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September 22, 2017

VIA E-MAIL & US MAIL

Alva Lambert
Executive Director
State Health Planning & Development Agency
100 North Union Street, Suite 870
Montgomery, AL 36130

Lenora W. Pate Attorney at Law lpate@sirote.com Tel: 205-930-5162 Fax: 205-212-3801

RECEIVED

Sep 22 2017

STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

Re:

DVA Renal Healthcare, Inc., d/b/a/ Red Mountain Home Training Dialysis ("Red Mountain")
Request for Non Reviewability Determination

RV2017-031

Additional Information Response

Dear Mr. Lambert:

This letter is written in response to your letter of July 26, 2017, a copy of which is attached hereto as **Exhibit A**, requesting additional information from Red Mountain regarding its Letter of Non-Reviewability Request RV2017-031 (the "LNR Request"), a copy of which is attached hereto as **Exhibit B**, filed per CON Rule 410-1-7-.02, with the State Health Planning and Development Agency ("SHPDA") on July 17, 2017, and with the required filing fee submitted separately. The LNR Request set forth Red Mountain's proposal to provide home hemodialysis training, equipment, and supplies to end stage renal disease ("ESRD") home training patients admitted to Red Mountain, but who reside at Talladega Healthcare Center, Inc. ("Rehab Select/Talladega Healthcare") (the "Proposal").

This letter provides supplemental factual and legal information and respectfully requests confirmation that the Proposal, as set forth in the LNR Request and as supplemented below, is not subject to CON review under Section 410-1-7-.02 of the Alabama CON Program Rules and Regulations (the "CON Rules") and Alabama Code §§ 22-21-260, et seq., and does not require a CON because it does not involve a new institutional health service or any health care facility expenditures in excess of the statutory thresholds requiring CON Review.

1. Facts

1.1 Red Mountain proposes to provide home health hemodialysis services to qualifying home training patients who will reside at Rehab Select/Talladega Healthcare, located at 616 Chaffee Street, Talladega, Alabama, 35160. The Proposal will allow such ESRD long-term care ("LTC") facility residents at Rehab Select/Talladega Healthcare to conveniently receive dialysis in their home, the LTC facility. Moreover, this home dialysis setting is the most suitable and cost efficient setting for treatment of patients who are admitted to and qualify for home dialysis through Red Mountain, and who also qualify for LTC placement at Rehab



Select/Talladega Healthcare. Rehab Select/Talladega Healthcare has determined that it is not cost effective to transport such LTC patients from an LTC to a freestanding ESRD facility or for such patients to remain in acute care dialysis in a hospital, if they qualify for home training, are admitted to Red Mountain, and qualify for admission to Rehab Select/Talladega Healthcare.

- 1.2 It is estimated that transport of an LTC facility patient to an ESRD facility three times per week would cost Rehab Select/Talladega Healthcare approximately \$1,600 per month. As a result, Rehab Select/Talladega Healthcare **currently does not accept** such ESRD patients who require such transport. Due to the cost prohibitive nature of such transportation, ESRD hospital patients, who would otherwise qualify for admission to Rehab Select/Talladega Healthcare, end up with more prolonged, costly hospital stays and hospital acute care dialysis than may be necessary. The Proposal would allow patients who would normally require costly transport from the LTC to a freestanding ESRD facility, or who are unable to be transported to a freestanding ESRD facility due to health reasons, to receive home hemodialysis services in their home, which is their LTC facility, without costly and risky transportation. Further, the Proposal would result in overall lower costs to the health care system by getting ESRD patients out of hospitals and into LTC facilities, where they can receive home dialysis without costly transportation.
- 1.3 Patients who will receive home dialysis under the Proposal must first qualify to be admitted as patients of Rehab Select/Talladega Healthcare and must also qualify **for home hemodialysis training and services** as admitted patients of Red Mountain.²
- 1.4 Under the Proposal, Red Mountain will provide home hemodialysis equipment and supplies to each admitted Red Mountain LTC patient, just as Red Mountain does for all of its home dialysis patients. Red Mountain will send the home dialysis supplies **directly** to the dialysis patient each month at their home, which is their LTC facility, for use in their home, just as Red Mountain does with other home hemodialysis patients who may reside in private homes. Thus, Red Mountain will **not** be adding any hemodialysis stations, rather, the qualifying Rehab Select/Talladega Healthcare patients will be admitted as home hemodialysis patients of Red Mountain for home training and services in their home, their LTC facility room at Rehab Select/Talladega Healthcare.
- 1.5 Patients and patients' partners, who will assist patients in performing home hemodialysis treatment, will each receive home hemodialysis training, under the charge and supervision of a Red Mountain

