractors approved by Medicaid. Contractor's performance guarantee and Contractor's responsibility for damages shall apply whether performance or non-performance was by Contractor or one of its subcontractors. Medicaid shall not release Contractor from any claims or defaults of this contract which are predicated upon any action or inaction or default by any subcontractor of Contractor, even if such subcontractor was approved by Medicaid as provided above. Contractor shall give Medicaid notice in writing by registered mail of any action or suit made against Contractor by any subcontractor or vendor, which, in the opinion of Contractor, may result in litigation related in any way to this contract with the State of Alabama.

## **1.15 DEVIATIONS**

### **Program Requirements/Scope of Work**

Any bid which deviates, in any way whatsoever, from the detailed specifications and requirements in the ITB, shall explicitly identify and explain these deviations in the Transmittal Letter. Medicaid reserves the right, in its sole discretion, to reject any bid containing such deviations or to require clarifications before acceptance.

**Contract Terms and Conditions**

Bidders shall not place any qualification, exceptions, conditions, reservations, limitations, or substitutions in their bid concerning the contract terms and conditions. Any such qualifications, exceptions, conditions, reservations, limitations or substitutions shall result in rejection of the bid.

**1.16 EVALUATION OF BIDS**

In accordance with the law of the State of Alabama, bids will be evaluated as follows:

- a. The Director of Purchasing will review each bid to determine if it meets submission requirements. Bids not meeting said requirements will be rejected.
- b. All bids meeting submission requirements will be forwarded to Medicaid for evaluation of technical specifications.
- c. Medicaid will review the low price bid to determine if technical requirements are met.
- d. If the low price bid does not meet technical requirements, Medicaid will evaluate the next lowest price bid.
- e. The State reserves the right to reject any and all bids.
- f. In evaluating a bid, Medicaid reserves the right to request clarification from bidders for information provided in the bid for the purpose of determining responsibility of the bidder and responsiveness to the technical bid requirements.
- g. Bidders will be notified of their status by the Division of Purchasing pursuant to its policies and procedures.

**1.17 PREBID CONFERENCE**

There will be no prebid conference.

**1.18 RIGHTS OF MEDICAID**

This ITB does not commit the State of Alabama to award a contract, or pay any cost incurred in the preparation of the bid to this ITB. Medicaid reserves the right to reject all bids and at its discretion may withdraw or amend this ITB at any time. Medicaid may by written notice revise and amend the ITB prior to the due date for the bid. If, in the opinion of Medicaid, revisions or amendments will require substantive changes in the ITB, the due date may be extended at the sole discretion of Medicaid.

## **SECTION 2           PROGRAM REQUIREMENTS AND SPECIFICATIONS**

### **2.0 AGENCY OVERVIEW**

The Alabama Medicaid Agency is responsible for administration of the Alabama Medicaid Program under a federally approved State Plan for Medical Assistance. The Synagis Management Program, including the services found in this ITB, will be under the operation of a CMS-approved 1915 (b) (4) Waiver and will not be implemented without CMS approval. The mission of the Agency is to empower recipients to make educated and informed decisions regarding their health and the health of their families. Through teamwork, the Agency strives to operate and enhance a cost efficient system by building an equitable partnership with health care providers, both public and private.

Medicaid's central office is located at 501 Dexter Avenue, Montgomery, Alabama 36104 (mailing address is P.O. Box 5624, Montgomery, Alabama 36103-5624). The majority of Medicaid's budgeted administrative positions are located at this site. The central office personnel are responsible for data processing, program management, financial management, program integrity, general support services, professional services, and recipient eligibility services. For certain recipient categories, eligibility determination is made by Medicaid personnel located throughout the State. For additional program information please refer to Annual Report at [http://medicaid.alabama.gov/CONTENT/2.0\\_Newsroom/2.3.4\\_Annual\\_Report\\_Archive.aspx](http://medicaid.alabama.gov/CONTENT/2.0_Newsroom/2.3.4_Annual_Report_Archive.aspx)

### **2.1 PROGRAM COMPONENTS**

#### **Contractor will be responsible for:**

- Maintaining an Inventory of Synagis®
- Implementing and Operating a Synagis® Dispensing and Delivery System
- Responding to General Inquiries and Complaints
- Developing Policies and Procedures which supports Alabama Medicaid's policies
- Reporting
- Develop and Maintain Performance Standards and Corrective Action Plans

### **2.2 PERFORM QUALITY ASSURANCE MONITORING**

Contractor must monitor the quality of its utilization operations. Reports must be generated as described in this ITB. Medicaid staff will monitor the quality of the Contractor's utilization operations through rigorous retrospective audits. Liquidated damages will be applied as described in this ITB if applicable.

## 2.3 REPORTING REQUIREMENTS

Contractor shall produce and submit to the Medicaid Pharmacy program, in formats approved by Medicaid, monthly reports as described below. Unless otherwise stated, reports should be delivered to Medicaid by the tenth of each month. Reports shall be provided in electronic format via email to Medicaid.

Reports must provide accurate data and clear and concise narrative explanations. Reports should include charts and graphs to illustrate points. Medicaid will confer with the selected Contractor to determine Department-held data that the selected Contractor must routinely use to allow it to effectively meet its reporting obligations.

The selected Contractor must submit all specified reports electronically in Microsoft® Word™ or Microsoft Excel™ versions.

In addition to the minimum reports the selected Contractor must submit to Medicaid specified below, the selected Contractor must confer with Medicaid to determine additional reports that would be of use to Medicaid and generate other relevant reports identified by Medicaid throughout the term of the contract.

- a. **Status Report.** Beginning the week of September 1, 2013, through the first three months of full operation of the Synagis® Program, the selected Contractor must submit weekly status reports covering activities, problems and recommendations. During the first three (3) months of operation the weekly status reports must also include the information outlined below. After the first three (3) months of operation, the selected Contractor must submit status reports with the information outlined below on a monthly basis.

The status report must summarize all information for the reporting period and the year-to-date and provide analysis and commentary on the statistical data presented in the reports.

The status reports must include:

1. Therapy Management Statistics
  - a. Therapy compliance issues
  - b. Dispensing accuracy/dispensing errors
  - c. Average turnaround times for delivery
  - d. Delivery problems
  - e. Dosing accuracy
  - f. Number of active recipients
  - g. Call Center performance statistics:
  - h. Call abandonment rate
    - i. Call waiting time
    - ii. Average speed for answering calls
    - iii. Percentage of calls answered in no more that 60 seconds or less
  - i. Resolution during first call
  - j. Inquiry and complaint statistics:
    - i. Number and type of inquiries and complaints from recipients
    - ii. Number and type of inquiries and complaints from providers

- iii. Disposition or resolution of complaints and inquiries.
- iv. Number of inquiries and complaints not responded to within the timeframe specified in the RFP.

- b. **Problem Identification Report.** The selected Contractor must provide a report identifying problem areas on an “as required” basis, as determined by Medicaid. The report should describe the problem and its impact on the overall Synagis® Program and on each affected task. It should list possible courses of action with advantages and disadvantages of each, and include the selected Contractor’s recommendations with supporting rationale.
- c. **Ongoing Evaluation of the Synagis® Program.** The selected Contractor must participate with Medicaid and its Contractor in the ongoing evaluation of the Synagis® Program, including partnering with Medicaid in developing an outcomes analysis of the Program. The selected Contractor must have the capability to receive, store, analyze and report on data sufficient to meet this requirement.

## 2.4 ADDITIONAL CONTRACTOR RESPONSIBILITIES

- Contractor shall be expected to perform all responsibilities and deliverables within this ITB. Additional Contractor responsibilities are listed below. Contractor shall coordinate with the Medicaid Project Manager throughout the term of this contract for any questions and further direction as it relates to the functions of this ITB.

## 2.5 ADDITIONAL MEDICAID RESPONSIBILITIES

- Medicaid shall be expected to follow the additional Medicaid responsibilities below. Medicaid agrees to correspond to inquiries from the Contractor in a timely and accurate manner interpreting Medicaid policy so that Contractor is able to respond and provide deliverables as indicated throughout this ITB.
- Medicaid shall review and approve any changes in the form of communication to the Provider by the Contractor which may include, but is not limited to, changes in form letters, report formats, new forms or new reports, audit or review tools to be used by the Contractor.
- Medicaid shall review Pharmacy Program criteria based upon clinical review or recommendations made by the Medicaid Medical or Clinical Services Director(s) or Contractor.
- Medicaid shall initiate and distribute public notice of policy changes to include recipient and provider notices and alerts.
- Medicaid shall notify Contractor in writing of any additional review requirements or changes within 14 calendar days.

- Medicaid will retrospectively review Contractor's claims and/or invoices for appropriate billing and claims filing. Any claims that do not meet Medicaid's billing policy may be recouped.

## **2.6 INFORMAL REVIEW AND FAIR HEARING**

All adverse review decisions made by the Contractor may be subject to an appeal by the requesting provider or recipient (Aggrieved Party). An Aggrieved Party may request an informal review and a fair hearing for denied Medicaid benefits. However, an informal review must be requested and adjudicated before advancing to a fair hearing.

### **a. Informal Review**

An Aggrieved Party may request reconsideration of an adverse decision through the informal review process by filing a written request with Contractor within 30 days for Prior Authorization Requests. Upon receipt of a reconsideration request, the Contractor's consulting physician shall review the documentation and render a decision based on Medicaid-approved criteria within five working days of receipt of a complete reconsideration request. Contractor shall mail notice of the reconsideration decision to the Aggrieved Party and enter the decision into the system for Prior Authorizations and must generate and mail notices to providers.

### **b. Fair Hearing**

An Aggrieved Party may request a Fair Hearing by filing a written request with the Medicaid Administrative Hearings Office within 60 calendar days of the date of the reconsideration denial notice by the Contractor. The Contractor's consulting physician and other appropriate personnel who were involved in the denial shall be available at Medicaid's request to provide justification for the denial and participate in any Fair Hearings.

## **2.7 MONITORING, PERFORMANCE STANDARDS AND CORRECTIVE ACTION PLANS**

Medicaid will monitor the Contractor's performance according to the requirements contained within this ITB.

Medicaid will inform Contractor when performance does not comply with the contract requirements and of any liquidated damage assessments. Contractor must prepare and submit for approval a corrective action plan for each identified problem within the timeframe determined by the Agency. The corrective action plan must include, but is not limited to:

- Brief description of the findings.
- Specific steps the Contractor will take to correct the situation or reasons why the Contractor believes corrective action is not necessary.
- Name(s) and title(s) of responsible staff person(s).

- Timetable for performance of each corrective action step.

Contractor must implement the corrective action plan within the timeframe specified by the Agency. Failure by the selected Contractor to implement corrective action plans, as required by the Agency, may result in further action by the Agency.

## 2.8 OPERATIONAL REQUIREMENTS

Contractor will be responsible for entering and/or interfacing with the Agency claims processing Contract, currently held by Hewlett Packard, HP, if needed.

Contractor shall also provide appropriate backup/emergency plan in the event of power outage or natural disaster.

Contractor must have a HIPAA-compliant system with effective security measures to prevent the unauthorized use of, or access to, data. The selected Contractor must maintain confidentiality and only use information from the Agency to fulfill its contractual obligations.

## 2.9 KEY PERSONNEL

Contractor must maintain sufficient staffing levels to meet program requirements. At a minimum, Contractor's key personnel must include the following positions:

- a. **Project Manager (PM).** Contractor shall propose a PM with a minimum of an undergraduate degree who shall have day-to-day responsibility for supervising the performance and obligations under this Contract, as well as receive policy direction from the Medicaid Contract Administrator. The PM shall be the person assigned under this contract who is responsible for operation of contract duties including the inventory control, dispensing/delivery system, clinical support, help desk, policies, reports, and corrective action plans. In the event the PM does not meet the requirements of Medicaid before or after implementation, Contractor shall recommend a candidate to Medicaid who is capable of performing contract obligations. Contractor shall not change its PM without prior written approval from Medicaid, and such approval shall not be unreasonably delayed or withheld. Contractor shall make a good faith effort to use the PM for not less than 12 months to ensure successful contract performance. Contractor shall notify Medicaid in writing of any proposed change in Project Manager at least 30 days prior to change. Contractor shall furnish with its response to the ITB a resume for the proposed PM which shall include the individual's name, current address, current title and position, experience with Contractor, experience in implementation or performing PA functions, experience with provider relations, experience with drug utilization review, relevant education and training and management experience. Contractor shall provide a minimum of two work references for the PM.

Contractor's PM shall serve as liaison between Medicaid and Contractor and shall be available and responsible for consultation and assistance with issues arising out of the scope of the Contract. PM shall attend, upon request, Medicaid meetings, fair hearings, meetings and hearings of legislative committees and interested governmental bodies,

agencies, and officers. PM shall provide timely and informed responses when operational and administrative issues arise in relations to obligations under this contract. Whenever the PM is not available, Contractor shall provide a designated alternate fully capable of meeting the requirements of this ITB.

Additional responsibilities of the PM include but are not limited to:

- Assure timely compliance with all contract responsibilities and deliverables
- Attend monthly contract status meetings and other meetings upon Medicaid request
- Notify Medicaid's Contract Administrator of any proposed changes in personnel; organizational changes; any system problems; etc., within time period specified within this ITB.

#### **b. Account Pharmacist(s)**

The Contractor shall assign Account Pharmacist(s) to work with the program. The Account Pharmacist(s) assigned to work on the Synagis Management program shall possess superior clinical competence and demonstrate proficiency in drug therapy management, must be licensed in the state of Alabama and must be in good standing with the Alabama Board of Pharmacy. Contractor shall staff enough pharmacist time to meet all requirements of this ITB.

## **2.10 OTHER PERSONNEL**

Contractor shall demonstrate the ability to secure and retain professional staff to meet contract requirements. This shall include staff members with billing history (accounting, billing, business degree, etc.) and other clinical and administrative personnel, pharmacists, certified pharmacy technicians, help desk staff, etc.

Medicaid shall have the absolute right to approve or disapprove Contractor's and any subcontractor's staff assigned to the contract, to approve or disapprove any proposed changes in this personnel, or to require the removal or reassignment of any personnel found by Medicaid to be unwilling or unable to perform under the terms of the contract. Contractor shall upon request provide Medicaid with a resume of any members of its staff or a subcontractor's staff assigned to or proposed to be assigned to any aspect of the performance of this contract. Personnel commitments made on Contractor's response shall not be changed except as herein above provided or due to the resignation of any named individual.

## **2.11 ORGANIZATIONAL PLAN**

Contractor shall submit an organizational chart to Medicaid for approval prior to contract implementation. This plan shall include a breakdown of job duties and responsibilities of

management staff. Any subsequent changes to the organizational plan shall be approved by the Agency.

It is permitted by Medicaid to have one individual assigned by Contractor for Project Manager and Account Pharmacist as long as the individual is qualified to perform duties outlined for these positions.

Any subsequent changes to the organizational plan must be approved by Medicaid.

## **2.12 WORK PLAN AND IMPLEMENTATION SCHEDULE**

Contractor must provide a proposed work plan and implementation schedule as a part of this ITB response submission. A revised work plan and implementation schedule must be provided to Medicaid in electronic format within 30 business days of contract award.

The work plan must identify major tasks, the work elements of each task, the resources assigned to the task, the time allotted to each element and the deliverable items the selected Contractor will produce.

## SECTION 3 SCOPE OF WORK

### 3.0 SCOPE OF WORK OVERVIEW

The contract support has been described in this ITB in key personnel. Additional staff shall be available to provide whatever clinical, administrative and technical support personnel Contractor deems necessary to accomplish the scope of work described herein.

#### Required components of the program are:

- Maintaining an Inventory of Synagis®
- Implementing and Operating a Synagis® Dispensing and Delivery System
- Responding to General Inquiries and Complaints
- Developing Policies and Procedures which supports Alabama Medicaid's policies
- Reporting
- Develop and Maintain Performance Standards and Corrective Action Plans

Medicaid will maintain responsibility for administration of the program, and be responsible for policy decisions and quality oversight. The Agency will monitor and assess the program through the assigned Contract Administrator.

### 3.1 MAINTAINING AN INVENTORY OF SYNAGIS®

The selected Contractor will be required to maintain an inventory of Synagis® sufficient to meet the needs of the Alabama recipient population for whom Synagis® is prescribed and authorized. The selected Contractor will be responsible for the following deliverables:

- a. **Manufacturer, Wholesaler, and Distributor Relationships.** The selected Contractor must provide, and update as necessary, a list of manufacturers, wholesalers, and distributors of Synagis®, with whom the selected Contractor has a contractual relationship, addressing the items listed below:
1. Name of manufacturer, wholesaler, or distributor
  2. Product
  3. Length of relationship and remaining term of agreement
  4. Scope of agreement (general description of products and services)
  5. Regions and markets covered
  6. Alabama-specific regions and markets covered
  7. Penetration and quality of coverage within Alabama-covered regions and markets
  8. Alabama-specific regions and markets not covered
  9. Experience with physician offices in Alabama regions
  10. Limitations and exclusions
  11. Service expectations and standards (turnaround time)

- b. **Product Recall.** The selected Contractor must develop and maintain policies for product recalls.
- c. **Purchasing Volume.** The selected Contractor must identify its total purchasing volume and stratified annual purchasing volume.
- d. **Stock-Out Rates and Out of Stock Process.** The selected Contractor must identify its stock out rates for Synagis®, and develop and maintain a policy and procedure for providing Synagis® when it is out of stock.
- e. **Returns/Undeliverable Medications.** The selected Contractor must develop and maintain policies to manage product returns and products deemed “undeliverable” by either the recipient or the selected Contractor.
- f. **Short-Dated and Temperature-Sensitive Medications.** Each shipped package of Synagis® must include a document with the correct storage and handling procedures.

**The Alabama Medicaid Agency shall:**

- Establish policies and guidelines as outlined in the Provider Billing Manual, Administrative Code, etc.
- Answer questions from Contractor related to this requirement

**3.2 IMPLEMENT AND OPERATE A SYNAGIS® DISPENSING AND DELIVERY SYSTEM**

The selected Contractor must provide reliable and convenient dispensing and delivery systems for providers that facilitate care in clinically appropriate settings.

The selected Contractor must demonstrate its capacity to accept, dispense, and deliver patient-specific requests for Synagis® in a manner that is responsive to both prescribers and recipients, complies with Program regulations and requirements and requirements of the Alabama Board of Pharmacy, and minimizes the potential for waste. The selected Contractor will be responsible for performing the following tasks and the proposal must describe how the selected Contractor will perform these tasks.

- a. **Operate an Efficient, Accurate and Responsive Ordering and Refill Process**
  - 1. **Operate a Toll-Free Line for Providers.** The selected Contractor must serve as the single point of contact and maintain a distinct toll-free telephone line for prescribers of Synagis®, providers administering those

- drugs, and hospital discharge planners. This telephone line must be dedicated exclusively to provider requests for prescriptions, refills, and prior authorization questions, and other inquiries and complaints as described in Task 4.
2. **Maintain a Direct Contact for Prior Authorization questions.** The selected Contractor must identify and maintain a direct contact (to include email address, direct phone line, and alternative phone number) for the PA contractor to coordinate questions/issues related to dispensing of Synagis®.
  3. **Call Line Hours of Operation.** The selected Contractor's call line (for providers) must be operational during routine business hours, defined as Monday through Friday, 8:30 a.m. to 5:00 p.m., during the months of September through March. Selected Contractor may operate their call center on an on-call basis after business hours, on weekends, and holidays.
  4. **Receive prescriptions in alternative formats.** The selected Contractor must have the capacity to receive prescriptions and requests for refills in a hard copy paper format, by telephone, by fax, and by ePrescribing. The selected Contractor may support alternative format(s). All formats must follow State and Federal guidelines (including tamper resistant policy).
  5. **Prior Authorizations must follow Alabama Medicaid guidelines, and the Contractor may not complete nor submit PAs for Synagis®.** All PAs for Synagis® must be completed and submitted directly by the prescribing physician to the Pharmacy Administrative Contractor.
  6. **Call Center Tracking.** The selected Contractor must have the capacity to track and report Call Center abandonment rates, average call wait times, average speed of answer, first call resolution, average call duration, and on-call response times for each toll free number.
- b. **Ensure adequate staffing of pharmacies**  
The selected Contractor must:
1. Provide a sufficient number of pharmacies, central distribution centers and any additional distribution sites necessary to meet the requirements of this RFP.
  2. Develop and maintain an adequate staffing plan for its pharmacies, distribution centers and sites, including staffing patterns, that are adequate to meet the requirements of the Synagis® Program.
- c. **Process Prescriptions, Dispense Synagis®, and Submit Claims**
1. When processing prescriptions and refills for Synagis®, the selected Contractor must:
    - a. Conform to accepted standards of practice and quality of service and Alabama Medicaid policies and procedures.
    - b. Provide the prescribed medication in the dose ordered or, if inventory supply does not allow, place a call to the prescriber to change the order; substitution of products is not permitted without the approval of the prescriber.
    - c. Verify recipient eligibility.
    - d. Validate that the prescription was prior authorized by Medicaid.
    - e. Submit accurate claims using the claims adjudication system.

- f. Coordinate benefits – Because Alabama Medicaid is the payer of last resort and a recipient must exhaust his or her other coverage before the Program will pay the claim, if recipient has other private or public coverage, the selected Contractor must first submit a claim to the recipient’s other payor before submitting a claim to the Program.
  - g. Turnaround “clean” (no intervention required) prescriptions within two (2) business days of receipt.
  - h. A registered pharmacist in the state of Alabama will reach out to the prescribing physician with any questions related to submitted prescriptions within 1 business day of receiving the prescription, and call/contact the prescribing physician each subsequent business day until a resolution is obtained. The final prescription must be turned around within two business days of the the final resolution.
2. The selected Contractor must develop and maintain dispensing policies and procedures for each of the following:
    - a. Refills, including steps to address compliance and adherence, avoid stockpiling and address dose escalation.
    - b. Replacement costs of Synagis® damaged during distribution and delivery.
    - c. Dispensing of drugs with short expiration dates.
    - d. Waste management.

**d. Operate an Efficient, Accurate and Responsive Distribution and Delivery System**

The selected Contractor must implement and operate a distribution and delivery system that reflects “best practices” and optimizes distribution and delivery by ensuring that recipients receive their Synagis® when and where it is needed. The system must provide the following, at a minimum:

1. Steps in distribution and delivery to the site of administration, the prescribers’ offices, clinics, and outpatient infusion sites. Steps must include an explanation of how the selected Contractor will inform dispensing providers and recipients regarding the expected time frames for receipt of delivered items. Alabama Medicaid is not responsible for any medication that is wasted due to patient/physician’s inability to store or handle the medication properly.
2. Standard shipping methods and practices.
3. Name of delivery vendor(s) and delivery services provided by each vendor.
4. Provisions for timely delivery, proper handling and security of drug delivered.
5. The average turn-around time for a prescription (i.e., maximum response time from receipt of request to delivery of the drug).
6. The distribution system back-up system.
7. The distribution system disaster recovery strategy and process.
8. Training offered by the selected Contractor to prescribers, hospital discharge planners, providers administering the drug, office staff and MA recipients

and their families, related to distribution, delivery, handling and storage of Synagis®.

### **3.3 RESPOND TO GENERAL INQUIRIES AND COMPLAINTS**

- a. Contractor must maintain its own toll-free telephone line for providers to call with general inquiries and complaints (See Section 3.2.a.) The selected Contractor must also have the capacity to receive and respond to general inquiries and complaints submitted in writing. The selected Contractor may also offer fax or Internet communication methods.
- b. The selected Contractor must respond to general inquiries and address complaints as soon as possible, but no later than one business day. In situations where the general inquiry cannot be addressed by a selected Contractor (e.g., questions about eligibility for services), the selected Contractor must provide the caller with the telephone number of the Medicaid agency contact that the caller should contact. Medicaid will provide the selected Contractor with a list of Department agencies and telephone numbers.
- c. The selected Contractor must develop a system to track and report to Medicaid all general inquiries and complaints received, as well as the outcome of each general inquiry and complaint.

### **3.4 POLICIES AND PROCEDURES**

The selected Contractor must develop and submit for Medicaid approval, before implementation of the Synagis® Program, its policies and procedures for each of the following:

- a. Quality Control and Quality Assurance.
- b. Call centers/toll-free line.
- c. Communications with prescribers and recipients (before dispensing a medication; regarding recipient-specific needs and interventions; updates on recipient's progress and ongoing therapy; when a recipient is determined ineligible for the date of service; etc.).

- d. Process to admit new recipients into the program and assess their needs as they relate to the management program.
- e. Staffing of pharmacies, distribution centers, and call centers.
- f. Therapy management.

The selected Contractor must modify the policies and procedures as directed by Medicaid. The policies and procedures must be available for Medicaid review prior to and during the readiness review period. The selected Contractor must review policies and procedures annually, and update them as directed by Medicaid. Medicaid may also require new or updated policies and procedures during the course of the Contract.

Medicaid must approve in writing every new policy or procedure and any modification and/or addition to any existing policy or procedure before the selected Contractor may implement the policy or procedure.

### **3.4 MONITORING, PERFORMANCE STANDARDS, AND CORRECTIVE ACTION PLANS**

- a. Medicaid Monitoring.** The selected Contractor must cooperate with Medicaid when Medicaid monitors the selected Contractor's performance.

During implementation and the first 2 months of operation, the selected Contractor must hold weekly status meetings with Medicaid, or as otherwise directed by Medicaid. After the first 2 months of operation, the selected Contractor must conduct, at a minimum, monthly status meetings with Medicaid, or as otherwise directed by Medicaid. The selected Contractor must develop the agenda and provide the agenda and status report to Medicaid at least 3 business days prior to each meeting. The agenda are subject to Medicaid's review and approval.

- b. Contractor Monitoring.** The selected Contractor must monitor and report on its performance on an ongoing basis. See Section 2.3, Reports.

- c. Performance Standards.** Medicaid will monitor the selected Contractor's performance according to the performance standards specified below.

1. Operation of Call Centers during business hours as described above.
2. Adequately staffing pharmacies and toll-free line sufficient to meet the performance thresholds listed in number 6 below.
3. Successful product recall within twenty-four (24) hours of notice from manufacturer or distributor.
4. Delivery of medication to the site of administration within the average turnaround timeframes specified in the proposal.

5. Compliance with toll-free line performance thresholds, including:
    - a. Call abandonment rate no greater than 5%.
    - b. Call waiting time no greater than 2 minutes
    - c. Average speed of answer no greater than 30 seconds.
    - d. Answering 75% of all calls in no more that 60 seconds.
    - e. Responding to on-call calls within 30 minutes.
    - f. Resolution of the issue(s) in the first call.
  6. Compliance with the timeframes for responding to inquiries and addressing complaints.
  7. Providing reports within the timeframes specified in Section 2.3 Reports.
  8. Substitution of products/directions only with the approval of the prescriber.
  9. Conformance with accepted standards of practice and quality standards.
  10. Compliance with Medicaid regulations and requirements including accurate claims submission.
  11. Dispensing accuracy of  $\geq 99.9\%$ . Dispensing accuracy is defined as the percentage of all prescriptions dispensed accurately for recipients with no errors according to the prescription written and the recipient's plan of care. Dispensing accuracy percentage is calculated as the total number of non-conformance events divided by the total number of prescriptions dispensed for Medicaid recipients.
  12. Timely turnaround of  $\geq 99.9\%$  of "clean" (no intervention required) prescriptions. Turnaround time is measured in business days from the date a prescription is received by the selected Contractor (via paper, telephone, fax, or acceptable alternative format such as Internet or ePrescribing) to the date the medication is mailed or shipped. Timely turnaround percentage is calculated as the number of "clean" prescriptions processed within two business days divided by the total number of "clean" prescriptions received.
  13. Maintaining verification that the drug and any ancillary supplies were delivered to the site of administration.
- d. **Corrective Action Plans.** Medicaid will inform Contractor when the Contractor's performance does not comply with the Contract requirements. The selected Contractor must prepare and submit for Department 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 and/or discontinuance of contract.

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 and/or discontinuance of contract.

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 Pharmacy) to find an alternative provider to ensure that the coordination of care/transition follows the minimum standards as set forth in this document.

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## **SECTION 4                      TERMS AND CONDITIONS**

### **4.0 GENERAL**

This ITB and any amendments thereto, Contractor's bid, and all questions and answers made final shall be incorporated into the contract by the execution of a formal agreement. No alteration or variation of the terms of the contract shall be valid unless made in writing and duly signed by the parties thereto.

### **4.1 INTENT TO AWARD**

The Division of Purchasing shall provide a notice of intent to award of all contracts let by competitive bid by electronic posting to the Division of Purchasing website. Any bidder adversely affected by intent to award a contract let by competitive bid shall file with the Director of Purchasing a notice of protest within five calendar days after the notice of intent to award is electronically posted. The notice of protest may be filed by mail, by hand delivery, by email or by facsimile. The notice of protest must be filed with the Director of Purchasing by 5:00 PM, Central Time, on the fifth calendar day after the notice of intent to award is electronically posted. A formal written protest shall be filed within seven days, excluding Saturday, Sunday, and State holidays, after the notice of protest is filed. The formal written protest may be filed by email in PDF format or by mail or hand delivery. The formal written protest must be filed with the Director of Purchasing by 5:00 PM, Central

Time, on the seventh day after filing the notice of protest. The bidder or its legal representative must sign the formal written protest or it will not be accepted. Failure to file either the notice of protest or the formal written protest within the time limits prescribed herein shall constitute a waiver of any protest of the award of contract.