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¹ 42 C.F.R. § 494.10 defines home dialysis as "dialysis performed at home by an ESRD patient or caregiver who has completed an appropriate course of training as described in § 494.100(a) of this part," and CMS has considered LTC facilities "as the patient's home for purposes of this benefit." See CMS S&C-04-24, Clarification of Certification Requirements and Coordination of Care for Residents of Long-Term Care (LTC) Facilities Who Receive End Stage Renal Disease (ESRD) Services, p. 4.

² The Medicare Benefit Policy Manual for End Stage Renal Disease provides that "ESRD beneficiaries who permanently reside in a nursing home or LTC facilities and who meet the home dialysis requirements set forth under 42 CFR §494.100 are considered home dialysis patients." See Medicare Benefit Policy Manual, Chapter 11 – End Stage Renal Disease (ESRD).



qualified home training nurse.³ If a patient does not have a family member partner, Red Mountain may initially contract with Rehab Select/Talladega Healthcare, which will reimburse Red Mountain for all costs incurred by Red Mountain, to provide a Red Mountain employee to act as the patient's partner for the purpose of assisting the patient in the patient's home dialysis service at Rehab Select/Talladega Healthcare. In time, Rehab Select/Talladega Healthcare may add its own qualified and trained staff to perform such patient partner duties.

- 1.6 As required by CMS, Red Mountain and Rehab Select/Talladega Healthcare will also enter a written coordination agreement which will delineate both parties' respective duties, responsibility and accountability for both routine and emergency care, care planning, and communication with regard to the Proposal. Red Mountain will be responsible for providing all CMS-required home hemodialysis training and services.⁴
- 1.7 The Proposal will result in **no construction costs**; **no equipment costs**; **and no new first year annual operating costs**, because Red Mountain is **not** opening or operating a new healthcare facility or providing new institutional health services and is not adding any new stations. Rather, Red Mountain will provide home hemodialysis training/treatment services and supplies to qualified LTC facility home hemodialysis patients in their home, the LTC facility, in the same manner Red Mountain provides such services and supplies to any of its admitted home hemodialysis patients. Further, the costs for providing a patient partner to Rehab Select/Talladega Healthcare home dialysis patients who may require them will be contracted for and paid by Rehab Select/Talladega Healthcare pursuant to a contract between Red Mountain and Rehab Select/Talladega Healthcare, which will set out the fair market value for the provision of the patient partner.

2. SHPDA-Requested Information

In accordance with the facts set forth above, Red Mountain addresses the following questions and concerns specifically noted by SHPDA in its July 26, 2017 letter in response to Red Mountain's LNR Request:

2.1 A skilled nursing facility by the name of "Rehab Select" cannot be located in Talladega, Alabama. Please provide the licensed name of this skilled nursing facility. As advertised on Rehab Select's website, attached hereto, in relevant part, as Exhibit C, Rehab Select at Talladega is a 234-bed Skilled Nursing Facility located at 616 Chaffee Street, Talladega, Alabama, 35160. The licensed name of Rehab Select at Talladega, as listed in the Alabama Department of Public Health ("ADPH") Facility Directory, attached hereto, in relevant part, as Exhibit D, is Talladega Healthcare Center, Inc.

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³ As required by CMS, "[a] qualified home training nurse of the approved ESRD facility must be in charge of all home training both for home patients and for individuals who assist patients in home dialysis." See CMS S&C-04-37, Addendum I to S&C Letter 04-24 on the Care for Residents of Long-Term Care (LTC) Facilities Who Receive End Stage Renal Disease (ESRD) Services, p. 3.

⁴ According to CMS guidelines, "The ESRD facility is responsible for providing dialysis treatments, including training the patient and caregiver, monitoring the patient and patient's home, dietary and nutritional consultations, assuring continuity of care, installing and maintaining the equipment, testing and treating the water, and ordering supplies." CMS S&C-04-24, Clarification of Certification Requirements and Coordination of Care for Residents of Long-Term Care (LTC) Facilities Who Receive End Stage Renal Disease (ESRD) Services, p. 4.