The formal written protest shall state with particularity the facts and law upon which the protest is based. Within 30 calendar days of receipt of the timely filed, formal written protest, the Director of Purchasing shall issue a written decision with respect to the protest. Should the decision by the Director of Purchasing be adverse to the bidder, the bidder may seek relief in accordance with section 41-16-31 of the Code of Alabama.

## **4.2 CONTRACT OFFERING**

A bid filed in response to this ITB is an offer to contract with Medicaid based upon the terms, conditions, scope of work and specifications of the ITB. Bids do not become contracts unless and until the Division of Purchasing accepts them. A contract is formed when the Division of Purchasing provides written notice of award to the successful bidder and has delivered to the successful bidder, all of the terms and conditions of the contract contained in this solicitation, solicitation amendments and subsequent contract modifications, if any, signed by Medicaid. After such contract is fully executed and approved by all applicable authorities, it will be considered binding. Medicaid may also, at its option, modify any requirements described herein. The successful bidder will be notified of award.

Submission of a response to this ITB, acceptance of the award, and signing of the contract and applicable attachments constitute evidence of Contractor's understanding of an agreement to the terms and conditions expressed in this bid and contract.

## **4.3 CONTRACT REQUIREMENTS MEETING**

After contract award, but prior to commencement of work, Medicaid and the successful Contractor will meet to ensure that Contractor understands, and agrees to accept the obligations contained in the ITB, including the applicable rules and regulations, any amendments to the bid, and ITB questions and answers. Any areas in the Contractor's proposal which require, at the sole discretion of Medicaid, further clarification to ensure understanding and acceptance by the Contractor of all the duties and responsibilities required by Medicaid for the firm and fixed price bid shall be addressed by Medicaid prior to commencement of work. Any unwillingness by Contractor to meet these requirements may result in cancellation of the award and consideration by Medicaid of the proposal submitted by the next lowest, responsive and responsible bidder. The meeting is to be conducted within 20 calendar days of contract award. Subsequent meetings may be scheduled when deemed necessary for the execution of this contract.

## **4.4 CONTRACT TERM**

The initial contract term shall be for one year beginning August 1, 2013. Medicaid shall have two, one-year options for extending this contract. At the end of the initial contract period Medicaid may at its discretion, exercise the extension option and allow the period of

performance to be extended at the **rate accepted in the bid**. In no event shall the term of the original contract plus the extension option exceed a total of five years. Any extension will operate under the same terms and conditions as the initial contract.

**Contractor acknowledges and understands that this contract is not effective until it has received all requisite state and federal government approvals.** Contractor shall not begin performing work under this contract until notified to do so by Medicaid. Contractor is entitled to no compensation for work performed prior to the effective date of this contract.

## 4.5 CONTRACT ELEMENTS

The contract shall include the following:

- a. Executed contract,
- b. ITB, and any amendments thereto,
- c. Contractor's response to the ITB,

And the applicable provisions of:

- a. Title XIX of the Social Security Act (SSA), as amended and regulations promulgated thereunder by HHS and any other applicable federal statutes and regulations
- b. The statutory and case law of the State of Alabama
- c. The Alabama State Plan for Medical Assistance under Title XIX of the SSA as amended
- d. The Alabama Medicaid Agency Administrative Code
- e. Medicaid's written response to prospective bidder's questions
- f. Medicaid Provider Billing Manual

It is the responsibility of the Contractor to be aware of and maintain current copies of the contract elements.

## 4.6 COOPERATION

Effective implementation and maintenance of these services shall require close cooperation between Medicaid and Contractor. To this end, the parties agree to work mutually in solving problems. Contractor shall make known and fully describe to Medicaid, in writing, any difficulties encountered that threaten required performance or when such a potential exists. Such difficulties may include, but are not limited to:

- a. interpretation of Medicaid policies and procedures
- b. meeting reporting requirements
- c. identification of errors in calculations submitted

Contractor shall notify Medicaid's designee for Project Manager, by telephone within one business day of discovery of any problem that has already occurred, or within one working day of the identification of potential problems that threaten required performance. All telephone notices shall be followed up in writing, including any action taken, within three business days.

## **4.7 COMPLIANCE WITH STATE AND FEDERAL REGULATIONS**

Contractor shall perform all services under the contract in accordance with applicable federal and state statutes and regulations. Medicaid retains full operational and administrative authority and responsibility over this contract in accordance with the requirements of the federal statutes and regulations as the same may be amended from time to time.

## **4.8 IMMIGRATION**

Pursuant to Ala. Code §31-13-9(k), by signing this contract, the contracting parties affirm, for the duration of the agreement, that they will not violate federal immigration law or knowingly employ, hire for employment, or continue to employ an unauthorized alien within the state of Alabama. Furthermore, a contracting party found to be in violation of this provision shall be deemed in breach of the agreement and shall be responsible for all damages resulting therefrom.

## **4.9 CONFIDENTIALITY**

Contractor shall treat all information, and in particular information relating to enrollees that is obtained by or through its performance under the contract, as confidential information to the extent confidential treatment is provided under State and Federal laws including 45 CFR §160.101 – 164.534. Contractor shall not use any information so obtained in any manner except as necessary for the proper discharge of its obligations and duties under this contract.

All information as to personal facts and circumstances concerning enrollees obtained by Contractor shall be treated as privileged communications, shall be held confidential, and shall not be divulged to anyone other than the agencies already specified without written consent of Medicaid or the enrollee, provided that nothing stated herein shall prohibit the disclosure of information in summary, statistical, or other form that does not identify particular individuals. The use or disclosure of information concerning enrollees shall be limited to purposes directly connected with the administration of the State Plan. Upon signing of this contract by all parties, the terms of the contract become available to the public pursuant to Alabama law.

Contractor agrees to allow Medicaid or its designee access to all documents, papers, letters, or other material generated under this contract. Contractor will not allow access to such documents to any other person or entity without express written consent of Medicaid.

Contractor shall ensure safeguards that restrict the use or disclosure of information concerning applicants and recipients to the purpose directly connected with the administration of the State Plan in accordance with 42 CFR Part 431, Subpart F, as specified in 42 CFR § 434.6(a)(8). Purposes directly related to the State Plan administration include:

a. Establishing eligibility;

- b. Determining the amount of medical assistance;
- c. Providing services for recipients; and
- d. Conducting or assisting an investigation, prosecution, or civil or criminal proceedings related to the administration of the State Plan.

Pursuant to requirements of the Health Insurance Portability and Accountability Act (HIPPA) of 1996 (Public Law 104-191), the successful Contractor shall be required to sign a Business Associate agreement with Medicaid (Attachment B).

#### **4.10 FEDERAL NON-DISCLOSURE REQUIREMENTS**

Each officer or employee of any person to whom Social Security information is or may be disclosed shall be notified in writing by such person that Social Security information disclosed to such officer or employee can be only used for authorized purposes and to that extent and any other unauthorized use herein constitutes a felony punishable upon conviction by a fine of as much as \$5,000 or imprisonment for as long as five years, or both, together with the cost of prosecution. Such person shall also notify each such officer or employee that any such unauthorized further disclosure of Social Security information may also result in an award of civil damages against the officer or employee in an amount not less than \$1,000 for each instance of unauthorized disclosure. These penalties are prescribed by IRC Sections 7213 and 7431 and set forth at 26 CFR 301.6103(n).

Additionally, it is incumbent upon the Contractor to inform its officers and employees of penalties for improper disclosure implied by the Privacy Act of 1974, 5 U.S.C. 552a. Specifically 5 U.S.C. 552a(i)(1), which is made applicable to contractors by 5 U.S.C. 552a(m)(1), provides that any officer or employee of a Contractor, who by virtue of his/her employment or official position, has possession of or access to agency records which contain identifiable information, the disclosure of which is prohibited by the Privacy Act or regulations established thereunder, and who knowing that disclosure of specific material is prohibited, willfully discloses that material in any manner to any person or agency, not entitled to receive it, shall be guilty of a misdemeanor and fined not more than \$5000.

Contractors shall take all reasonable precautions to ensure the safety and security of all information, data, procedures, methods, and funds involved in the performance under the contract, and shall require the same from all employees so involved. In compliance with 42 CFR §431.300 et seq. Contractor shall conform to the requirements of federal and state regulations regarding confidentiality of information about eligible recipients. Contractors shall not release any data or other information relating to the Medicaid Program without prior written consent of Medicaid. This provision covers both general summary data as well as detailed, specific data. Contractor shall not be entitled to use of Medicaid Program data in its other business dealings without prior written consent of Medicaid. All requests for program data shall be referred to Medicaid for response by the Commissioner only.

#### **4.11 CONTRACT AMENDMENTS**

Only amendments in writing and signed by duly authorized representatives of the

Contractor, Medicaid and the Governor of the State of Alabama shall be effective. No covenant, condition, duty, obligation or undertaking contained in or made a part of the contract shall be waived except by written agreement of the parties. The contract may be amended by written agreement duly executed by the parties. Every such amendment shall specify the date its provisions will be effective as agreed to by the parties. The contract and amendments, if any, are subject to approval by the Governor of the State of Alabama and the Agency of Health and Human Services, Centers for Medicare and Medicaid Services (CMS).

#### **4.12 NOTICE TO PARTIES**

Any notice to Medicaid under the contract shall be sufficient when mailed to the project manager listed in Section 1.2. Any notice to the Contractor shall be sufficient when mailed to Contractor at the address given in the response to this ITB or on the contract after signing. All notices shall be given by certified mail, return receipt requested.

#### **4.13 FORCE MAJEURE**

Both parties to this contract shall be excused from performance hereunder for any period that the State or Contractor is prevented from performing such services pursuant hereto in whole or in part as a result of an act of God, war, civil disturbance, epidemic, or court order; such non-performance shall not be a ground for termination for default.

#### **4.14 DISASTER RECOVERY PLAN**

Contractor shall provide Medicaid, for approval, prior to contract start date, a written implementation plan addressing satisfactory back-up arrangements for data processing equipment and files to provide continued contract performance in the event of machine failure or loss of records.

#### **4.15 WARRANTIES AGAINST BROKER'S FEES**

Contractor warrants that no person or selling agent has been employed or retained to solicit or secure the contract upon an agreement or understanding for a commission percentage, brokerage or contingency fee excepting bona fide employees.

In the event of a breach of this warranty by the Contractor, Medicaid shall have the right to terminate this contract without any liability whatsoever, or, in its discretion, to deduct from the contract price or consideration or otherwise recover the full amount of such fee, commission, percentage, brokerage fee, gift or contingent fee.

#### **4.16 PROHIBITION AGAINST ASSIGNMENT**

Contractor may not assign this contract to any third party without prior written approval of Medicaid.

#### **4.17 NOVATION**

In the event of a change in the corporate or company ownership of Contractor, Medicaid shall retain the right to continue the contract with the new owner or terminate the contract. The new corporate or company entity must agree to the terms of the original contract and any amendments thereto. During the interim between legal recognition of the new entity and Medicaid execution of the novation agreement, a valid contract will continue to exist between Medicaid and the original Contractor. When, to Medicaid's satisfaction, sufficient evidence has been presented of the new owner's ability to perform under the terms of the contract, Medicaid may approve the new owner and a novation agreement shall be executed.

#### **4.18 EMPLOYMENT BASIS**

All services rendered by Contractor or any subcontractor shall be as an independent contractor and not as an employee (merit or otherwise) of the state of Alabama, and Contractor shall not be entitled to or receive merit system benefits.

#### **4.19 DISPUTES**

Except in those cases where the bid response exceeds the requirements of the ITB, any conflict between the bid response of the Contractor and the ITB shall be controlled by the provisions of the ITB. Any dispute concerning a question of fact arising under this contract which is not disposed of by agreement shall be decided by the Commissioner of Medicaid.

The Contractor's sole remedy for the settlement of any and all disputes arising under the terms of this contract shall be limited to the filing of a claim with the Board of Adjustment for the State of Alabama. Pending a final decision of a dispute hereunder, the Contractor must proceed diligently with the performance of the contract in accordance with the disputed decision.

For any and all disputes arising under the terms of this contract, the parties hereto agree, in compliance with the recommendations of the Governor and Attorney General, when considering settlement of such disputes, to utilize appropriate forms of non-binding alternative dispute resolution including, but not limited to, mediation by and through private mediators.

#### **4.20 LITIGATION**

Any litigation brought by Medicaid or the Contractor regarding any provision of these contracts shall be brought in either the Circuit Court of Montgomery County, Alabama, or the United States District Court for the Middle District of Alabama, Northern Division, according to the jurisdictions of these courts. This provision shall not be deemed an attempt to confer any jurisdiction on these courts which they do not by law have, but is a stipulation and agreement as to forum and venue only.

#### **4.21 ATTORNEY FEES**

In the event that the State shall prevail in any legal action arising out of the performance or non-performance of this contract, Contractor must pay, in addition to any damages, all expenses of such action including reasonable attorneys' fees and costs. This requirement applies regardless of whether Medicaid is represented by staff counsel or outside counsel. Fees and costs of defense shall be deemed to include administrative proceedings of all kinds, as well as all actions at law or equity.

#### **4.22 WAIVERS**

No covenant, condition, duty, obligation, or undertaking contained in or made a part of the contract can be waived except by written agreement of the parties.

#### **4.23 NOT TO CONSTITUTE A DEBT OF THE STATE**

Under no circumstances shall any commitments by Medicaid constitute a debt of the State of Alabama as prohibited by Article XI, Section 213, Constitution of Alabama of 1901, as amended by Amendment 26. It is further agreed that if any provision of this contract shall contravene any statute or Constitutional provision or amendment, whether now in effect or which may, during the course of this Contract, be enacted, then that conflicting provision in the contract shall be deemed null and void.

#### **4.24 DEBARMENT**

Contractor hereby certifies that neither it nor its principals nor any subcontractor or its principals, is presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation by any Federal Department or Agency.

#### **4.25 TERMINATION OF CONTRACT**

This Contract may be terminated by Medicaid for any or all of the following reasons:

- For any default by the Contractor;
- For the convenience of Medicaid;
- In the event of the insolvency of or declaration of bankruptcy by the Contractor;
- In the event sufficient appropriated or otherwise obligated funds, either state or federal, no longer exist for the payment of Medicaid's obligation hereunder.

Each of these is described in the following subsections.

#### **4.26 TERMINATION FOR DEFAULT**

The failure of the Contractor to perform or comply with any term, condition, or provision of this contract shall constitute a default by the Contractor. In the event of default, Medicaid shall notify the Contractor by certified or registered mail, return receipt requested, of the specific act or omission of the Contractor which constitutes default. A copy of written notice shall be sent to any surety for Contractor's Performance Guarantee.

Contractor will have 30 calendar days from the date of receipt of such notification to cure such default. In the event of default, and during the above-specified period, performance under the contract shall continue as though the default had never occurred. In the event the default is not cured in 30 calendar days, Medicaid may, at its sole option, terminate the contract for default and proceed to seek appropriate relief from Contractor and Surety. Such termination shall be accomplished by written notice of termination forwarded to the Contractor by certified or registered mail, return receipt requested, and shall be effective at the close of business on the date specified in the notice. If it is determined, after notice of termination for default, that the Contractor's failure was due to causes beyond the control of and without error or negligence of the Contractor, the termination shall be deemed a termination for convenience.

#### **4.27 TERMINATION FOR CONVENIENCE**

Medicaid may terminate performance of work under the Contract in whole or in part whenever, for any reason, Medicaid shall determine that such termination is in the best interest of the State. In the event that Medicaid elects to terminate the contract, pursuant to this provision, it shall so notify the Contractor by certified or registered mail, return receipt requested. The termination shall be effective as of the date specified in the notice.

#### **4.28 TERMINATION FOR BANKRUPTCY OR INSOLVENCY**

The filing of a petition for voluntary or involuntary bankruptcy of a company or a corporate reorganization pursuant to the Bankruptcy Act shall, at the option of Medicaid, constitute default by Contractors effective the date of such filing. Contractors must inform Medicaid in writing of any such action(s) immediately upon occurrence by the most expeditious means possible. Recipients and/or subcontractors cannot be held liable for unpaid debt caused by the Contractor's bankruptcy or insolvency.

#### **4.29 TERMINATION FOR UNAVAILABILITY OF FUNDS**

Performance by the State of Alabama of any of its obligations under the contract is subject to and contingent upon the availability of state and federal monies lawfully applicable for such purposes. This contract is conditional upon the availability of funds. Should funds become unavailable during the term of the contract, the contract shall terminate upon notice by Medicaid to Contractors and Contractors will be entitled to reimbursement for services provided prior to termination upon submission of a certified itemized invoice that details the work performed prior to termination.

### **4.30 PROCEDURE FOR TERMINATION**

Contractor must:

- a. Stop work under the contract on the date and to the extent specified in the notice of termination;
- b. Place no further orders or subcontracts for materials, services, except as may be necessary for completion of such portion of work under the contract as is not terminated;
- c. Terminate all orders and subcontracts to the extent that they relate to the performance of work terminated by the notice of termination;
- d. Assign to Medicaid in the manner and to the extent directed by Medicaid all of the rights, title, and interest of the Contractor under the orders or subcontracts so terminated, in which case Medicaid shall have the right, in its discretion, to settle or pay any and all claims arising out of termination of such orders and subcontracts;
- e. With the approval or ratification of Medicaid, settle all outstanding liabilities and all claims arising out of such termination or orders and subcontracts, the cost of which would be reimbursable in whole or in part, in accordance with the provisions of contract;
- f. Complete the performance of such part of the work as shall not have been terminated by the notice of termination; and
- g. Take such action as may be necessary, or as Medicaid may direct for the protection and preservation of any and all property or information related to the contract which is in the possession of the Contractor and in which Medicaid has or may acquire an interest.

### **4.31 TERMINATION CLAIMS**

After a receipt of a notice of termination, Contractor must submit to Medicaid any termination claim in the form and with the certification prescribed by Medicaid. Such claims shall be submitted promptly but in no event later than 60 days from the effective date of termination. Upon failure of the Contractor to submit its termination claims within the time allowed, Medicaid may, subject to any review required by State procedures in effect as of the date of execution of the contract, determine, on the basis of information available, the amount, if any, due to the Contractor by reason of termination and shall thereupon cause to be paid to the Contractor the amount determined.

Contractor has no entitlement to receive any amount for lost revenues or anticipated profits or for expenditures associated with this or in any other contract. Contractor will be paid only by the following upon termination:

- a. At the contract price(s) for completed deliverables and services

- delivered to and accepted by Medicaid;
- b. At a price mutually agreed upon by the Contractor and Medicaid for partially completed deliverables.

In the event of the failure of the Contractor and Medicaid to agree in whole or in part as to the amounts with respect to costs to be paid to the Contractor in connection with the total or partial termination of work pursuant to this article, Medicaid shall determine on the basis of information available the amount, if any, due to the Contractor by reason of termination and shall pay to the Contractor the amount so determined.

#### **4.32 CONTRACTOR'S DUTIES UPON EXPIRATION/TERMINATION**

##### **a. Transfer of Documents**

At Medicaid's discretion, but no later than three working days following the expiration or termination of the contract, Contractor at its own expense, shall box, label, and deliver to Medicaid the following:

- All unprocessed and pending Prior Authorization requests
- All supporting documentation and correspondence regarding prior authorizations and clinical appeals
- Any information, data, manuals, records, claims or other documentation which shall permit Medicaid to continue contract performance or contract for further performance with another Contractor. Contractor shall organize and label this documentation by contract component.

##### **b. Dialogue**

Contractor shall at any time during the transition period and up to 90 calendar days after expiration of the contract answer all questions and provide all dialogue and training that Medicaid deems necessary to enable the successor Contractor to take over the provision of independent assessment services. All such communications shall be with or through the Project Manager.

#### **4.33 EMPLOYMENT PRACTICES**

##### **a. Nondiscrimination Compliance**

Contractor shall comply with Title VI of the Civil Rights Act of 1964, Section 504 of the Rehabilitation Act of 1973, the Age Discrimination Act of 1975, Executive Order No. 11246, as amended by Executive Order No. 11375, both issued by the President of the United States, the Americans with Disabilities Act of 1990, and with all applicable federal and state laws, rules and regulations implementing the foregoing statutes with respect to nondiscrimination in employment.

##### **b. Small and Minority Business Enterprise Utilization**

In accordance with the provisions of 45 CFR Part 74 and Attachment 0, paragraph 9 of OMB Circular A-102, affirmative steps shall be taken to ensure that small and minority businesses are utilized when possible as sources of supplies, equipment,

construction, and services.

**c. Worker's Compensation**

Contractor shall provide and maintain workman's compensation insurance for all of its employees under the contract or any subcontract thereof, if required by state law during the life of this contract.

**d. Employment of State Staff**

Contractor shall not knowingly engage on a full-time, part-time, or other basis during the term of this contract any professional or technical personnel or contractual consultants who are or have been in the employment of Medicaid during the 12 months prior to the effective date of this contract without the written consent of Medicaid. Certain Medicaid employees may be subject to more stringent employment restrictions under the Alabama Code of Ethics, §36-25-1 et seq. Code of Alabama 1975.

#### **4.34 GUARANTEES, WARRANTIES, CERTIFICATIONS**

**a. Indemnification**

Contractor shall hold harmless, defend and indemnify Medicaid as to any penalties or federal recoupment and any interest incurred by reason of any Title XIX noncompliance due to the fault of Contractor and/or any subcontractors. The term "Title XIX noncompliance" shall be construed to mean any failure or inability of Medicaid to meet the requirements of Title XIX of the Social Security Act-and/or any regulations promulgated by the federal government therewith due to an act or omission of Contractor or subcontractor.

Contractor shall be liable and agrees to be liable for and shall indemnify, defend, and hold the State and Medicaid and their officers, employees and agents harmless from all claims, suits, judgments or damages, including court costs and attorney fees, arising out of or in connection with this contract due to negligent or intentional acts of omissions of the Contractor and/or any subcontractors. Contractor shall hold the State and Medicaid harmless from all subcontractor liabilities under the terms of this contract.

Contractor agrees to indemnify, defend, and hold harmless Medicaid, its officers, agents, and employees from:

Any claims or losses attributable to a service rendered by Contractor or any subcontractor, person, or firm performing or supplying services, materials, or supplies in connection with the performance of the contract regardless of whether Medicaid knew or should have known of such improper service, performance, materials or supplies unless otherwise specifically approved by Medicaid in writing in advance;

Any claims or losses attributable to any person or firm injured or damaged by the erroneous or negligent acts, including without limitation, disregard of Federal or State Medicaid regulations or statutes, of Contractor, its officers, employees, or

subcontractors in the performance of the contract, regardless of whether Medicaid knew or should have known of such erroneous or negligent acts;

Any failure of Contractor, its officers, employees, or subcontractors to observe Alabama laws, including, but not limited to, labor laws and minimum wage laws, regardless of whether Medicaid knew or should have known of such failure.

If at any time during the operation of this contract, Medicaid gains actual knowledge of any erroneous, negligent, or otherwise wrongful acts by Contractor, its officers, employees, or subcontractors, Medicaid agrees to give Contractor written notice thereof. Failure by Medicaid to give said notice does not operate as a waiver of the Contractor's obligations to Medicaid, or as a release of any claims Medicaid may have against Contractor.

**b. Security**

Contractor shall take all reasonable precautions to ensure the safety and security of all information, data, procedures, methods, and funds involved in the performance under the contract, and shall require the same from all employees so involved.

**c. Share of Contract**

No official or employee of the State of Alabama shall be entitled to any share of the contract or to any benefit that may arise therefrom.

**d. Conflict of Interest**

The Contractor covenants that it presently has no interest and shall not acquire any interest, direct or indirect, which would conflict in any manner or degree with its performance hereunder. The Contractor further covenants that in the performance of the contract, no person having any such interest is presently employed or will be employed in the future by the Contractor.

**e. Performance Guarantee**

In order to assure full performance of all obligations imposed on a Contractor contracting with the State of Alabama, the Contractor will be required to provide a performance guarantee. The performance guarantee shall be in the amount equal to one month's payments of Synagis®, which is approximately \$1 million. The performance guarantee must be submitted by Contractor at least ten calendar days prior to the contract start date. The form of performance guarantee shall be one of the following:

- (1) Cashier's check (personal or company checks are not acceptable)
- (2) Other type of bank certified check
- (3) Money order
- (4) An irrevocable letter of credit
- (5) Surety bond issued by a company authorized to do business within the State of Alabama

The Director of Purchasing shall be the custodian of the performance guarantee. The performance guarantee shall reference this ITB and it shall be made payable to the

State of Alabama.

If Contractor fails to deliver the required performance guarantee, the proposal shall be rejected and the contract may be awarded to the provider of the next ranked proposal.

In the event of a breach of contract, Medicaid will notify Contractor in writing of the default and may assess reasonable charges against the Contractor's performance guarantee. If after notification of default, the Contractor fails to remedy the State's damages within 30 calendar days, Medicaid may initiate procedures for collection against Contractor's performance guarantee.

Failure of the Contractor to perform satisfactorily, breach of contract, or termination of contract shall cause the performance guarantee to become due and payable to the state of Alabama to the extent necessary to cover the costs incurred by Medicaid as a result of the Contractor's failure to perform its contractual obligations.

These costs include, but are not limited to, costs to correct any Medicaid errors caused by the Contractor's default and costs incurred by Medicaid for completion of contracted work including any costs associated with preparation, solicitation, and award of a competitive bid for these contract services and any federal, state or other penalties, sanctions, disallowances, or any other costs incurred by Medicaid as a result of the Contractor's default and any liquidated damages necessary as a result of the Contractor's default.

In order to achieve the greatest economy for the State, Medicaid may choose the next responsive bidder, re-release the ITB, or complete any other action consistent with state purchasing laws. The performance guarantee will be released within 60 days of the end of the contract term.

**f. Provision of Gratuities**

Neither the Contractor nor any person, firm or corporation employed by the Contractor in the performance of this contract shall offer or give, directly or indirectly, to any employee or agent of the State, any gift, money or anything of value, or any promise, obligation or contract for future reward or compensation at any time during the term of this contract.

**4.35 CONTRACT SANCTIONS-LIQUIDATED DAMAGES**

In the event that Contractor fails to meet the ITB and contract requirements, and damages are sustained by Medicaid; Contractor agrees to pay Medicaid the sums set forth below as liquidated damages unless these damages are waived by Medicaid.

Contractor shall be liable for any penalties and late deliverables or disallowance of Federal Financial Participation incurred by Medicaid due to Contractor's failure to comply with the terms of the contract. Imposition of liquidated damages may be in addition to other

contract remedies, and does not waive Medicaid's right to terminate the contract. Any liquidated damages imposed on the contractor shall not include rebate amounts. The amount imposed to contractor for any liquidated damages shall be imposed to contractor at a net cost to Medicaid.

The following liquidated damages shall be assessed against contractor for:

- Failure to produce required report or any contractor deliverable - \$100 per day per report.
- Failure to respond to turn around a "clean" prescription request within two business days- \$1,000 per per day for each prescription up to time the order is shipped. Penalty assessed in full day increments. No partial penalties will be allowed.
- Use of educational materials and newsletter without prior review and approval by Medicaid - \$1,000 per instance.
- Failure to follow Medicaid criteria and/or directives in approval/denial of PA requests or Override requests - \$1000 per instance or net cost to Medicaid, whichever is greater.
- Failure to include Medicaid requested changes/corrections/revisions in reports, minutes of DUR Board meetings, newsletters or any other contractor deliverable - \$100 per change/correction/revision per document.
- Failure of designated contractor staff to be punctual for meetings - \$100 per minute past scheduled start time.
- Presentations to or meetings with groups/associations/drug manufacturers or others regarding this contract and work thereunder without prior approval of Medicaid - \$5,000 per instance.
- Failure to safeguard confidential information of providers, recipients or the Medicaid program - \$2,500 per instance plus any penalties incurred by Medicaid for said infractions.
- Completion or assistance (outside of coordination with the prior authorization contractor) with any prescriber of Synagis with their prior authorization form - \$1,000 per instance/prior authorization. No partial penalties allowed.
- Failure of Help Desk staff to provide correct information to a provider: (Information shall include Medicare directives, criteria, or any information that has been provided during an education training or in writing to help desk staff) \$100 per instance/day, not to exceed \$500 per month.

Contractor shall receive written notice from Medicaid upon a finding of failure to comply with contract requirements, which contains a description of the events that resulted in such a finding. Contractor shall be allowed to submit rebuttal information or testimony in opposition to such findings. Medicaid shall make a final decision regarding implementation of liquidated damages.

#### **4.36 METHOD OF PAYMENT AND INVOICES**

For any terms of the contract which allow reimbursement for the cost of procuring goods, materials, supplies, equipment, or services, such procurement shall be made on a competitive basis (including the use of competitive bidding procedures) where practicable, and reimbursement for such cost under the contract shall be in accordance with 48 CFR,

Chapter 1, Subchapter E, Part 31. Further, if such reimbursement is to be made with funds derived wholly or partially from federal sources, such reimbursement shall be subject to Contractor's compliance with applicable federal procurement requirements, and the determination of costs shall be governed by federal cost principles.

#### **4.37 INVOICE SUBMISSION**

Contractor shall submit a claims to Medicaid for compensation for Synagis® on a per claim basis. Reimbursement will not exceed what is listed on the bid submission.

#### **4.38 PAYMENT**

Payments to Contractor shall be dependent upon successful completion and acceptance of described work and delivery of required documentation.