- 2.2 Will each patient provide their own dialysis station? The Project does not involve the addition of any new stations. Red Mountain will provide only home hemodialysis training, equipment, and supplies for admitted LTC home hemodialysis patients in the same manner as Red Mountain provides for any of its other admitted home hemodialysis patients residing in private homes.
- 2.3 How many total stations will be utilized for patients? As stated in section 2.2, the Project does not involve the addition of any new stations. Red Mountain will provide home hemodialysis equipment for admitted LTC home hemodialysis patients in the same manner as Red Mountain provides for any other admitted home hemodialysis patient who resides in a private home.
- 2.4 Who will be responsible for providing the supplies needed for these stations? As stated in section 2.2, the Project does not involve the addition of any new stations. Further, Red Mountain will provide the supplies for the home hemodialysis services and will send such supplies directly to the patient in their home, their room at the LTC facility, just as Red Mountain provides and sends to any of its other admitted home hemodialysis patients at their private homes.
- 2.5 Will each station be utilized in the patient's room or in a common area? As stated in section 2.2, the Project does not involve the addition of any new stations. It is anticipated that Red Mountain will provide home hemodialysis equipment for admitted LTC home hemodialysis patients for use in the patients' rooms. Equipment may be used in a common area, also a part of the patient's entire home, if the patient's room does not have the size or capacity needed to facilitate the use of the hemodialysis equipment (i.e., adequate water supply).
- 2.6 There are no equipment, capital, annual lease, or construction costs reported for this project. The anticipated first year annual operating costs to Red Mountain must be included to ensure Certificate of Need thresholds are not exceeded.
- a. There are no equipment costs because the Proposal does not involve the addition of any new stations or equipment. Red Mountain will not equip or build out stations; rather, Red Mountain will provide training, equipment, and supplies to be billed to the LTC home hemodialysis patient or such patient's third party payor.
- b. There are **no capital costs** associated with the Proposal because the Proposal does not require any new purchases or capital expenditures. Red Mountain will not equip or build out any new stations. Red Mountain is simply providing home hemodialysis training, equipment, and supplies to qualifying home hemodialysis patients who happen to reside in an LTC facility.
- c. There are **no costs associated with a lease** because the Proposal does not involve the rental of any space. Red Mountain is not opening or operating a new healthcare facility or providing a new institutional health service within Rehab Select/Talladega Healthcare. Red Mountain is simply providing home hemodialysis training, equipment, and supplies to qualifying home hemodialysis patients who happen to reside in an LTC facility.



- d. There are **no construction costs** associated with the Proposal because, as stated in section 2.6(a), Red Mountain will not equip or build out stations; rather, Red Mountain will provide training, equipment, and supplies to qualifying home hemodialysis patients.
- e. There are no anticipated, new first year annual operating costs associated with the Proposal because Red Mountain will not build or operate a new health care facility. Red Mountain will provide, as it currently does, home hemodialysis training and services to admitted home hemodialysis patients. Further, it is anticipated that Rehab Select/Talladega Healthcare will pay the cost of any partner, which may be provided by Red Mountain to a home hemodialysis patient who does not have a family partner to assist in home training, pursuant to a contract between Red Mountain and Rehab Select/Talladega Healthcare. It is anticipated that any partner provided by Red Mountain will be a part of the existing Red Mountain staff; however, if a part-time person may be hired to meet this need initially, if needed, the costs will be reimbursed by Rehab Select/Talladega Healthcare and will not trigger any CON statutory threshold.⁵

3. Legal Analysis

- 3.1 The Proposal does not involve a "new institutional health service" subject to CON Review within the meaning of Alabama Code § 22-21-263 and CON Rule 410-1-4-.01, in that the Proposal does not include:
 - a. the construction, development, acquisition through lease or purchase or other establishment of a new health care facility or health maintenance organization;
 - any expenditure by or on behalf of a health care facility or health maintenance organization, the capital expenditure of which exceeds the CON statutory thresholds for major medical equipment, new annual operating costs, or any other capital expenditure by or on behalf of a health care facility;
 - c. the addition of any new health care facility beds or stations;
 - d. any health service which is proposed to be offered which was not offered on a regular basis within the preceding twelve (12) month period; or
 - e. any other reviewable event under the existing CON Laws, Rules, or Regulations of the State of Alabama.