#### **4.39 RECORDS RETENTION AND STORAGE**

In accordance with 45 CFR 74.53 Contractor shall maintain financial records, supporting documents, statistical records, and all other records pertinent to the Alabama Medicaid Program for a period of three years from the date of the final payment made by Medicaid to the Contractor under this contract.

However, if audit, litigation, or other legal action by or on behalf of the State or Federal Government has begun but is not completed at the end of the three-year period, or if audit findings, litigation, or other legal action have not been resolved at the end of the three-year period, the records shall be retained until resolution. Subsequent to the contract term, documents shall be returned to Medicaid within three working days following expiration or termination of the contract. Micromedia copies of source documents for storage may be used in lieu of paper source documents subject to Medicaid approval.

#### **4.40 INSPECTION OF RECORDS**

Contractor agrees that representatives of the Comptroller General, HHS, the General Accounting Office, the State of Alabama Department of Examiners of Public Accounts, Medicaid and their authorized representatives shall have the right during business hours to inspect and copy Contractor's books and records pertaining to contract performance and costs thereof. Contractor shall cooperate fully with requests from any of the agencies listed above and shall furnish free of charge copies of all requested records. Contractor may require that a receipt be given for any original record removed from Contractor's premises.

#### **4.41 CHOICE OF LAW**

The construction, interpretation, and enforcement of this contract shall be governed by the substantive contract law of the State of Alabama without regard to its conflict of laws provisions. In the event any provision of this contract is unenforceable as a matter of law, the remaining provisions will stay in full force and effect.

#### **4.42 ALABAMA INTERCHANGE INTERFACE STANDARDS**

Contractor hereby certifies that any exchange of MMIS data with the Agency's fiscal agent will be accomplished by following the Alabama interChange Interface Standards Document. The Alabama interchange Interface Standards Document can be located in the Bidders Library.

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**Bid Pricing Schedule**


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**Pricing Schedule A**

All reimbursement rates submitted below should list final price/rate, to include any and all administrative/delivery/dispensing fees. Rates should be calculated as a percentage of the Wholesale Acquisition Cost (WAC).

<b>NDC/Strength</b>	<b>Rate as a Percentage off of WAC</b>
60574411401 50mg/0.5ml and 60574411301 100mg/ml and any future NDCs of brand or generic	WAC minus  _____%

As a point of reference, the following rates were applied to Alabama Medicaid pharmacy claims during the 2012-2013 RSV season for ingredient cost only:

NDC60574411401 (50mg/0.5 ml): \$1353.2064 (this rate is per 0.5ml)

NDC60574411301 (100mg/ml): \$2555.25816 (this rate is per 1 ml)

**Evaluated Price**

Signature \_\_\_\_\_ Date \_\_\_\_\_

**Attachment A**

**Sample Contract**

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CONTRACT  
BETWEEN  
THE ALABAMA MEDICAID AGENCY  
AND  
Contractor's name here

KNOW ALL MEN BY THESE PRESENTS, that the Alabama Medicaid Agency, an Agency of the State of Alabama, and \_\_\_\_\_, Contractor, agree as follows:

Contractor shall furnish all labor, equipment, and materials and perform all of the work required under the Invitation to Bid (ITB) Number \_\_\_\_\_, dated \_\_\_\_\_, strictly in accordance with the requirements thereof and Contractor's response thereto.

Contractor shall be compensated for performance under this contract in accordance with the provisions of the ITB and the price provided on the ITB Cover Sheet response, in an amount not to exceed \_\_\_\_\_.

Contractor and the Alabama Medicaid Agency agree that the initial term of the contract is \_\_\_\_ to \_\_\_\_\_.

This contract specifically incorporates by reference the ITB, any attachments and amendments thereto, and Contractor's response.

**ALABAMA MEDICAID AGENCY**

This contract has been reviewed for and is approved as to content.

\_\_\_\_\_  
Contractor's name here

\_\_\_\_\_  
Stephanie McGee Azar  
Acting Commissioner

\_\_\_\_\_  
Date signed

\_\_\_\_\_  
Date signed

\_\_\_\_\_  
Printed Name

This contract has been reviewed for legal form and complies with all applicable laws, rules, and regulations of the State of Alabama governing these matters.

Tax ID: \_\_\_\_\_

APPROVED:

\_\_\_\_\_  
Legal Counsel

\_\_\_\_\_  
Governor, State of Alabama

ALABAMA MEDICAID AGENCY  
BUSINESS ASSOCIATE ADDENDUM

This Business Associate Addendum (this "Agreement") is made effective the \_\_\_\_\_ day of \_\_\_\_\_, 20\_\_\_\_, by and between the Alabama Medicaid Agency ("Covered Entity"), an agency of the State of Alabama, and \_\_\_\_\_ ("Business Associate") (collectively the "Parties").

## 1. BACKGROUND

- a. Covered Entity and Business Associate are parties to a contract entitled \_\_\_\_\_ (the "Contract"), whereby Business Associate agrees to perform certain services for or on behalf of Covered Entity.
- b. The relationship between Covered Entity and Business Associate is such that the Parties believe Business Associate is or may be a "business associate" within the meaning of the HIPAA Privacy Rule (as defined below).
- c. The Parties enter into this Business Associate Addendum to the Contract with the intention of complying with the HIPAA Privacy Rule provision that a covered entity may disclose protected health information to a business associate, and may allow a business associate to create or receive protected health information on its behalf, if the covered entity obtains satisfactory assurances that the business associate will appropriately safeguard the information.

## 2. DEFINITIONS

**Unless otherwise clearly indicated by the context, the following terms shall have the following meaning in this Agreement:**

- a. "Breach" shall mean the acquisition, access, use or disclosure of protected health information which compromises the security or privacy of such information, except where an unauthorized person to whom such information is disclosed would not reasonably have been able to retain such information.
- b. "Electronic Health Record" shall mean an electronic record of health-related information on an individual that is created, gathered, managed, and consulted by authorized health care clinicians and staff.
- c. "Electronic Protected Health Information" means Protected Health Information that is transmitted by Electronic Media (as defined in the Security and Privacy Rule) or maintained in Electronic Media.
- d. "HIPAA" means the Administrative Simplification Provisions, Sections 261 through 264, of the federal Health Insurance Portability and Accountability Act of 1996, Public Law 104-191.
- e. "Individual" shall have the same meaning as the term "individual" in 45 CFR 164.501 and shall include a person who qualifies as a personal representative in accordance with 45 CFR 164.502(g).

- f. “Personal Health Record” shall mean an electronic record of identifiable health information on an individual that can be drawn from multiple sources and that is managed, shared and controlled by or primarily for the individual.
- g. “Privacy Rule” shall mean the Standards for Privacy of Individually Identifiable Health Information at 45 CFR part 160 and part 164, subparts A and E.
- h. “Protected Health Information” (PHI) shall have the same meaning as the term “protected health information” in 45 CFR 160.103, limited to the information created or received by Business Associate from or on behalf of Covered Entity.
- i. “Required By Law” shall have the same meaning as the term “required by law” in 45 CFR 164.103.
- j. “Secretary” shall mean the Secretary of the United States Department of Health and Human Services or his designee.
- k. “Security Incident” shall mean the attempted or successful unauthorized access, use, disclosure, modification, or destruction of information or interference with system operations in an information system.
- l. “Security Rule” shall mean the Security Standards for the Protection of Electronic Protected Health Information at 45 CFR Parts 160 and 162, and Parts 164, Subparts A and C. The application of Security provisions Sections 164.308; 164.310, 164.312, and 164.316 of title 45, Code of Federal Regulations shall apply to a business associate of a covered entity in the same manner that such sections apply to the covered entity.
- m. Unless otherwise defined in this Agreement, capitalized terms used herein shall have the same meaning as those terms have in the Privacy Rule.
- n. “Unsecured Protected Health Information” is information that is not rendered unusable, unreadable, or indecipherable to unauthorized individuals by mean of technology or methodology specified by the Secretary of Health and Human Services in the guidance issued under section 13402(h)(2) of Public Law 111–5.

### **3. OBLIGATIONS OF BUSINESS ASSOCIATE**

- a. Use and Disclosure of PHI. Business Associate agrees to not use or disclose PHI other than as permitted or required by this Agreement or as Required By Law.
- b. Appropriate Safeguards. Business Associate agrees to use appropriate safeguards to prevent use or disclosure of the PHI other than as provided for by this Agreement. The Business Associate agrees to take steps to safeguard, implement and maintain PHI in accordance with the HIPAA Privacy Rule.
- c. Mitigation. Business Associate agrees to mitigate, to the extent practicable, any harmful effect that is known to Business Associate of a use or disclosure of PHI by Business Associate in violation of the requirements of this Agreement.
- d. Report Unauthorized Use or Disclosure. Business Associate agrees to promptly report to Covered Entity any use or disclosure of PHI not provided for by this Agreement of which it becomes aware.
- e. Applicability to Business Associate’s Agents. Business Associate agrees to ensure that any agent, including a subcontractor, to whom it provides PHI received from, or created or received by the

Business Associate on behalf of, Covered Entity agrees to the same restrictions and conditions that apply through this Agreement to Business Associate with respect to such information. The Business Associate agrees to have HIPAA-compliant Business Associate Agreements or equivalent contractual agreements with agents to whom the Business Associate discloses Covered Entity PHI.

- f. Access. Upon receipt of a written request from Covered Entity, Business Associate agrees to provide Covered Entity, in order to allow Covered Entity to meet its requirements under 45 CFR 164.524, access to PHI maintained by Business Associate in a Designated Record Set within thirty (30) business days.
- g. Amendments to PHI. Business Associate agrees to make any amendment(s) to PHI maintained by Business Associate in a Designated Record Set that Covered Entity directs or agrees to, pursuant to 45 CFR 164.526 at the request of Covered Entity, within thirty (30) calendar days after receiving a written request for amendment from Covered Entity.
- h. Availability of Documents. Business Associate agrees to make internal practices, books, and records, including policies and procedures and PHI, relating to the use and disclosure of PHI received from, or created or received by the Business Associate on behalf of, Covered Entity, available to Covered Entity or to the Secretary for purposes of the Secretary determining Covered Entity's compliance with the Privacy and Security Rules, within five business days' after receipt of written notice.
- i. Documentation of PHI Disclosures. Business Associate agrees to keep records of disclosures of PHI and information related to such disclosures as would be required for Covered Entity to respond to a request by an individual for an accounting of disclosures of PHI in accordance with 45 CFR 164.528.
- j. Accounting of Disclosures. The Business Associate agrees to provide to Covered Entity, within 30 days of receipt of a written request from Covered Entity, information collected in accordance with the documentation of PHI disclosure of this Agreement, to permit Covered Entity to respond to a request by an Individual or an authorized representative for an accounting of disclosures of PHI in accordance with 45 CFR 164.528.
- k. The Business Associate shall maintain a comprehensive security program appropriate to the size and complexity of the Business Associate's operations and the nature and scope of its activities as defined in the Security Rule.
- l. The Business Associate shall notify the Covered Entity immediately following the discovery of a breach of Protected Health Information (PHI).
- m. The Business Associate shall provide the Covered Entity the following information when a breach of unsecured protected health information is discovered:
  - 1) The number of recipient records involved in the breach.
  - 2) A description of what happened, including the date of the breach and the date of the discovery of the breach if known.
  - 3) A description of the types of unsecure protected health information that were involved in the breach (such as whether full name, social security number, date of birth, home address, account number, diagnosis, disability code, or other type information were involved).

- 4) Any steps the individuals should take to protect themselves from potential harm resulting from the breach.
  - 5) A description of what the Business Associate is doing to investigate the breach, to mitigate harm to individuals and to protect against any further breaches.
  - 6) Contact procedures for individuals to ask questions or learn additional information, which shall include the Business Associate's toll-free number, email address, Web site, or postal address.
  - 7) A proposed media release developed by the Business Associate.
- n. The Business Associate shall obtain Covered Entity approval prior to reporting any breach required by 45 CFR Part 164, Subpart D.
  - o. The Business Associate shall, after receiving Covered Entity approval, provide the necessary notices to the recipient, prominent media outlet, or the Secretary of Health and Human Services (HHS) to report Business Associate breaches as required by 45 CFR Part 164, Subpart D.
  - p. Covered Entity will coordinate with the Business Associate in the determination of additional specific actions that will be required of the Business Associate for mitigation of the breach.
  - q. If the Business Associate is a vendor of personal health records, notification of the breach will need to be made with the Federal Trade Commission.
  - r. The Business Associate shall be responsible for any and all costs associated with the notification and mitigation of a breach that has occurred because of the negligence of the Business Associate.
  - s. The Business Associate shall pay all fines or penalties imposed by HHS under 45 CFR Part 160 HIPAA Administrative Simplification: Enforcement rule for breaches made by any employee, officer, or agent of the Business Associate.
  - t. The Business Associate shall be subject to prosecution by the Department of Justice for criminal violations of HIPAA if the Business Associate obtains or discloses individually identifiable health information without authorization, and shall be responsible for any and all costs associated with prosecution.

#### **4. PERMITTED USES AND DISCLOSURES**

Except as otherwise limited in this Agreement, if the Contract permits, Business Associate may use or disclose PHI to perform functions, activities, or services for, or on behalf of, Covered Entity as specified in the Contract, provided that such use or disclosure would not violate the Privacy Rule if done by Covered Entity;

- a. Except as otherwise limited in this Agreement, if the Contract permits, Business Associate may use PHI for the proper management and administration of the Business Associate or to carry out the legal responsibilities of the Business Associate.
- b. Except as otherwise limited in this Agreement, if the Contract permits, Business Associate may disclose PHI for the proper management and administration of the Business Associate, provided that:

- 1) disclosures are Required By Law; or

- 2) Business Associate obtains reasonable assurances from the person to whom the information is disclosed that it will remain confidential and used or further disclosed only as Required By Law or for the purpose for which it was disclosed to the person, and the person notifies the Business Associate of any instances of which it is aware in which the confidentiality of the information has been breached.
- c. Except as otherwise limited in this Agreement, if the Contract permits, Business Associate may use PHI to provide data aggregation services to Covered Entity as permitted by 42 CFR 164.504(e)(2)(i)(B).
- d. Notwithstanding the foregoing provisions, Business Associate may not use or disclose PHI if the use or disclosure would violate any term of the Contract.

## 5. REPORTING IMPROPER USE OR DISCLOSURE

- a. The Business Associate shall report to the Covered Entity any use or disclosure of PHI not provided for by this agreement immediately from the time the Business Associate becomes aware of the use or disclosure.
- b. The Business Associate shall report to the Covered Entity any Security Incident and/or breach immediately from the time the Business Associate becomes aware of the use or disclosure.

## 6. OBLIGATIONS OF COVERED ENTITY

- a. Covered Entity shall notify the Business Associate of any limitation(s) in its notice of privacy practices in accordance with 45 CFR 164.520, to the extent that such limitation may affect Alabama Medicaid's use or disclosure of PHI.
- b. Covered Entity shall notify the Business Associate of any changes in, or revocation of, permission by an Individual to use or disclose PHI, to the extent that such changes may affect the Business Associate's use or disclosure of PHI.
- c. Covered Entity shall notify the Business Associate of any restriction to the use or disclosure of PHI that Covered Entity has agreed to in accordance with 45 CFR 164.522, to the extent that such restriction may affect the Business Associate's use or disclosure of PHI.
- d. Covered Entity shall not request Business Associate to use or disclose PHI in any manner that would not be permissible under the Privacy Rule if done by Covered Entity.
- e. Covered Entity shall provide Business Associate with only that PHI which is minimally necessary for Business Associate to provide the services.

## 7. TERM AND TERMINATION

- a. **Term.** The Term of this Agreement shall be effective as of the effective date stated above and shall terminate when the Contract terminates.
- b. **Termination for Cause.** Upon Covered Entity's knowledge of a material breach by Business Associate, Covered Entity may, at its option:

1. Provide an opportunity for Business Associate to cure the breach or end the violation, and terminate this Agreement if Business Associate does not cure the breach or end the violation within the time specified by Covered Entity;
2. Immediately terminate this Agreement; or
3. If neither termination nor cure is feasible, report the violation to the Secretary as provided in the Privacy Rule.

**c. Effect of Termination.**

1. Except as provided in paragraph (2) of this section or in the Contract, upon termination of this Agreement, for any reason, Business Associate shall return or destroy all PHI received from Covered Entity, or created or received by Business Associate on behalf of Covered Entity. This provision shall apply to PHI that is in the possession of subcontractors or agents of Business Associate. Business Associate shall retain no copies of the PHI.
2. In the event that Business Associate determines that returning or destroying the PHI is not feasible, Business Associate shall provide to Covered Entity notification of the conditions that make return or destruction not feasible. Business Associate shall extend the protections of this Agreement to such PHI and limit further uses and disclosures of such PHI to those purposes that make the return or destruction infeasible, for so long as Business Associate maintains such PHI.

**8. GENERAL TERMS AND CONDITIONS**

- a. This Agreement amends and is part of the Contract.
- b. Except as provided in this Agreement, all terms and conditions of the Contract shall remain in force and shall apply to this Agreement as if set forth fully herein.
- c. In the event of a conflict in terms between this Agreement and the Contract, the interpretation that is in accordance with the Privacy Rule shall prevail. Any ambiguity in this Agreement shall be resolved to permit Covered Entity to comply with the Privacy Rule.
- d. A breach of this Agreement by Business Associate shall be considered sufficient basis for Covered Entity to terminate the Contract for cause.
- e. The Parties agree to take such action as is necessary to amend this Agreement from time to time for Covered Entity to comply with the requirements of the Privacy Rule and HIPAA.

**IN WITNESS WHEREOF, Covered Entity and Business Associate have executed this Agreement effective on the date as stated above.**

**ALABAMA MEDICAID AGENCY**

Signature: \_\_\_\_\_

Printed Name: Clay Gaddis

Title: Privacy Officer

Date: \_\_\_\_\_

**BUSINESS ASSOCIATE**

Signature: \_\_\_\_\_

Printed Name: \_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_



2. List below the name(s) and address(es) of all family members of public officials/public employees with whom you, members of your immediate family, or any of your employees have a family relationship and who may directly personally benefit financially from the proposed transaction. Identify the public officials/public employees and State Department/Agency for which the public officials/public employees work. (Attach additional sheets if necessary.)

NAME OF FAMILY MEMBER	ADDRESS	NAME OF PUBLIC OFFICIAL/ PUBLIC EMPLOYEE	STATE DEPARTMENT/ AGENCY WHERE EMPLOYED

If you identified individuals in items one and/or two above, describe in detail below the direct financial benefit to be gained by the public officials, public employees, and/or their family members as the result of the contract, proposal, request for proposal, invitation to bid, or grant proposal. (Attach additional sheets if necessary.)

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Describe in detail below any indirect financial benefits to be gained by any public official, public employee, and/or family members of the public official or public employee as the result of the contract, proposal, request for proposal, invitation to bid, or grant proposal. (Attach additional sheets if necessary.)

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List below the name(s) and address(es) of all paid consultants and/or lobbyists utilized to obtain the contract, proposal, request for proposal, invitation to bid, or grant proposal:

NAME OF PAID CONSULTANT/LOBBYIST	ADDRESS

***By signing below, I certify under oath and penalty of perjury that all statements on or attached to this form are true and correct to the best of my knowledge. I further understand that a civil penalty of ten percent (10%) of the amount of the transaction, not to exceed \$10,000.00, is applied for knowingly providing incorrect or misleading information.***

Signature \_\_\_\_\_ Date \_\_\_\_\_

Notary's Signature \_\_\_\_\_ Date \_\_\_\_\_ Date Notary Expires \_\_\_\_\_

*Act 2001-955 requires the disclosure statement to be completed and filed with all proposals, bids, contracts, or grant proposals to the State of Alabama in excess of \$5,000.*

## Evaluation Checklist

### **NOTICE TO VENDOR:**

**It is highly encouraged that the following checklist be used to verify completeness of Proposal content. It is not required to submit this checklist with your proposal.**

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Vendor Name

---

Project Director

---

Review Date

<input checked="" type="checkbox"/> IF CORRECT	<b><u>BASIC PROPOSAL REQUIREMENTS</u></b>
<input type="checkbox"/>	1. Vendor's original response received on time at correct location.
<input type="checkbox"/>	2. Vendor submitted specified number of copies and in an electronic format.
<input type="checkbox"/>	3. The response includes a completed and signed ITB Price Sheet.
<input type="checkbox"/>	4. The response is a complete and independent document, with no references to external documents or resources.
<input type="checkbox"/>	5. Vendor submitted signed acknowledgement of any and all addenda to ITB.
<input type="checkbox"/>	6. The response includes written confirmation that the Vendor understands and shall comply with all of the provisions of the ITB.
<input type="checkbox"/>	7. The response includes 3 client references (with all identifying information in specified format and order).
<input type="checkbox"/>	8. The response includes a corporate background.
<input type="checkbox"/>	9. The response includes a detailed description of each element of the scope of work.
<input type="checkbox"/>	10. The response includes the Certificate of Authority (CA) or a letter/form showing application has been made for a CA.



## **Analysis of Alabama Medicaid Data – Palivizumab Utilization October 1, 2011 – March 31, 2012**

### Introduction

Synagis<sup>®</sup> (palivizumab) is FDA approved for the prevention of respiratory syncytial virus (RSV) in selected infants and children. Palivizumab requires prior authorization (PA) for reimbursement through the Alabama Medicaid Agency. Prior authorization criteria are based on manufacturer labeling and current American Academy of Pediatrics (AAP) recommendations. Criteria are reviewed and evaluated annually. Health Information Designs, Inc. (HID) is contracted with the Agency to manage the PA helpdesk and the PA process, which includes palivizumab PAs.

The purpose of this analysis is to provide an overview of the most recent RSV season in terms of palivizumab utilization and cost to the Alabama Medicaid Agency. Trending information, including data from past RSV seasons, will be included in this report.

The Centers for Disease Control and Prevention (CDC) has a laboratory-based system, called the National Respiratory and Enteric Virus Surveillance System (NREVSS), which monitors patterns associated with different viruses, including respiratory syncytial virus. According to the NREVSS website, RSV activity in Alabama became significant week- ending (WE) 01/07/12, peaked WE 02/18/12, and became statistically nonsignificant WE 03/31/12 (see Appendix A for details). This information supports the Alabama Medicaid policy of limiting the palivizumab PA time frame.

### Changes for 2011-2012 Season

There were no major changes for the 2011-12 Alabama Medicaid palivizumab season. Providers were still required to submit a hospital discharge summary from birth with each prior authorization request. If the discharge summary was unavailable to the requesting provider, the recipient's first office visit documentation was acceptable. All diagnoses/ICD-9 codes submitted on the prior authorization form must be found in the included documentation.

The AAP did not release or update any recommendations regarding palivizumab. The last recommendations were published in June 2009, prior to the start of the 2009-10 palivizumab season.

All policies related to palivizumab coverage are based on clinical literature and recommendations and are intended to ensure that medication is available to all children who meet the criteria.

Prior to the start of the 2011-12 palivizumab season, HID determined that having a registered, experienced pediatric nurse available to manage the palivizumab PA process would be advantageous to the provider community. Jessica O'Donnell, RN, BSN, managed the palivizumab prior authorization process for the 2011-12 season.

During the months preceding the start of palivizumab season, the Medicaid Pharmacy Specialists conducted face-to-face visits with all physicians and pharmacies that prescribe and/or dispense palivizumab to Alabama Medicaid recipients to discuss the criteria and forms. All documents related to palivizumab were posted on the Agency website so that they would be readily available to providers. To help track palivizumab patients and their doses, HID utilizes an electronic tracking system, which allows

HID to maintain a database of doses given and doses needed – the database also allows clinical personnel to monitor the recipient weight to help avoid waste.

Once the palivizumab season started, the prior authorization team made a commitment to call Synagis providers – in the event a second denial for a specific recipient was issued – to explain what was needed to complete their request. Monthly reports were provided to the Alabama Medicaid Agency so that trends could be easily identified and the PA process be carefully monitored.

Overall Utilization and Cost

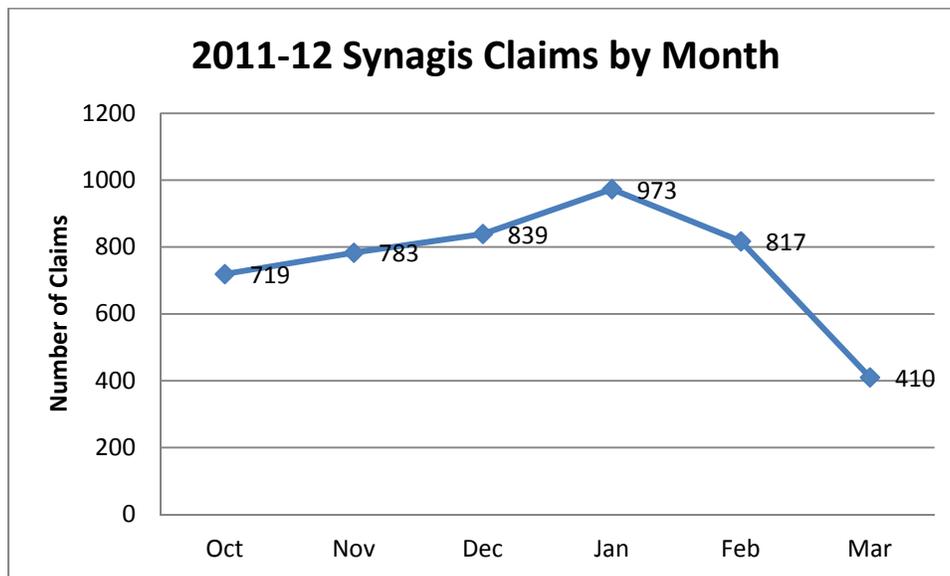
The following chart details palivizumab claims billed during the 2011-2012 season.

Drug Name	NDC	Total Number of Claims	Total Reimbursement Amount	Total Number of Patients*
Synagis 50mg/0.5mL vial	60574411401	1459	\$1,909,443	**
Synagis 100mg/1mL vial	60574411301	3082	\$8,264,451	**
<b>Total</b>		<b>4541</b>	<b>\$10,173,894</b>	<b>1088</b>

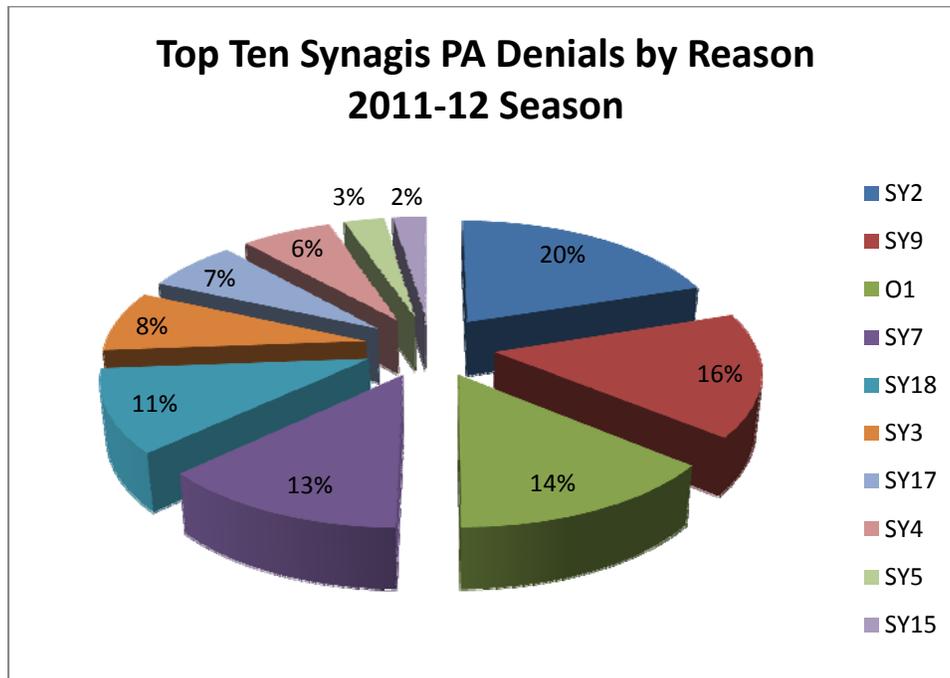
\*Recipients are counted only once in a season.

Post Season Analysis Results

The chart below details claims paid per month.



During the review of palivizumab prior authorization requests, several reasons for PA denial were identified. The following table details those denials.