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⁵ The current CON thresholds as set forth in SHPDA's "New Certificate of Need Application Fee and Monetary Threshold for Review Effective October 1, 2016," are 2,923,059.00 for major medical equipment; \$1,169,223.00 for new annual operating costs; and \$5,846,117.00 for any other capital expenditure. Effective October 1, 2017, and as set forth in SHPDA's "New Certificate of Need Application Fee and Monetary Threshold for Review Effective October 1, 2017," the health care facility expenditure threshold for major medical equipment is \$2,981,520.00; the new annual operating cost threshold is \$1,192,607.00; and the threshold for any other capital expenditure is \$5,963,039.00.



- 3.2 As noted above in section 2.6, there are no construction costs, no leases, no new health care facilities or health services, no equipment costs, no capital expenditures, and no anticipated, new first year annual operating costs associated with the Proposal.
- 3.3 Red Mountain is not requesting approval for or opening new hemodialysis stations, adding hemodialysis stations, or opening a new healthcare facility at Rehab Select/Talladega Healthcare; it is simply training and providing home dialysis services to qualified home hemodialysis patients who reside in a long term care facility, and who otherwise might not be able to be admitted as a patient at Rehab Select/Talladega Healthcare or receive dialysis due to transportation cost or health issues that preclude transportation of the LTC patient to an in-center ESRD facility. Therefore, the Proposal is due to be determined by SHPDA as **not** subject to CON review.
- 3.4 As stated above, Red Mountain is not adding hemodialysis stations under this Proposal. Even if Red Mountain were adding home hemodialysis stations, which clearly it is not, and should not be construed to be, Section 410-2-3-.05(2)(a) of the State Health Plan provides that home training dialysis stations are not considered in the determination of need for additional hemodialysis stations, which is based upon the utilization of present in-center hemodialysis stations and any anticipated increases of census. In calculating the "present capacity" of any in-center hemodialysis stations, Section 410-2-3-.05(2)(a) provides that "stations used for home hemodialysis training will be removed from the total number of stations..." Because stations used for hemodialysis training are not used in calculating need, Red Mountain's Proposal will have no adverse impact on any other existing freestanding ESRD facilities.

4. Conclusion and Request

- 4.1 Pursuant to Alabama Code §§ 22-21-260, et seq., and the CON Rules, including CON Rule 410-1-7-.02, a CON is not required to provide existing home hemodialysis training to qualified and admitted home hemodialysis patients in their home, their LTC facility, or to provide the same home hemodialysis support services as provided to other home hemodialysis patients.
- 4.2 Therefore, the Proposal is due to be determined as non-reviewable in accordance with the Alabama CON Law, Rules, and Regulations.

Thank you for your prompt consideration and publication of RV2017-031 and the supplemental information contained herein. Time is of the essence.

We look forward to receiving written confirmation from you that no further regulatory approvals are required for the Red Mountain Proposal by you, SHPDA, or the CON Review Board, in accordance with the laws and regulations cited above.

We appreciate the opportunity to provide additional information in connection with the LNR Request. Please give me a call if you have any questions.



Alva Lambert September 22, 2017

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Very truly yours,

Lenora W. Pate FOR THE FIRM

LWP

Jacki L. Ward c:

Karen McGuire **Deborah Compton**

I hereby certify that a PDF text searchable copy of the above and foregoing requested supplemental informational letter was electronically filed this the 22nd day of September, 2017, with the State Health Planning and Development Agency via shpda.online@shpda.alabama.gov in accordance with CON Rule 410-1-3-.09.

Of Counsel

Affirmation of Requesting Party:

The undersigned, being first duly sworn, hereby make oath or affirm that she, Jacki L. Ward, is the Group Facility Administrator of DVA Renal Healthcare, Inc. d/b/a Red Mountain Home Training Dialysis, Southland Division, has knowledge of the facts set forth in the original Red Mountain LNR Request, attached hereto as Exhibit B, and this requested supplemental informational letter to SHPDA on September 22, 2017, and to the best of her information, knowledge and belief, such facts are true and correct.

SUBSCRIBED AND SWORN to before me this 22 day of Septentel, 2017

Notary Public

My commission expires: 8/21/18

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Exhibit A SHPDA July 26, 2017 Letter



STATE HEALTH PLANNING AND DEVELOPMENT AGENCY 100 NORTH UNION STREET, SUITE 870 MONTGOMERY, ALABAMA 36104

July 26, 2017

Ms. Jacki L. Ward Group Facility Administrator Davita, Southland Division 3500 Blue Lake Drive, Suite 230 Birmingham, Alabama 35243

RE: RV2017-031

SHPDA ID: 073-D3734 Red Mountain Home Unit 300 B Street South

Birmingham, Alabama 35233

Dear Ms. Ward:

This will acknowledge receipt of the referenced letter of non-reviewability request filed July 17, 2017. In this request you state that Red Mountain Home Training Dialysis (Red Mountain) would like to provide home assisted treatment for home hemodialysis services at Rehab Select located in Talladega, Alabama. Additional information is required on behalf of this determination.

A skilled nursing facility by the name of "Rehab Select" cannot be located in Talladega, Alabama. Please provide the licensed name of this skilled nursing facility.

Specific information regarding the proposed services is required. For instance, will each patient provide their own dialysis station? How many total stations will be utilized for patients? Who will be responsible for providing the supplies needed for these stations? Will each station be utilized in the patient's room or in a common area?

There are no equipment, capital, annual lease, or construction costs reported for this project. The anticipated first year annual operating costs to Red Mountain must be included to ensure Certificate of Need thresholds are not exceeded. Financial interests by any other health care facilities or groups must also be provided.

ALA. ADMIN. CODE r 410-1-7-.02(1) requires the following affirmation to be included in all requests for non-reviewability:

RE: RV2017-031 July 26, 2017 Page 2

"Affirmation of Requesting Party:

The undersigned, being first duly sworn, hereby make oath or affirm that he/she is [Include position with entity requesting the determination], has knowledge of the facts in this request, and to the best of his/her/their information, knowledge and believe, such facts are true and correct.

| Afflant | (SEAL) |
|--|--------|
| SUBSCRIBED AND SWORN to before me this | day of |
| | |
| VA. A A ASSESSMENT OF THE STATE | |
| Notary Public | |

My commission expires:"

Upon receipt of the requested information, additional review can be conducted regarding this request.

Please contact Karen McGuire, <u>karen.mcguire@shpda,alabama.gov</u>, (334) 242-4103, should you have any questions.

Sincerely,

Alva M. Lambert Executive Director

alva m. Lambert

AML/kwm

Exhibit B Red Mountain LNR Request

July 12, 2017

Mr. Alva M. Lambert, Esquire Executive Director State Health Planning & Development Agency 100 North Union Street, Suite 870 Montgomery, AL 36104

Dear Mr. Lambert,

My purpose for writing this letter is to request a letter of non-reviewability determination relating to our Red Mountain Home Unit located at 300B Street South, Birmingham, AL 35233. It appears that the services described below do not meet the thresholds or requirements for a CON, however we would like to have it formally confirmed. The following generally summaries the proposed services.

Description:

As a free standing home training unit, Red Mountain Home would like to provide home assisted treatment for Home Hemodialysis services at the Rehab Select facility (a CMS certified Skilled Nursing Facility) located in Talladega, Alabama. Patients would be residents of the Rehab Select facility, but would also be admitted to and receive dialysis services through the Red Mountain Home Unit. The skilled nursing facility would be listed appropriately as their home. DaVita's Red Mountain Home facility would provide RN assisted Home Hemodialysis treatments at the Rehab Select facility, possibly to multiple patients simultaneously. We understand that such services are in compliance with CMS policy as detailed in the CMS Benefit Policy Manual Ch. 11, § 40.D and as outlined in CMS' survey guidance S&C 04-24 and S&C 04-37.

Services:

The services provided would be Home Hemodialysis support, training and assistance. The patients of the Rehab Select facility would be managed through the Red Mountain Home Unit and be a part of the quality assurance process there. All dialysis services would be provided through the Red Mountain Home facility and coordinated with the Rehab Select facility via a Coordination of Care Agreement as required by CMS.