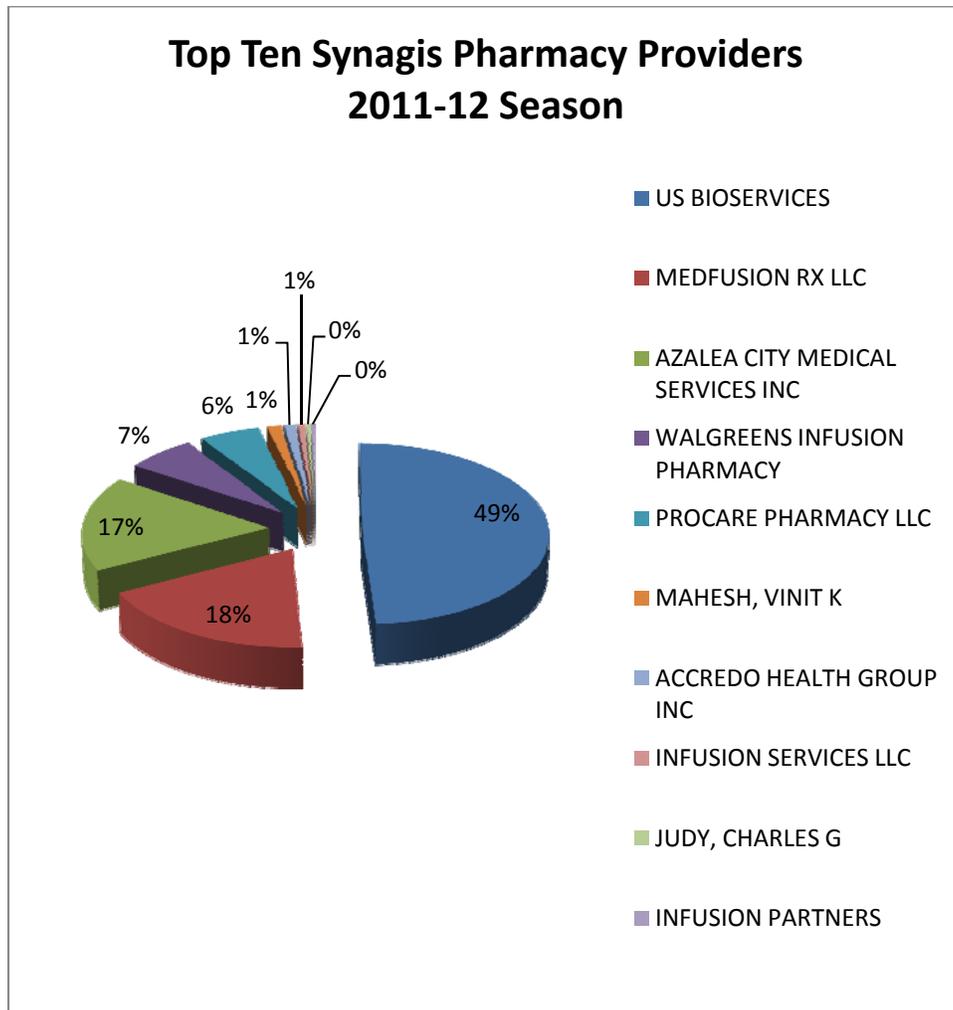


\*There were 870 total palivizumab denials in the 2011-12 season.

The expanded denials are below:

SY2	Does not meet chronological/gestational age requirement
SY9	Hospital discharge summary from birth must be resubmitted with AL Medicaid Synagis request form (form 351).
O1	Other Failed Criteria
SY7	Required documentation of one (1) AL Medicaid approved risk factor
SY18	Physician must sign AL Medicaid Synagis request form 351. Use of stamped/copied physician's signature is not allowed.
SY3	Recipient must be born < (less than) 3 months before or during the RSV season
SY17	Please provide the appropriate ICD-9 code for CHD.
SY4	Requires documentation of appropriate medication, including start and stop dates.
SY5	Must indicate current weight
SY15	Synagis not covered for ICD-9 code indicated on form 351

There were several providers closely involved with the distribution of palivizumab during the RSV season. The following chart details those pharmacies and physicians and the percentage of palivizumab PAs approved for each.



#### Trending

Comparative annual data is presented in an effort to identify and evaluate trends related to palivizumab use among Alabama Medicaid recipients over several years. To fully understand the trending information, it is important to note that criteria is reviewed and refined each season. For example, during the 2005-06 season, following the American Academy of Pediatrics (AAP) recommendation, the number of doses was decreased from 6 per season to 5 per season. The length of the season (6 months) remained the same, to allow providers flexibility of dosing. For 2008-09, it was determined that the chronological age would be the patient's age at the beginning of the season. For the 2009-10 season, criteria were changed according to updated AAP guidelines.

All policies related to palivizumab coverage are based on clinical literature and recommendations and are intended to ensure that medication is available to all children who meet the criteria.

The chart below shows palivizumab utilization during previous seasons.

<b>Drug Name</b>	<b>NDC</b>	<b>Total Number of Claims</b>	<b>Total Reimbursement Amount</b>	<b>Total Number of Patients*</b>
<i>2005-06 Season</i>				
Synagis 50mg vial	60574411201	717	\$514,354	-
Synagis 50mg/0.5mL vial	60574411401	1443	\$1,043,190	-
Synagis 100mg vial	60574411101	1512	\$2,266,982	-
Synagis 100mg/1mL vial	60574411301	2825	\$4,256,705	-
<i>Total</i>		<i>6497</i>	<i>\$8,081,231</i>	<i>1279</i>
<i>2006-07 Season</i>				
Synagis 50mg/0.5mL vial	60574411401	2739	\$2,113,735	-
Synagis 100mg/1mL vial	60574411301	5450	\$8,945,261	-
<i>Total</i>		<i>8189</i>	<i>\$11,058,996</i>	<i>1559</i>
<i>2007-08 Season</i>				
Synagis 50mg/0.5mL vial	60574411401	3673	\$3,101,902	-
Synagis 100mg/1mL vial	60574411301	7018	\$13,431,560	-
<i>Total</i>		<i>10,691</i>	<i>\$16,533,462</i>	<i>1980</i>
<i>2008-09 Season</i>				
Synagis 50mg/0.5mL vial	60574411401	3156	\$2,940,434	-
Synagis 100mg/1mL vial	60574411301	6265	\$12,851,931	-
<i>Total</i>		<i>9421</i>	<i>\$15,792,365</i>	<i>2050</i>
<i>2009-10 Season</i>				
Synagis 50mg/0.5mL vial	60574411401	1311	\$1,360,792	-
Synagis 100mg/1mL vial	60574411301	2782	\$5,972,010	-
<i>Total</i>		<i>4093</i>	<i>\$7,332,802</i>	<i>959</i>
<i>2010-11 Season</i>				
Synagis 50mg/0.5mL vial	60574411401	1441	\$1,705,147	-
Synagis 100mg/1mL vial	60574411301	3022	\$7,333,287	-
<i>Total</i>		<i>4463</i>	<i>\$9,038,434</i>	<i>1072</i>
<i>2011-12 Season</i>				
Synagis 50mg/0.5mL vial	60574411401	1459	\$1,909,443	-
Synagis 100mg/1mL vial	60574411301	3082	\$8,264,451	-
<i>Total</i>		<i>4541</i>	<i>\$10,173,894</i>	<i>1088</i>

\*Recipients are counted only once in a season.

The chart below details palivizumab usage and other information pertinent for trending purposes.

	2005-06	2006-07	2007-08	2008-09	2009-10	2010-11	2011-12
# of Recipients	1279	1559	1980	2050	959	1072	1088
# of Claims	6497	8189	10,691	9421	4093	4463	4541
Cost/vial – 50mg/0.5mL	\$705.10	\$773.49	\$843.10	\$926.56	\$1030.93	\$1159.80	\$1288.77
Cost/vial – 100mg/1mL	\$1331.40	\$1460.55	\$1592.00	\$1749.61	\$1946.69	\$2190.02	\$2433.58
Average Cost Per Claim	\$1244	\$1350	\$1546	\$1676	\$1792	\$2025	\$2240
Total Cost	\$8,081,231	\$11,058,996	\$16,533,462	\$15,792,365	\$7,332,802	\$9,038,434	\$10,173,894
Avg Cost Per Recip	\$6318	\$7094	\$8350	\$7704	\$7646	\$8431	\$9351
Total PAs Requested	4633	4355	5240	8686	3078	3037	2753
# of PAs Approved	2546	2894	3562	3245	1696	1891	1883
# of PAs Denied	2087	1461	1678	5441	1382	1146	870
% of PAs Approved	55.0%	66.5%	68.0%	37.4%*	55.0%	62.3%	68.4%

\*Due to potential inaccuracies, in late October and November 2008, all approved PAs for palivizumab were deactivated and physicians were asked to resubmit the patient information. This may account for the increased number of PAs requested, and denied.

The table below gives an estimated number of doses per recipient for each season.

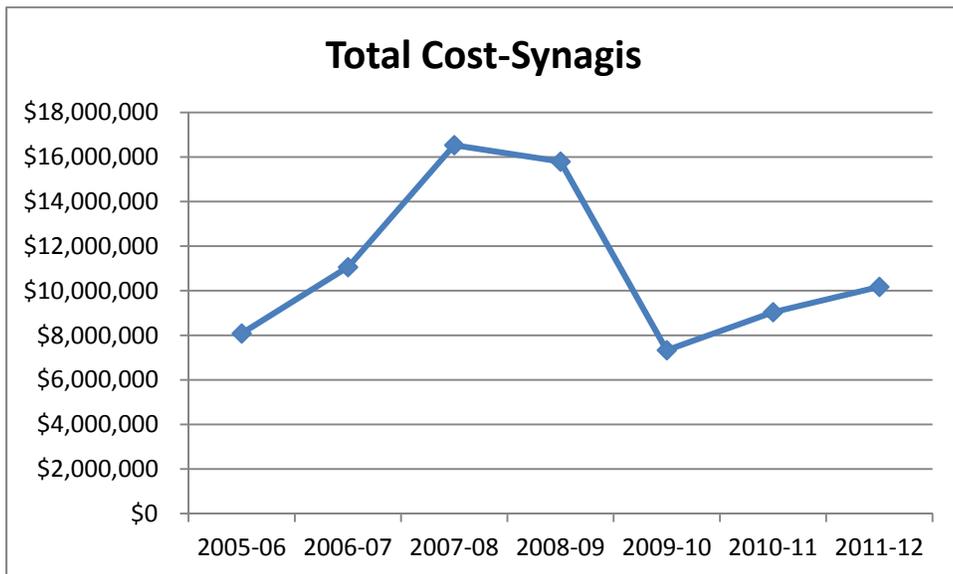
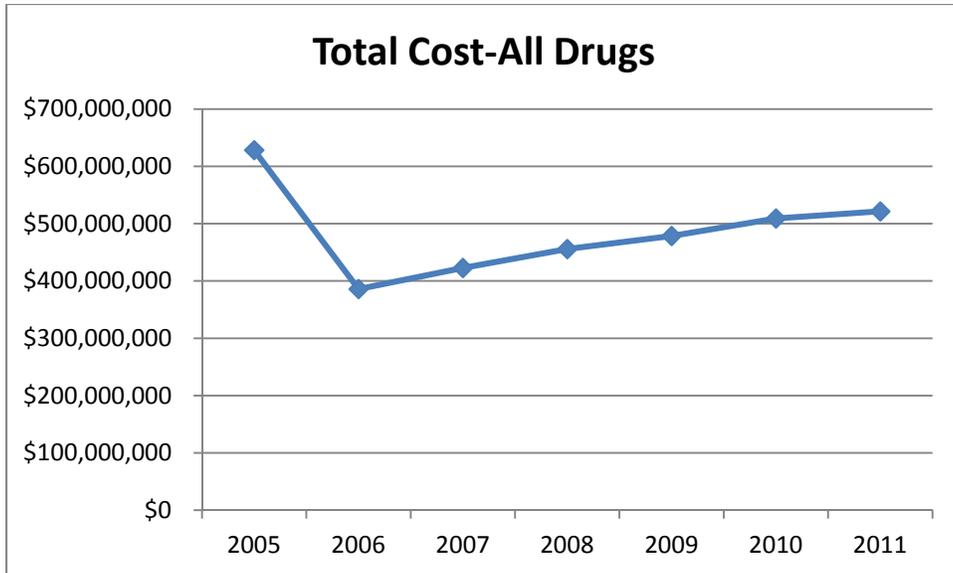
	2005-06	2006-07	2007-08	2008-09	2009-10	2010-11	2011-12
# of Recipients	1279	1559	1980	2050	959	1072	1088
Est. # of Doses	4803	5938	7491	6746	3051	3396	3472
Est. # Doses/Recip	3.8	3.8	3.8	3.3	3.2	3.2	3.2
Total Cost	\$8,081,231	\$11,058,996	\$16,533,462	\$15,792,365	\$7,332,802	\$9,038,434	\$10,173,894
Avg Cost/Dose	\$1683	\$1862	\$2207	\$2341	\$2403	\$2661	\$2930

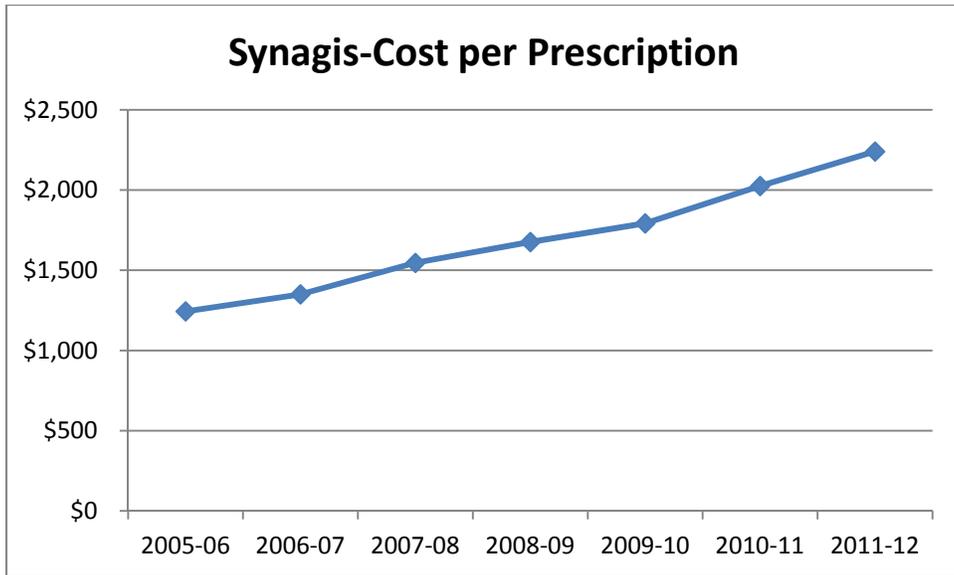
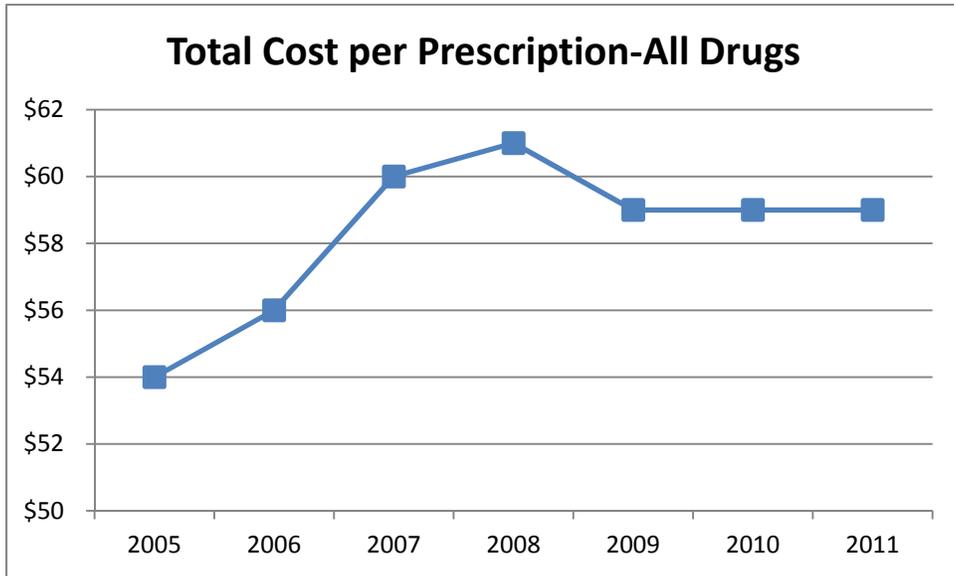
\*Number of doses was estimated by reviewing recipient ID numbers and palivizumab NDC numbers. Each instance of a palivizumab NDC was counted as one dose, unless there was another claim billed within one day. In that instance the two claims were counted as one dose. Each season was independently evaluated. These numbers were verified by random audit checks.

Although the number of beneficiaries and the cost of the product have increased over the past several years, it should be noted that the number of claims per recipient and the estimated number of doses per recipient decreased after the 2004-05 season. This trend can be directly correlated to the implementation of the 5-dose limit.

Trend Analysis

It is important to compare the utilization and cost of palivizumab to all drugs covered by the program. The charts below illustrate total cost and cost per prescription of palivizumab versus the program totals.

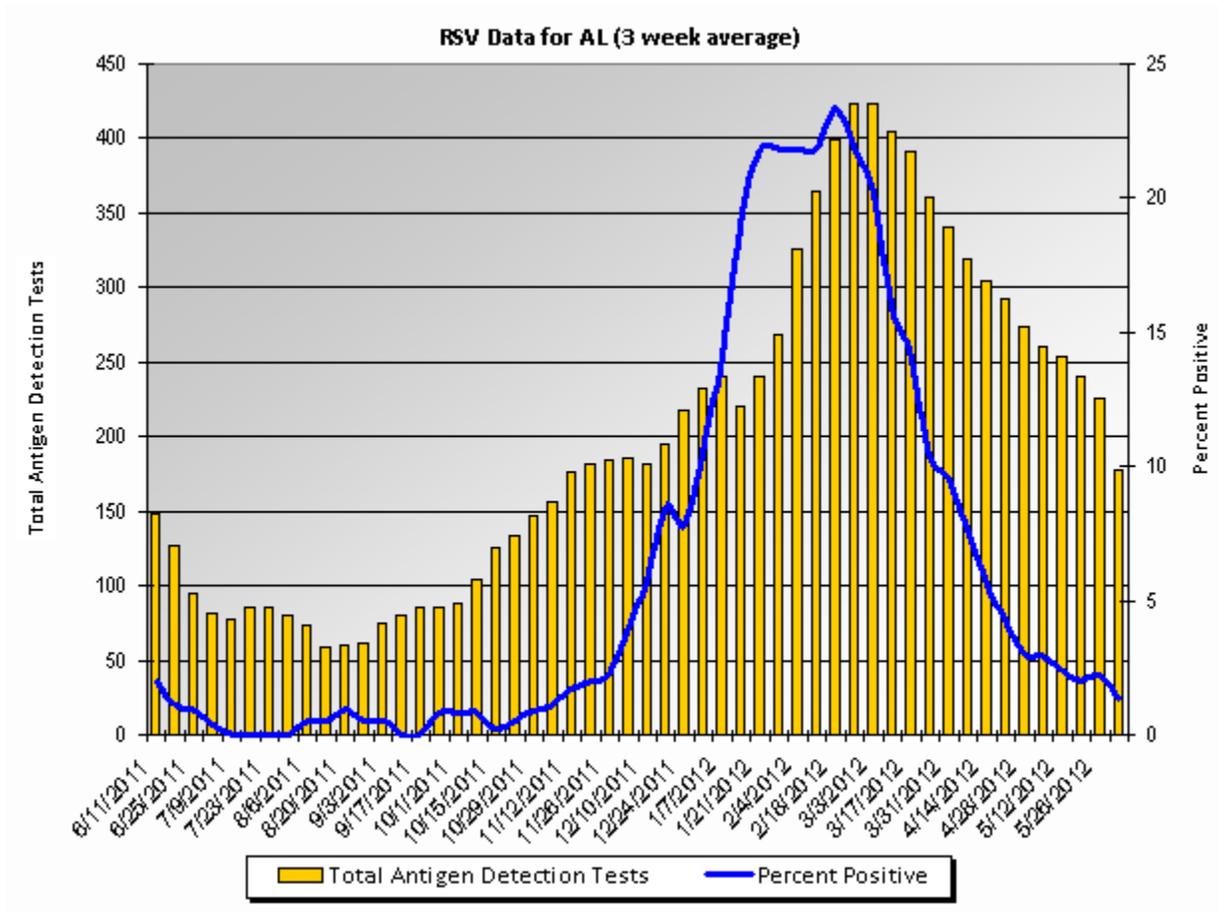




### Conclusion

Each season, the Alabama Medicaid Agency, as well as HID, makes every effort to work with and be available to palivizumab providers. HID also strives to review palivizumab PAs in an impartial, consistent, and effective manner. Our goals are to ensure appropriate utilization of this medication, to encourage consistent compliance with the administration regimen, and to minimize waste.

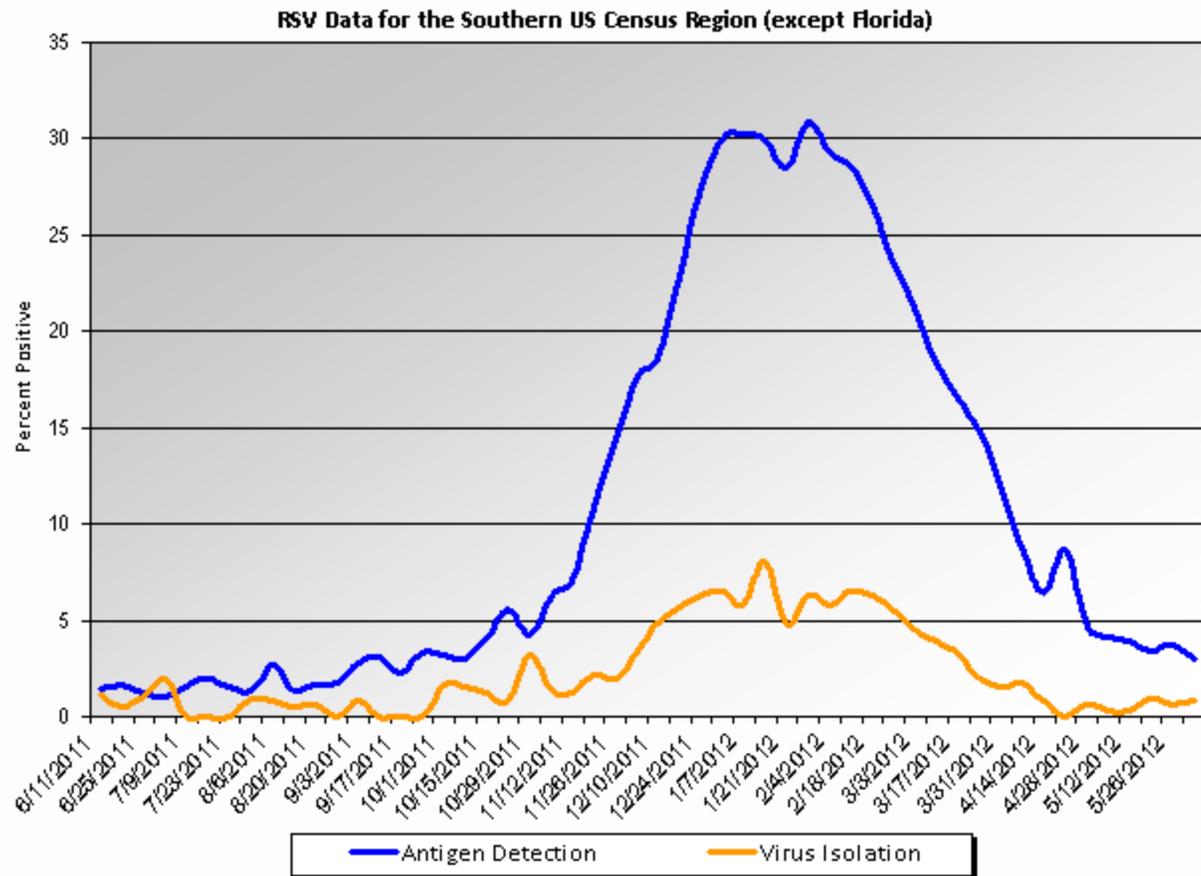
## Appendix A



### The NREVSS participating labs in the AL area:

- Atmore Hospital Lab - Atmore, AL
- Baptist South - Montgomery, AL
- Crestwood Medical Center - Clinical Laboratory - Huntsville, AL
- Elmore Community Hospital Laboratory - Wetumpka, AL
- Marshall Medical Center South - Boaz, AL
- NE Alabama Regional Med Center - Anniston, AL
- Springhill Memorial Hospital - Mobile, AL
- UAHSF Diagnostic Virology Laboratory - Birmingham, AL
- University of South Alabama Medical Center - Mobile, AL

Source: <http://www.cdc.gov/surveillance/nrevss/rsv/state.html#AL>. Accessed on 05/30/2012.

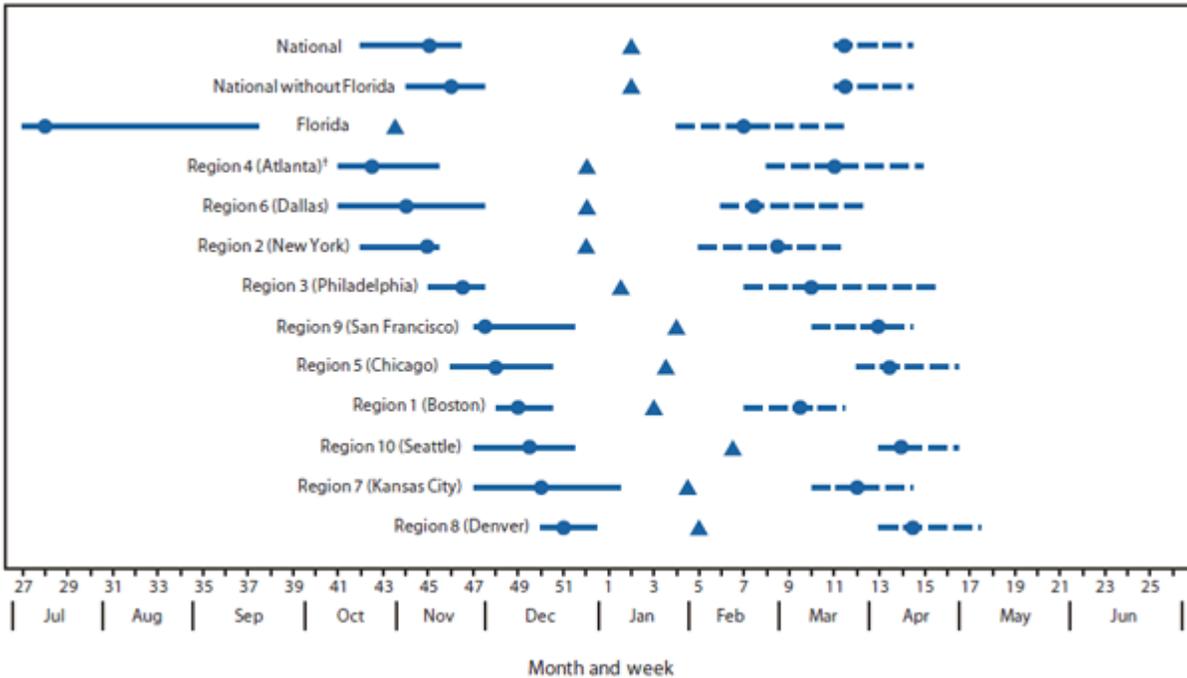


Source: <http://www.cdc.gov/surveillance/nrevss/region.html#south>. Accessed on 05/30/2012.

The following tables were taken from the Centers for Disease Control (CDC) Morbidity and Mortality Weekly Report, September 9, 2011; Volume 60(35); page 1189-1232.

<b>TABLE. Summary of 2010-11 respiratory syncytial virus season, by U.S. Department of Health and Human Services Region and in Florida – National Respiratory and Enteric Virus Surveillance System, July 2010 - June 2011</b>					
<b>HHS Region or State</b>	<b>States</b>	<b>2010—11 Season</b>			
		<b>No. of laboratories reporting</b>	<b>Onset week ending</b>	<b>Offset week ending</b>	<b>Season duration (weeks)</b>
National	All contributing states and DC	179	11/20	4/9	21
National without FL	All contributing states and DC without FL	157	11/27	4/9	20
Florida	FL	22	9/18	3/19	27
Region 2 (New York)	NJ, NY	16	11/13	3/19	19
Region 4 (Atlanta)*	AL, GA, KY, MS, NC, SC, TN	22	11/13	4/9	22
Region 6 (Dallas)	AR, LA, NM, OK, TX	26	11/27	3/26	18
Region 9 (San Francisco)	AZ, CA, HI, NV	25	11/27	4/2	19
Region 3 (Philadelphia)	DE, DC, MD, PA, VA, WV	17	11/27	4/16	21
Region 1 (Boston)	CT, ME, MA, NH, RI, VT	6	12/18	3/12	13
Region 10 (Seattle)	AK, ID, OR, WA	7	12/18	4/2	16
Region 5 (Chicago)	IL, IN, MI, MN, OH, WI	22	12/18	4/23	19
Region 7 (Kansas City)	IA, KS, MO, NE	8	1/1	4/9	15
Region 8 (Denver)	CO, MT, ND, SD, UT, WY	8	1/1	4/30	18
*Excludes data from Florida					

**FIGURE. Respiratory syncytial virus (RSV) season onset and offset range and median, by U.S. Department of Health and Human Services Region\* and in Florida---National Respiratory and Enteric Virus Surveillance System, July 2007—June 2011**



\* Listed by region number and headquarters city. Region 1 (Boston): Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont. Region 2 (New York): New Jersey and New York. Region 3 (Philadelphia): Delaware, District of Columbia, Maryland, Pennsylvania, Virginia, and West Virginia. Region 4 (Atlanta): Alabama, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, and Tennessee. Region 5 (Chicago): Illinois, Indiana, Michigan, Minnesota, Ohio, and Wisconsin. Region 6 (Dallas): Arkansas, Louisiana, New Mexico, Oklahoma, and Texas. Region 7 (Kansas City): Iowa, Kansas, Missouri, and Nebraska. Region 8 (Denver): Colorado, Montana, North Dakota, South Dakota, Utah, and Wyoming. Region 9 (San Francisco): Arizona, California, Hawaii, and Nevada. Region 10 (Seattle): Alaska, Idaho, Oregon, and Washington. Idaho, Maine, New Mexico, and the District of Columbia did not have any participating laboratories in the four-season (2007--2011) analysis.

† Excludes data from Florida.