Financial Scope:

| Equipment Cost: | \$0 |
|--------------------|-----|
| Capital Costs: | \$0 |
| Annual Lease: | \$0 |
| Construction Cost: | \$0 |

If you agree that these services do not meet the threshold for a CON I kindly request a letter of non-reviewability confirming this position.

If you have any further questions or need additional information please contact me at 205-807-9602.

Sincerely,

Jacki L. Ward Group Facility Administrator Davita, Southland Division 3500 Blue Lake Drive Suite 230 Vestavia, AL 35243

Exhibit C Rehab Select at Talladega Webpage



To call a facility, click here.

Patient referral and job inquiries only: 1-844-734-2200

REFER A PATIENT



Home > Welcome to Talladega Health & Rehab

WELCOME TO TALLADEGA HEALTH & REHAB

Rehab Select at Talladega Health & Rehab is a 234-bed, state-of-the-art rehabilitation and long-term care facility located at the heart of the Talladega, Alabama community.

With a one-on-one, personalized, rigorous rehabilitation and a physician-led approach, we are dedicated to helping patients achieve the best, most successful recovery possible in the shortest time possible.

Our Staff:

- · Caring, dedicated, non-contract
- Therapy up to 6 days a week, up to 3 hours per day
- 24/7 hour RN coverage available
- Physician on staff 7-days a week
- Psychiatrist and psychologist rounding weekly
- On-staff orthopedic surgeon
- GI physician rounding weekly
- Wound care physician rounding weekly

Special Services:

- Noted complete wound care and wound vac treatment
- Family visits allowed 24/7
- 9 tracheostomy beds
- Capable of handling a wide variety of medically complex diagnoses
- Virtual physical therapy program
- 49-bed male and female Alzheimer/Dementia Unit
- 29 bed rehab unit
- Life-Vest defibrillator

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Events Seminars



Map & Directions

TALLADEGA GALLERY









OUR LOCATIONS

Rehab Select at Shelby Ridge

881 3rd Street, NE Alabaster, AL 35007 205-620-8500

Rehab Select at Talladega

616 Chaffee Street Talladega, AL 35160 256-362-4197

Rehab Select at Hillview Terrace

100 Perry Hill Road Montgomery, AL 36109 334-272-0171

Rehab Select at Albertville

750 AL Hwy 75 N Albertville, AL 35951 256-878-1398 ABOUT US EVENTS FACILITIES SCHEDULE A TOUR CAREERS

CONTACT US

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Exhibit D ADPH Facility Directory – Talladega County

Nursing Homes

Talladega County

Coosa Valley Nursing Facility
315 West Hickory Street
Sylacauga, AL 35150 (256) 401-4000
85 bed Skilled Nursing Facility
Licensee Type: Healthcare Authority
Administrator: William Joseph McMichen
Fac ID: N6102 License: Regular
Medicare: 01-5010 Medicaid: 47-5010

Davis/Orman Intermediate Care Facility
202 Hope Drive
PO Box 740 (Mailling Address)
Eastaboga, AL 36260-0740 (256) 831-0919
16 bed Intermediate Care Facility/Individuals with Intellectual Disabilities
Licensee Type: No Data Provided
Administrator: Stentson Carpenter
Fac ID: N0806 License: Not subject to licensure

Medicare: 01-G011 Medicaid: 4958170I

Strickland/Stringfellow ICF/IID

101 Horizon Drive
P O Box 740 (Mailing Address)
Eastaboga, AL 36260-0740 (256) 831-0919

10 bed Intermediate Care Facility/Individuals with Intellectual Disabilities
Licensee Type: Corporation
Administrator: Stentson Carpenter
Fac ID: N6104 License: Not subject to licensure

.....

1007 West Fort Williams Street
Sylacauga, AL 35150 (256) 245-7402
149 bed Skilled Nursing Facility
Licensee Type: Limited Liability Company
Administrator: Valerie Scoggins
Fac ID: N6101 License: Regular
Medicare: 01-5160 Medicaid: 47-5317

Medicare: 01-G012 Medicaid: N/A

Sylacauga Health and Rehab Services

Talladega County

Talladega Healthcare Center, Inc.
616 Chaffee Street
Talladega, AL 35160 (256) 362-4197
234 bed Skilled Nursing Facility
Licensee Type: Corporation
Administrator: Mary Tuberville
Fac ID: N6103 License: Regular
Medicare: 01-5162 Medicald: 47-5021